

# PoCTGP



Point of Care Testing in General Practice

## POINT OF CARE TESTING IN GENERAL PRACTICE TRIAL

### FINAL REPORT

January 2009

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*The Point of Care Testing in General Practice Trial was funded by the  
Australian Government Department of Health and Ageing*



**Australian Government**

**Department of Health and Ageing**



## ACKNOWLEDGEMENTS

The three lead organisations contracted by the Department of Health and Ageing to deliver the Trial are:

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The University of Adelaide

### EXTERNAL QUALITY ASSURANCE PROVIDER

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The Trial Manager and evaluation team would like to acknowledge the contribution of the following people during the PoCT Trial.

- The Evaluation Working Group members: Caroline Laurence, Angela Gialamas, Lisa Yelland, Tanya Bubner, Briony Glastonbury, Philip Ryan, Kristyn Willson and members of the Trial Management Committee;
- Lisa Yelland, from the Data Management and Analysis Centre, Discipline of Public Health, the University of Adelaide who as the statistician on the Trial undertook the majority of the analysis and provided expert advice in the design, analysis and interpretation of results;
- Philip Ryan and Kristyn Willson from the Data Management and Analysis Centre, Discipline of Public Health, the University of Adelaide, who provided statistical and practical expertise to the evaluation team throughout the Trial;
- Liddy Griffith and Brian McDermott from the Data Management and Analysis Centre, Discipline of Public Health, the University of Adelaide for their assistance with the data management for the Trial and support to the Evaluation Team;
- John Moss and Nancy Briggs for their expert input and advice on the cost-effectiveness analysis.
- Justin Beilby for his input and support throughout the Trial;
- Andrew St John in his role as consultant to the Trial and particularly for his input into the systematic review;
- Phil Tideman and Rosy Tirimacco from ICARnet who formed part of the consortia which obtained funding for the Trial
- Rosy Tirimacco in her role as a consultant to the Trial and particularly her input into the accreditation design and implementation.
- Mark Shephard from the Device Group who co-wrote Chapter 5 (Assessment of Internal Quality Control) and provided comment in relation to the Conclusion.
- Janice Gill from the RCPA Quality Assurance Programs Pty Ltd who co-wrote Chapter 5 (Assessment of Quality Assurance) and provided comment in relation to the Conclusion.

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The Australian Government Department of Health and Ageing:

Wendy Akers, David Barton, Fifine Cahill, Tracey Frey, Pamela McKittrick, Jacqui Millard, Debbie Stanford from the Pathology Section.

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## ABBREVIATIONS

AACB	Australasian Association of Clinical Biochemists
ACE	Angiotensin Converting Enzyme
ACR	Albumin Creatinine Ratio
AGPAL	Australian General Practice Accreditation Limited
ANOVA	Analysis of Variance
ARA	Angiotensin Receptor Antagonist
AR-DRG	Australian Refined Diagnosis Related Group
ALP	Allowable Limits of Performance
ARI	Adelaide Research and Innovation Pty Ltd
BIDS	Bath Information and Data Services
BMI	Body Mass Index
CASP	Critical Appraisal Skills Program
CCF	Congestive Cardiac Failure
CEAC	Cost Effectiveness Acceptability Curve
CHD	Coronary Heart Disease
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CLSI	Clinical and Laboratory Standards Institute
CNA	Case Note Audit
CONSORT	Consolidated Standards of Reporting Trials
CPI	Consumer Price Index
CPD	Continuing Professional Development
CV	Coefficient of Variation
DEC	Departmental Ethics Committee
DEFF	Design Effect
DO	Device Operator
DoHA	Department of Health and Ageing
DMAC	Data Management and Analysis Centre
EMBASE	Excerpta Medica Database
EOI	Expression of Interest
EPTP	External Proficiency Testing Provider
EQA	External Quality Assurance
FACRRM	Fellow of the Australian College of Rural and Remote Medicine
FMC	Flinders Medical Centre
FRACGP	Fellow of the Australian College of General Practitioners
FTE	Full Time Equivalent
GEE	Generalised Estimating Equations
GP	General Practice

GPs	General Practitioners
GPA	General Practice Accreditation
HbA1c	Glycated Haemoglobin
HDL-C	High Density Lipoprotein - Cholesterol
HIC	Health Insurance Commission (now Medicare Australia)
ICER	Incremental Cost Effectiveness Ratio
IHD	Ischaemic Heart Disease
INR	International Normalised Ratio
ITT	Intention to treat
IQ	Interquartile Range
IQC	Internal Quality Control
ISO	International Organization for Standardization
LDL-C	Low Density Lipoprotein - Cholesterol
LN	Lot Number
MARS-5	Medication Adherence Reporting Scale
MBS	Medical Benefits Schedule
MCMC	Markov Chain Monte Carlo
MeSH	Medical Subject Headings
MI	Myocardial Infarction
MIS	Management Information System
MSAC	Medical Services Advisory Committee
NATA	National Association of Testing Authorities
NCCLS	National Committee for Clinical Laboratory Standards
NCEP	National Cholesterol Education Program
NPAAC	National Pathology Accreditation Advisory Council
NPT	Near Patient Testing
NSO	Node Support Officer
OTD	Overseas Trained Doctor
PBS	Pharmaceutical Benefits Scheme
PEI	Patient Episode Initiation
PIP	Practice Incentive Program
PoC	Point of Care
PoCT	Point of Care Testing
QA	Quality Assurance
QAP	Quality Assurance Program
QAAMS	Quality Assurance for Aboriginal Medical Services
QALY	Quality Adjusted Life Year
QC	Quality Control
RACGP	Royal Australian College of General Practitioners

RCPA	Royal College of Pathologists of Australasia
RAM	Random Access Memory
RCT	Randomised Controlled Trial
RRMA	Rural, Remote and Metropolitan Areas
SAE	Serious Adverse Event
SAEs	Serious Adverse Events
SD	Standard Deviation
SIP	Service Incentive Payment
SNAP	Smoking, Nutrition, Alcohol, Physical Activity
TE	Total Error
TC	Total Cholesterol
TG	Triglycerides
TGA	Therapeutic Goods Administration
VAS	Visual Analogue Scale
VR	Vocationally Registered



## GLOSSARY

Node Support Officer A Node Support Officers (NSO) was appointed in each region to oversee the implementation of the Trial in practices in each designated region. NSO were based in Bendigo, Victoria (Monash Department of Rural Health/Bendigo Regional Clinical School), Broken Hill, NSW (Department of Rural Health) and Adelaide, SA (Discipline of General Practice, The University of Adelaide).

DCA 2000	The DCA 2000 analyser (marketed in Australia by Bayer Australia Ltd) measures HbA1c and urine ACR.
Cholestech LDX	The Cholestech LDX analyser (Point of Care Diagnostics Australia Pty Ltd) measures blood lipids.
CoaguChek S	The CoaguChek S analyser (Roche Diagnostics Australia Pty Ltd) measures prothrombin time and reports the results as INR.
Treatment group/s	Refers to the intervention group/arm or control group/arm of the Trial.
Target range	Target is the goal for the particular investigation parameter that has evidence for the reduction of morbidity and mortality in association with the condition being managed, taking into account other risk factors and other co-morbidities.
Analyte	The pathology test that is being measured.
Analytical goal	A profession-based guide to the standard of analytical performance that methods for pathology tests should be able to achieve to provide good patient care.
Accuracy	The closeness between the measured result and the 'true' value of a pathology test.
Bias (or inaccuracy)	The actual difference between the measured result and the true value of a pathology test.
Imprecision	An estimate of the spread (or width of dispersion) of results when the same test is measured repeatedly in a given sample.
Coefficient of variation (CV%)	A statistical measure of imprecision, which is calculated as the standard deviation divided by the mean of repeated measurements and expressed as a percentage. Thus $CV\% = (SD/mean) * 100$ . The lower the CV%, the better (that is, less imprecise) the method.
Total error	The sum of the bias and imprecision, usually defined by the formula $TE = [bias] + 1.65 * \text{precision}$ ; where bias does not have a sign.



## EXECUTIVE SUMMARY

<b>I.</b>	<b>Overview</b>
<b>II.</b>	<b>Trial Preparation</b>
<b>III.</b>	<b>Key Findings and Conclusions for Key Research Questions</b>
	1. Is it safe to perform PoCT in general practice?
	2. Is the effectiveness the same or better than for the same tests using pathology laboratory testing?
	3. Is it the same or more cost-effective to perform PoCT compared with pathology laboratory testing?
	4. Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?
	5. Are there differences between urban, rural and remote geographic regions in any of the parameters measured?
	6. Would the regulatory environment used for the Trial meet the needs of all the stakeholders if PoCT were to be made more generally available?
	7. What would be the appropriate Medical Benefits Schedule (MBS) fee for the tests selected in the Trial?
<b>IV.</b>	<b>Evaluation of the PoCT Trial Implementation</b>
<b>V.</b>	<b>Overall Conclusions and Summary</b>

### **I: OVERVIEW**

The Point of Care Testing (PoCT) in General Practice Trial (the Trial) was an Australian Government-funded multi-centre, cluster randomised controlled trial (RCT), to investigate and evaluate the safety, clinical effectiveness cost effectiveness and satisfaction of PoCT in a general practice environment.

The Trial also sought to determine:

- if there were any differences between urban, rural and remote geographic regions in any of the parameters measured
- if the regulatory environment used for the Trial would meet the needs of all the stakeholders if PoCT were to be made more generally available
- what would be the appropriate Medical Benefits Schedule (MBS) fee for the tests selected in the Trial?

The Trial involved:

- an 18-month 'live' period from 1 September 2005 to 28 February 2007
- a total of 58 practices over a large geographic area (urban, rural and remote areas in South Australia, New South Wales and Victoria)

- a broad range of 26 practices randomised to the control group and 32 practices randomised to the intervention group
- the participation of 247 General Practitioners (GPs)
- 5,234 patients recruited from the practices of which 944 patients were on anticoagulant therapy, 1,967 had established diabetes and 3,819 had established hyperlipidaemia
- the use of PoC for seven tests used in the management of patients with diabetes (HbA1c, urine albumin and albumin creatinine ratio), hyperlipidaemia (total cholesterol, high density lipoprotein (HDL-C) and triglycerides) and patients on anticoagulant therapy (INR)
- 80 practice staff trained as Device Operators – five were GPs and the rest other practice staff
- 23 pathology providers/laboratories representing 10 parent companies linked to the practices recruited for the Trial.

The aim of the PoCT Trial was to answer the primary research question 'Should PoCT in general practice be implemented by the Australian Government (for patients with established diabetes, established hyperlipidaemia or on anticoagulant therapy)?'

The evaluation protocol and data collection processes took into account the large number of patients, the broad range of practice types distributed over a large geographic area, and the inclusion of pathology test results from multiple pathology laboratories. The evaluation protocol also reflected the complexity of the Trial setting, the Trial Design and the approach taken within the funding provided.

The PoCT Trial is regarded as a pragmatic RCT, evaluating the effectiveness of implementing PoCT in general practice. Every effort was made to ensure that, in these circumstances, internal and external validity was maintained.

## **II: TRIAL PREPARATION**

### **a) Selection of devices for the Trial and training of Device Operators**

Flinders Consulting Pty Ltd (Flinders Consulting) was contracted by the Department of Health and Ageing to supply and distribute the testing devices and provide training and ongoing support for Device Operators. In conjunction with researchers at Flinders University Rural Clinical School, Flinders Consulting selected the devices and suppliers to be used for the Trial. Based on best available evidence in 2004, the following devices were selected:

- *DCA 2000+* as the point of care analyser for HbA1c and urine ACR, supplied by Bayer Australia (now Siemens);
- *Cholestech LDX* as the point of care analyser for lipids (total cholesterol, HDL-C and triglyceride) supplied by Point of Care Diagnostics; and
- *CoaguChek S* as the point of care analyser for INR supplied by Roche Diagnostics Australia.

Flinders Consulting provided initial training and ongoing support for operators of the devices during the trial.

The key conclusion is:

- the devices selected for the trial were satisfactory# and the training and ongoing support was appropriate

# In October 2006 Roche Diagnostics Australia advised of an international recall of testing strips for the CoaguChek S INR testing device. The Product Safety Notice identified that the testing strips might occasionally lead to an abnormally high INR test result due to a manufacturing fault. An urgent notice was

issued by Flinders Consulting providing instructions on the duplicate testing procedure to be followed when using testing strips from a different batch to ensure the integrity of testing and the subsequent data analysis.

## **b) Recruitment of participants**

Practices were recruited through the support of local Node Support Officers and Divisions of General Practice. Randomisation and allocation to treatment group occurred prior to the initial training on use of PoCT devices, the Trial protocols and data collection processes.

Interest from all stakeholders in participating in the Trial was high and the Trial achieved excellent retention rates.

## **c) Participant baseline description**

Baseline characteristics of the four participant groups involved in the PoCT Trial – patients, GPs, Device Operators and Pathology Providers – were collected through baseline questionnaires. A high response rate was obtained for all groups except Pathology Providers.

The key findings were:

- the practices based in rural and remote locations tended to be solo (48%), bulk billed (100%), had smaller patient numbers and an older patient profile
- a higher percentage of urban practices used their computer systems for disease register (82%) and recall systems (100%)
- the characteristics of the GPs in the Trial were similar to those found across the GP workforce. The majority were vocationally registered (89%), with a median number of years in general practice of 16 years, worked between five and nine sessions per week and were male (63%)
- Device Operators were mainly female (93%), with a median age of 45 years and were qualified as nurses
- patients recruited to the Trial tended to be older (75%), male (53%), married (72%), born in Australia (77%) and many had retired (54%)
- the most common co-morbidities for patients (other than the conditions in the Trial) were previous heart attack (15%), coronary heart disease (15%), and depression or anxiety (14%)
- atrial fibrillation was the most common reason for patients being on anticoagulant therapy (38%)
- the Pathology Providers recruited for the Trial had similar characteristics. They serviced a mixture of private and public patients, provided laboratory and collection services, with technicians and scientists forming the majority of staff.

The key conclusions are:

- on the whole, participants in each treatment group had similar characteristics, although when analysed by geographic location, a number of rural/urban differences were found
- the characteristics and patterns found in the baseline descriptions reflect the general practice workforce profile and the practice structure. The characteristics of patients reflect the conditions being evaluated.

## **d) Systematic review of PoCT in general practice literature**

A systematic review of the literature on PoCT was conducted to assess whether the available evidence relating to the safety, clinical effectiveness, cost and patient and health professional

satisfaction supported the introduction of PoCT for diabetes, hyperlipidaemia and patients requiring anticoagulant therapy on a population-wide basis in Australian general practice.

Studies of adults 18 years and older treated for diabetes, hyperlipidaemia and anticoagulant therapy in a GP setting in either an urban, rural or remote geographic location were included. The studies included in the review were aimed at determining the safety, clinical effectiveness, cost and satisfaction of patients and health professionals with PoCT compared to usual care (pathology laboratory testing). All study designs were included in the search.

All titles and abstracts were independently assessed by two review authors. All randomised controlled trials were assessed independently by two review authors and all other study designs were assessed individually.

Twenty-nine studies were included in the review which included six RCTs of which three produced two papers.

The key findings were:

- in terms of clinical effectiveness, only one study found a significant difference between PoCT and usual care (pathology laboratory testing)
- studies relating to the safety or quality of PoCT by comparing agreement of PoCT results to pathology laboratory results were limited, with variable analytical methods used to show the agreement between the methods, making conclusions difficult to draw
- conclusions about the costs of PoCT were also difficult to draw because of limited studies with variable analyses and findings
- patient and health professional satisfaction towards PoCT was generally positive. However, small participant numbers and no comparative analyses completed in most of the studies were limitations that needed to be considered.

The key conclusion is:

- the systematic review of the PoCT literature in GP does not provide good evidence that PoCT improves patient health outcomes, that it has comparable analytical quality to pathology laboratory testing or that it is cost-effective compared to usual care. Most studies found that patients and health professionals were satisfied and found PoCT to be acceptable.

### **III: Key findings and conclusions for key research questions**

The Trial answered seven key questions relating to the three chronic conditions:

#### **1. Is it safe to perform PoCT in general practice?**

##### **i) Performance in quality management**

The methods used to establish a quality management system for the PoCT in General Practice Trial, and the results of quality testing undertaken to assess the analytical performance of the devices used in the Trial, are summarised below.

The quality management system incorporated;

- (i) an ongoing training and competency assessment program to ensure PoCT Device Operators had the skill set required to conduct PoCT safely and effectively
- (ii) the provision of Internal Quality Control (IQC) and External Quality Assurance (EQA) programs to continually monitor both operator competency and the analytical quality of the PoCT devices used in the Trial

- (iii) a comparison between the observed performance for IQC and EQA testing with the profession-derived analytical goals that were established for each PoC test for the Trial.

The PoCT Device Group was primarily responsible for training of practice staff and the implementation of an IQC program, while the Quality Assurance Program Group was responsible for the delivery of an EQA program. IQC and EQA are established quality practices undertaken by all Australian pathology laboratories.

### **Key Findings**

- all 80 Device Operators passed their initial competency assessment prior to the commencement of the live phase of the Trial
- the overall participation rate for IQC and EQA testing across the live phase of the Trial averaged greater than 90% for all POC tests
- Device Operator competency skills were maintained throughout the live phase of the Trial with only one operator having their competency revoked
- Device Operators conducted IQC testing to an analytical standard that met the goals set for the Trial for each PoC test (except HDL-C Level 1 QC where less than 60% of practices met the goal)
- Device Operators conducted EQA to an acceptable level of accuracy when compared to pathology laboratories (84% to 98% acceptable results)

Device Operators conducted EQA to an acceptable level of precision that met the goals set for the Trial for HbA1c and urine ACR. The other tests, particularly total cholesterol and HDL-C were not able to meet all assessments of precision.

### **ii) Standards and accreditation for PoCT in general practice**

A PoCT sub-committee first met in 2002 to begin developing standards to be followed in the Trial. It agreed that the National Pathology Accreditation Advisory Council (NPAAC) and the Royal Australian College of General Practitioners (RACGP) be approached to develop standards. NPAAC subsequently set up its own sub-committee to develop the standards with GP representatives of the RACGP included.

Members agreed to base the standards document on the headings outlined in the Quality Use of Pathology Committee PoCT Technical and Clinical Working Group *Draft Guidelines for Use of Point of Care Testing on General Practice in Australia* documents.

In March 2003, a first draft of the standards was circulated to various experts for comment. By June 2004, the standards had been finalised.

The standards were designed to support general practices in using PoCT to enhance the quality of patient care. The standards were intended to accommodate the expectation that PoCT and its clinical applications would significantly expand in the future, whilst the PoCT Trial would contribute to refining them to better meet the long-term need.

An evaluation of the (Interim) Standards for PoCT in General Practice and the accreditation program developed for the Trial was undertaken. As part of the analysis of the safety of PoCT in general practice, the results of practice compliance with the (Interim) Standards were also reviewed.

A Working Group developed the PoCT accreditation program based on the (Interim) Standards for PoCT in general practice. The accreditation program included: development of resources for practices participating in accreditation; development of an assessment process; and assessment through a site visit by a survey team and report on the outcome of the site visit.

## Key Findings

- for the first round of accreditation, 90% of practices passed; 1 of the 3 practices which did not comply with the requirements subsequently met the criteria and was accredited. The remaining 2 practices voluntarily withdrew from the Trial
- for the second round of accreditation, 100% of the practices complied fully with accreditation requirements
- evaluation of the accreditation process indicated that practices and members of the survey team found the process appropriate
- in terms of the (Interim) Standards, these were seen as realistic and achievable for general practice
- accreditation surveyors reported that the (Interim) Standards provided an achievable minimum standard for general practice
- GPs and Device Operators found the (Interim) Standards applicable and relatively easy to use.

### iii) Comparison of PoCT and pathology laboratory test results

An analysis of the comparison of PoCT and pathology laboratory test results was undertaken as part of Phase I of the Trial. This analysis formed part of the assessment of whether PoCT was safe to perform in general practice.

Pathology laboratory test results were matched with PoCT test results for patients in the intervention group for the first six months of the Trial. Agreement was assessed using three methods; the Bland and Altman approach which includes mean differences and 95% limits of agreement followed by clinician review to determine the clinical acceptability of the results; analysis of the concordance between PoCT and laboratory results; and for INR assessment using published clinically relevant agreements.

## Key Findings

- the estimated bias for INR was 0.0034. This means that on average PoCT results were 0.0034 above the corresponding pathology laboratory test results. The 95% limits of agreement were -0.7851 and 0.7919
- the estimated bias for HbA1c was -0.0504%. This means that on average, PoCT results were 0.0504% below the corresponding pathology laboratory test result. The 95% limits of agreement were -1.0658 and 0.9650%
- the estimated bias for urine albumin was -0.7632mg/L. This means that, on average, PoCT results were 0.7632mg/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -11.4719 and 9.9455mg/L
- the estimated bias for ACR was -0.1513mg/mmol. This means that on average, PoCT results were 0.1513mg/mmol below the corresponding pathology laboratory test result. The 95% limits of agreement were -2.0488 and 1.7461mg/mmol
- the estimated bias for total cholesterol was -0.2645mmol/L. This means that, on average, PoCT results were 0.2645mmol/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -1.0931 and 0.5641mmol/L
- the estimated bias for HDL-C was -0.0694mmol/L. This means that on average, PoCT results were 0.0694mmol/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -0.4899 and 0.3510mmol/L

- the estimated bias for triglycerides was 0.2014mmol/L. This means that PoCT results were 0.2014mmol/L above the corresponding pathology laboratory test result on average. The overall 95% limits of agreement were -0.9540 and 1.3569mmol/L
- concordance analysis found that 23.3% of INR results, 15.1% of total cholesterol results, 14.2% of HDL-C results, 10.6% of HbA1c results, 10.5% of ACR and triglyceride results and 2.5% of urine albumin results theoretically could have led to a different decision depending on whether the test was from the laboratory or PoCT
- evaluation of INR results showed that, overall, 86% of dual INR measurements were within 0.5 INR units of each other. For laboratory INR <2.00, 2.0-3.0, 3.1-4.0 and >4.0, 94%, 90%, 69% and 67% of readings were within 0.5 INR units, respectively
- for INR, clinical agreement occurred 91% and 89% of the time against published expanded and narrow criteria, respectively.

#### **iv) Serious adverse events and incidents**

An analysis of the serious adverse events (SAEs) and incidents reported during the Trial, which formed part of the assessment of the safety of PoCT was undertaken. SAEs were monitored by a Safety Subcommittee which assessed and made a recommendation to the Trial Management Committee regarding the likelihood or otherwise that a particular SAE was related to the Trial.

Weighted estimates of the number of SAEs, the number and percentage of patients experiencing one or more SAEs and the number of SAEs per 10,000 person-years were calculated both overall and by treatment group. A descriptive analysis of Trial incidents was also undertaken.

#### Key Findings

- no SAE reviewed was assessed to be attributable to PoCT
- for all three conditions, the number of SAEs per 10,000 person-years for the intervention (1319) group was lower than for the control (1446) group
- overall, the proportion of patients experiencing one or more SAE was the same for both the intervention (13%) and control (13%) groups
- a larger number of incidents was recorded by the Trial Management Group from patients and practices in the intervention group and that number reduced over the period of the Trial
- most calls to the QC/QA hotline related to interpretation and recording of QC results
- 15 test error codes were recorded during the Trial and these errors related to pre-analytical or operative factors.

#### **Key Conclusions (for i to iv)**

- in terms of performance in quality management it was safe to perform PoCT for HbA1c and ACR; however, the results were less clear for INR and lipids
- the methods established for the implementation and delivery of training, competency assessment, IQC and EQA programs were appropriate for the General Practice Trial and Device Operators conducted PoCT to a generally acceptable analytical standard
- the accreditation program developed by the Trial, based on the (Interim) Standards for PoCT, provided an acceptable framework for evaluating quality management for PoCT
- practices were able to meet the (Interim) Standards and obtain accreditation

- the (Interim) Standards for PoCT in general practice were acceptable to GPs and Device Operators and members of the survey teams
- a comparison of PoCT and pathology laboratory test results determined that the mean difference in results and the 95% limits of agreement were clinically acceptable
- PoCT did not result in a higher number of SAEs.

## **2. Is the effectiveness of PoCT the same or better than for the same tests using pathology laboratory testing?**

To answer this research question the Trial looked at four areas around the influence of PoCT on clinical effectiveness. These were therapeutic control, impact on patient care, number of visits to the GP and patient compliance with disease management.

Non-inferior analyses (the same or better) were used to measure therapeutic control and patient compliance with disease management. Descriptive analyses of the process of care actions, prescribing patterns and lifestyle activities were also undertaken. Various data sources were used in the analysis; test results, Medicare data, case note audit data and medicine and lifestyle questionnaires.

### **Key Findings**

- at a patient level PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing for HbA1c ( $p < 0.0001$ ), urine albumin ( $p = 0.0040$ ), ACR ( $p = 0.0367$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p = 0.0001$ ), but not for INR ( $p = 0.2389$ ) and HDL-C ( $p = 0.7723$ )
- at a test level PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing for INR ( $p = 0.0008$ ), HbA1c ( $p < 0.0001$ ), urine albumin ( $p = 0.0005$ ), ACR ( $p = 0.0129$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p < 0.0001$ ), but not for HDL-C ( $p = 0.7862$ )
- PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing in relation to the proportion of patients showing an improvement in their test result from baseline for HbA1c ( $p < 0.0001$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p = 0.0001$ )
- PoCT patients had significantly more GP visits ( $p = 0.0126$ ) and more testing
- GPs using PoCT recorded more process of care actions than control GPs for all conditions if tests were within target range. Fewer differences were found between actions undertaken by intervention GPs compared to control GPs if tests were outside target range
- PoCT had little impact on GP prescribing patterns for all three conditions
- PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing in relation to the proportion of questionnaire responses indicating compliance with disease management (medication compliance)
- in terms of lifestyle activities few differences were found between treatment groups.

### **Key Conclusions**

- in terms of therapeutic control, PoCT was found to be the same or better than pathology laboratory testing for most tests, suggesting that PoCT could assist GPs in better management of some chronic conditions

- the results also suggested that having an immediate test result was beneficial for patients in terms of medication compliance.

### **3. Is it the same or more cost-effective to perform PoCT compared with pathology laboratory testing?**

A comparative cost analysis and a cost-effectiveness analysis of PoCT in a general practice setting was undertaken.

A societal perspective was applied to the calculation for comparative costs between PoCT and pathology laboratory testing. An intermediate health outcome indicator, which was the proportion of patients within the therapeutic range for each condition, was used. In order to account for clustering at the patient and practice levels, Generalised Estimating Equations were used to model count and normal data and obtain estimated values for resource use. These values were then used to estimate total and mean costs and group differences. One-way sensitivity analysis was undertaken on all resource items for which the underlying variable had a distribution, using the upper and lower 95% confidence limits as comparative values. Cost-effectiveness was determined using the Incremental Cost Effectiveness Ratio (ICER). Joint probability distributions were also calculated.

#### **Key Findings**

- the INR strategy using PoCT was associated with a small reduction in the indirect costs per patient to the health care sector (95% CI -\$16 to -\$3)
- the other three PoCT strategies, HbA1c, urine ACR and lipids, did not generate a statistically significant difference in the direct costs per patient to the health care sector over the duration of the Trial
- for INR testing, PoCT was associated with significantly higher costs per patient for GP consultations (95% CI \$120 to \$367) and pharmaceuticals (95% CI \$6 to \$30)
- for HbA1c and urine ACR testing, PoCT was not associated with a statistically significant difference in any of the other measured categories of direct costs to the health care sector
- for lipids testing, PoCT was associated with significantly higher costs per patient for pharmaceuticals (95% CI \$143 to \$296)
- regarding the point estimates of the ICERs:
  - a. INR by PoCT was dominated by its comparator
  - b. for HbA1c, this was \$40 per additional patient within the therapeutic range
  - c. for lipids, this was \$10,082 per additional patient within the therapeutic range
  - d. for urine ACR, PoCT was dominant
- the one-way sensitivity analysis showed that the costs of all tests were particularly sensitive to hospital admissions
- all PoCT strategies led to a small reduction in patient travel costs and in indirect costs
- because most patients in this Trial were bulk-billed, the overall level of co-payments was low
- the comparative direct costs to the health care sector of the actual tests depend on whether or not the establishment costs, consumables and maintenance costs, and quality assurance and control costs, all of which were provided free during the Trial, should be included.

## Key Conclusion

- providing urine ACR testing using a PoCT device appeared to be dominant to its comparator in a general practice setting. On the other hand, INR using PoCT was dominated. The other two tests (HbA1c and lipids) generated health gains but at an extra cost.

## 4. Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?

The Trial assessed satisfaction in two ways: participants' attitudes; and satisfaction with PoCT.

The method of analysis for participants' attitudes used statements from the Baseline and Satisfaction Questionnaires, as measured by the Visual Analogue Score (VAS). Between and within-group analysis of attitudes was undertaken for GPs and patients. The analysis for participants' satisfaction used statements from the Satisfaction Questionnaire, as measured by the VAS. For all statements analysis was performed using a mixed model analysis of variance (ANOVA).

## Key Findings

- from baseline, intervention GPs reported a greater change in attitudes to all statements compared to the control GPs, with a majority of the statements (5 out of 9) reaching statistical significance ( $p < 0.05$ ). In particular, intervention GPs agreed more strongly than control GPs that PoCT would help with disease management, would not interrupt patient flow or add time to the consultation
- for all attitude statements, intervention patients showed a higher level of agreement compared to control patients, although for only one statement did the difference reach statistical significance ( $p < 0.0001$ )
- for Device Operators, there was no significant change in attitudes to PoCT from the commencement to the end of the Trial, except in the area of quality control, which they found more time-consuming ( $p = 0.0012$ )
- Pathology providers' attitudes did not alter by the end of the Trial and they were non-committal in their views about the analytical quality of PoCT or the availability of PoCT in general practice
- intervention GPs on average were more satisfied with PoCT compared to control GPs, particularly for the usefulness of clinical practice ( $p = 0.0097$ ) and confidence in PoCT results ( $p = 0.0022$ )
- for all statements measuring patient satisfaction, the intervention group showed a greater level of satisfaction compared to the control group, with all but one statement reaching statistical significance ( $p < 0.05$ )
- Device Operators indicated high levels of satisfaction with PoCT
- Pathology Providers indicated low levels of satisfaction with PoCT.

## Key Conclusion

- results supported patient, GP and Device Operator satisfaction and acceptability of PoCT in a general practice setting.

## 5. Are there differences between urban, rural and remote geographic regions in any of the parameters measured?

Analyses were undertaken to determine whether there were differences between urban, rural and remote geographic regions in any of the outcomes measured.

To test for evidence of effect modification by geographic location, analyses for clinical effectiveness and stakeholder satisfaction were repeated with a geographic location effect, as well as an interaction between treatment group and geographic location. Post hoc tests were performed to examine the effect of treatment separately within each geographic region. Descriptive analyses to determine the influence of geographic location were completed for QA test results, standards and accreditation, PoCT versus laboratory test results and SAEs and incidents. A Kruskal Wallis analysis was completed for QC results by geographic location.

### Key Findings

- analysis of the analytical imprecision observed for QC testing found, in general, no difference across geographic locations. There was no pattern for unacceptable results for QA testing by geographic location for all tests
- some variation was observed between geographic location and the level of agreement between the PoCT and laboratory testing. Remote practices had the widest limits of agreement
- the proportion of dual INR test results that satisfied the narrow (89.7% urban, 88.6% rural, 87.6% remote) and expanded (91.6% urban, 91.6% rural, 90.7% remote) criteria was similar across geographic location
- the proportion of dual readings within 0.5 units for INR by geographic location was similar for results <4.0. For results >4.0 there were lower levels of agreement across all geographic locations, particularly so for remote areas (58.8% compared to 82.3% rural and 68.1% urban)
- evaluation of the (Interim) Standards for PoCT found that urban GPs were more unsure about their applicability than rural and remote GPs, while Device Operator responses did not vary by geographic location
- all urban practices complied fully at the first accreditation visit, while 90% of rural practices and 70% of remote practices complied, the latter requiring review before achieving accreditation. All practices in all regions complied fully at the second accreditation visit
- while some differences in SAEs by geographic location were found, all SAEs were deemed unlikely to be related to the Trial
- the percentage of operator, patient and Trial related incidents was similar across all geographic regions
- there was no evidence of effect modification by geographic area for any of the hypotheses related to therapeutic control
- patients in the intervention group from rural and remote areas had a higher number of GP visits per person-year compared with the control group ( $p < 0.05$ ), whereas patients in both treatment groups from urban areas had similar numbers of GP visits
- there was no evidence of effect modification by geographic area for the hypothesis related to patient compliance with disease management (use of medicines)
- there was evidence of effect modification by geographic area for hypotheses relating to the average change in patient attitudes ( $p < 0.05$ )

- there was no evidence of effect modification by geographic area for hypotheses relating to the average change in attitudes for GPs and Device Operators
- there was no evidence of effect modification by geographic area for hypotheses relating to satisfaction for patients and GPs.

### **Key Conclusion**

- there were no consistent and significant differences found between geographic locations for any of the parameters measured.

## **6. Would the regulatory environment used for the Trial meet the needs of all the stakeholders if PoCT were to be made more generally available?**

To determine whether the intervention model used in the Trial would meet the needs of all stakeholders (General Practice, Patients, Pathology Providers and the Government) if PoCT were to be made more generally available, a number of key findings from the Trial need to be considered.

### **Key Findings**

- the quality management system, which included Device Operator training and certification, IQC and EQA overseen by an accreditation program based on the (interim) Standards for PoCT in general practice, was acceptable to all stakeholders. If PoCT were to be implemented in general practice more widely, it would be necessary for a similar system to be adopted to ensure that the success seen in the Trial could be translated into practice
- the (Interim) Standards for PoCT in GP were considered appropriate by all stakeholders. It was considered important that practices participate in a quality management system to provide GPs with the confidence that their clinical decisions were based on reliable and accurate results and to ensure patient safety was not compromised
- that intervention practices were required to nominate a GP who was given overseeing authority and responsibility for PoCT. An essential step in introducing PoCT more broadly would be to identify a GP with the primary responsibility for the implementation and management of PoCT within a practice
- that PoCT procedures were required to be conducted in association with an attendance of a GP. However, the manner in which testing was adopted in the practice was not mandated. Intervention practices were provided with protocols to follow for testing. These were seen as beneficial and it would be necessary for PoCT guidelines to be developed to assist GPs with device selection and the development of testing protocols, including interpreting and recording results
- that patients and practice staff found PoCT acceptable in the framework in which it was implemented in the Trial and revealed high levels of satisfaction. The model used in the Trial may have provided reassurance that patient care was not being compromised and operated within a quality framework equivalent to traditional pathology testing
- Pathology Providers indicated that they would like some involvement if PoCT were to be implemented in general practice. Pathology Providers are in a position to provide advice on test results, provide validation of PoCT results and support IQC and EQA and this role needs to be enhanced
- a number of organisations already exist that can take on various aspects of the Trial model. These organisations include Divisions of General Practice, the RACGP, NATA and the RCPA QAP Pty Ltd (QAP)

- the Australian Government provided funding for all aspects of PoCT examined in the Trial, many of which are likely to form a part of PoCT in general practice if the model is made more generally available. The Government was involved in the development of the Standards. An important role for the Government would be determining whether a quality management system should be mandatory, whether PoCT should be limited to the chronic disease areas investigated in the Trial and what the MBS fees for testing would be.

### Key conclusion

- the Trial model provides a framework that has been proven to work within the current regulatory environment and is acceptable to all stakeholders. The Trial model could form the basis of a framework for the implementation of PoCT in GP more broadly.

## 7. What would be the appropriate MBS fees for the PoC tests selected in the Trial?

### a) How the costs of PoC tests vary with volume

An analysis of how the costs of PoCT in general practice vary with volume and how these unit costs compare with unit costs of testing through a pathology laboratory was undertaken.

Unit costs for the four PoC tests were based on data obtained from the Trial and updated to 2008 values using the CPI. Costs were categorised as establishment costs, annual costs, monthly costs and per test costs.

Sensitivity analysis was used to examine the influence of volume on PoCT unit cost.

### Key Findings

- the estimated unit cost for PoCT is \$20.02 per test for INR, \$75.88 per test for HbA1c, \$87.80 for urine ACR and \$66.84 for lipid studies
- for all tests except INR, the unit costs were much higher in general practice compared with pathology practice
- cost per test varies with volume.

### b) Indicative MBS fees for PoC tests used in the Trial

For other pathology tests, an operating margin of 17% is added to the unit cost to determine the MBS fee. On this basis the following MBS fees would apply:

Urine ACR	\$87.80 unit cost plus 17%	=	\$105.78
HbA1c	\$75.88 unit cost plus 17%	=	\$91.42
INR	\$20.02 unit cost plus 17%	=	\$24.12
Lipids	\$66.84 unit cost plus 17%	=	\$80.53

Any suggested operating margin for potential PoC tests would be subject to further consideration.

### Key Conclusions

- the estimated cost per test for PoCT in general practice based on Trial volumes is much higher than the estimated cost for the tests provided through a pathology laboratory

- unless the typical GP can substantially reduce the amount of resources used in PoCT or the volume in routine best practice turns out to be considerably higher or there are other cogent reasons then the fee for PoCT would have to be substantially higher than the fee for an equivalent test performed by a pathology laboratory.

#### **IV: Evaluation of the PoCT Trial Implementation**

An evaluation of the PoCT Trial in terms of process, implementation and structure, focusing on quality, efficiency and satisfaction was undertaken.

Participants representing four key groups associated with the Trial were interviewed by an independent researcher. A rating scale was used to assess responses and a descriptive analysis was undertaken with the key themes identified from the qualitative questions.

##### Key findings

- respondents were very satisfied with the communication processes and information provided to participants during the Trial
- communication was seen as playing a key role in the management structure
- reports and documentation were provided in a timely manner and thought to be of very high quality
- the management structure was seen to be effective and the teams staffed appropriately. However, concerns were raised that the Evaluation Team was understaffed and more staff were needed at the developmental stages of the Trial
- the Trial Design was seen as being inadequate in a number of areas.

##### Key conclusion

- respondents thought the Trial was well managed, ran smoothly and was a valuable piece of research for Point of Care Testing in Australian general practice.

#### **V: Overall conclusions and summary**

The following conclusions relate to the seven key research questions for the Trial:

##### **1. SAFETY**

It was safe to perform PoCT as assessed by the competency of Device Operators, quality assurance performance for HbA1c and ACR, analytical standards achieved for quality control (QC) testing (overall), agreement between PoCT and laboratory results, compliance with the Standards (accreditation), SAEs attributable to PoCT, SAEs per person year (overall) and the proportion of patients experiencing one or more SAEs (overall).

However, the results were less clear for some areas and may require further investigation. Quality control results did not meet the analytical goals for imprecision for one QC level for HDL-C. Quality assurance acceptable levels of accuracy were not clear for INR, total cholesterol (all geographic areas), HDL-C and triglyceride tests in remote locations. QA results did not meet the imprecision analytical goals for total cholesterol, HDL-C and triglycerides. Remote locations showed more imprecision and this requires further investigation. There were also some differences in SAEs by geographic location but all SAEs were deemed unlikely to be related to the Trial.

## **2. CLINICAL EFFECTIVENESS**

The effectiveness of PoCT was the same or better (non-inferior) than pathology testing for the proportion of patients within target range for HbA1c, urine albumin, ACR, total cholesterol and triglycerides and the proportion of tests within target range for INR, HbA1c, urine albumin, ACR, total cholesterol and triglycerides. PoCT was non-inferior to pathology testing in relation to the proportion of MARS-5 responses indicating compliance with disease management. The number of GP visits for PoCT patients per person-year was different (greater) than control patients for all tests and PoCT GPs undertook a greater number of processes of care actions for INR and microalbumin compared to those carried out by control GPs.

However, for some areas the results were less clear and may require further investigation. The proportion of PoCT patients who had results within target range was not the same or better for intervention patients who underwent INR and HDL-C testing when compared with control patients. Additionally, the proportion of tests within the target range in PoCT practices was not the same or better for intervention patients who underwent HDL-C testing when compared with control patients. Finally, the processes of care actions undertaken by PoCT GPs were similar to those carried out by control GPs for total cholesterol, HDL-C, triglycerides, and HbA1c.

## **3. COST-EFFECTIVENESS**

In terms of the incremental cost-effectiveness ratio for PoCT versus laboratory testing, ACR testing using a PoCT device appeared to dominate its comparator in a general practice setting. On the other hand, INR using PoCT was dominated. The other two tests (HbA1c and lipids) generated health gains but at an extra cost.

## **4. SATISFACTION**

In terms of attitudes and satisfaction towards PoCT the Trial found an improvement in attitudes in most areas over the Trial period for patients, GPs and Device Operators. Patients, GPs and Device Operators were also more satisfied with PoCT in most areas. The only stakeholder where no change in the level of satisfaction with PoCT was found was with the Pathology Providers.

## **5. GEOGRAPHIC DIFFERENCES**

The Trial did not find any consistent and significant differences between urban, rural and remote geographic regions for any of the parameters measured. These included QC and QA, testing results, compliance with accreditation, incidences of SAEs, therapeutic control results, patient compliance and general satisfaction.

## **6. REGULATORY FRAMEWORK**

The regulatory environment used for the Trial was found to be acceptable and supported by all stakeholders (general practice, patients, pathology providers and government representatives) in the general practice setting.

## **7. ESTIMATED MBS TEST COST**

### Unit Cost

The estimated unit costs of PoCT in general practice calculated from data collected during the Trial and updated to 2008 prices are:

INR	\$20.02 per test
HbA1c	\$75.88 per test
UrineACR	\$87.80 per test
Lipids	\$66.84 per test

### Possible MBS Fees

If the same formula used for other pathology tests is applied to the PoCT unit cost for each test, the MBS fees would be as follows:

INR	\$24.12 per test
HbA1c	\$91.42 per test
Urine ACR	\$105.78 per test
Lipids	\$80.53 per test

### Existing MBS Fees

The existing MBS fees for these tests, if performed in a pathology laboratory, are as follows:

INR	\$14.05 per test
HbA1c	\$17.10 per test
Urine ACR	\$20.50 per test
Lipids	\$9.75 per test

It can be seen that the estimated costs based on calculations from the data collected from the Trial are much higher than the equivalent tests provided by a pathology laboratory.

### **Summary**

The PoCT Trial in a General Practice setting was formulated with the notion that PoCT could assist general practitioners and patients with the management of chronic illness. The Trial provides evidence that PoCT does have a role in assisting the primary health care team in the management of chronic disease, particularly in the areas of optimising therapy, engaging patients in their self-management and providing regular follow-up.

For other aspects, such as GPs adhering to evidence-based guidelines, the results are less clear. The cost-effectiveness analysis showed that PoCT was not cost-effective for any of the tests examined during the Trial with the exception of urine ACR testing. However, the decision to fund PoCT in a general practice setting needs to consider the positive health benefits of the intervention and potential societal gain of maintaining a patient within target range.

# 1. TRIAL DESIGN AND RATIONALE

## SUMMARY OF THE CHAPTER

This chapter provides an overview of the Trial Design and rationale. The PoCT in General Practice Trial was an Australian Government funded multi-centre, cluster randomised controlled trial to determine the safety, clinical effectiveness, cost-effectiveness and satisfaction of PoCT in a general practice setting.

The PoCT Trial covered an 18 month period with the intervention consisting of the use of PoCT for seven tests used in the management of patients with diabetes, hyperlipidaemia and patients on anticoagulant therapy.

The primary outcome measure was the proportion of patients within target range, a measure of therapeutic control. In addition, the PoCT Trial also investigated the safety of PoCT, impact of PoCT on patient compliance to medication, stakeholder satisfaction, cost effectiveness of PoCT versus laboratory testing, and influence of geographic location.

The chapter provides an overview of the Trial Design and the rationale for the research methodology chosen and how the Trial was implemented in a GP environment. The evaluation protocol and data collection processes took into account the large number of patients, the broad range of practice types distributed over a large geographic area, and the inclusion of pathology test results from multiple pathology laboratories.

The evaluation protocol developed reflected the complexity of the Trial setting, the Trial Design and the approach taken within the funding provided. The PoCT Trial was regarded as a pragmatic RCT, evaluating the effectiveness of implementing PoCT in GP, and every effort was made to ensure that, in these circumstances, internal and external validity was maintained.

## 1.1. INTRODUCTION

Point of care testing (PoCT) has been used for many years and is increasingly being utilised in the Australian general practice (GP) setting. PoCT is defined as any test that is performed at the time at which the test result enables a clinical decision to be made and an action taken that leads to an improved health outcome.<sup>1</sup> PoCT has the potential to provide better monitoring of chronic conditions, improved therapeutic control, more rational prescribing, better clinical decisions within the consultation timeframe, greater patient compliance with pathology requests, and fewer visits to the doctor.<sup>2 3 4</sup>

The literature suggests that there is a lack of evidence for several of these benefits, particularly those relating to clinical outcomes. Reduction in referrals, and earlier and more rationalised treatment has been reported in a study involving PoCT<sup>5</sup> but changes in prescribing patterns have not occurred. Some evidence is available on the role of PoCT in improving glycaemic control<sup>2, 6</sup>, cholesterol and lipid levels<sup>7</sup>, and oral anticoagulant control<sup>8</sup>, although not for microalbuminuria.

A primary concern relating to PoCT is quality management. For PoCT to be introduced into the GP environment, it is important that it is proven to be accurate and reliable.<sup>9</sup> This requires those practices undertaking such testing to meet both internal quality control (QC) and external quality assurance (QA) standards. Hobbs<sup>10</sup> suggests a model for PoCT in primary care that incorporates laboratory training for GP staff with external QA from a central laboratory. A necessary part of quality management is the adequate training of staff operating the PoCT devices and this includes the requirement for an understanding of QC and QA processes.<sup>11, 12</sup>

PoCT in GP will only be effective if the results obtained from the testing devices are comparable with laboratory results.<sup>1, 13</sup> A number of studies have shown that PoCT using a variety of portable

monitoring devices can produce test results similar to laboratory results for a number of specific tests including HbA1c<sup>2, 14</sup>, anticoagulation monitoring<sup>15 16 17 18 19</sup>, microalbuminuria and cholesterol.<sup>20</sup> Variability between laboratories and primary care sites, however, demonstrates the need for participation in QA programs.<sup>1</sup>

While a large number of studies have been undertaken on the use of PoCT in the primary care setting, few studies have undertaken an economic analysis of PoCT.<sup>5</sup> Hobbs et al's<sup>3</sup> systematic review of PoCT in primary care could not draw any conclusions regarding cost effectiveness of PoCT because of insufficient research data. Some studies indicate that PoCT is more expensive when compared to laboratory testing<sup>2, 21</sup>, but this may be offset by long term societal gains such as prolonged life or reduced hospital stays.<sup>5</sup> It should, however, be noted that the cost effectiveness of PoCT appears likely to vary according to the disease group and the test in question.<sup>2</sup>

The attitudes of key stakeholders and their satisfaction with PoCT form an important part of the assessment of introducing PoCT into GP. These stakeholders include patients, GPs, practice staff and pathology laboratories. PoCT may lead to greater convenience for GPs and patients but result in greater costs and require organisational changes that may reduce stakeholder satisfaction. There is conflicting research in this area. Hilton et al's<sup>22</sup> study on general practitioner and practice nurse attitudes to PoCT concluded that GPs did not find PoCT a useful addition to their practice, while nurses reported that pressure on their time was a limitation for PoCT. Grieve et al.<sup>2</sup> found no difference in patient satisfaction between diabetes clinics using PoCT or usual laboratory testing, however, patients did record a higher level of satisfaction with test information if they had PoCT rather than conventional testing. An Australian study investigating the attitudes of patients and GPs to PoCT found that GPs and patients supported PoCT because of its convenience, quality, role in patient care and efficiency. However, registration costs and QA fees were cited as areas of dissatisfaction by GPs.<sup>23</sup>

While a number of studies have been undertaken on the cost effectiveness, clinical effectiveness, safety or satisfaction with PoCT, there have been no randomised controlled trials (RCTs) that evaluate all these outcomes in the GP setting. The PoCT Trial was implemented to address this gap.

## **1.2. METHOD**

### **1.2.1. Overview of design**

The PoCT Trial was a cluster randomised controlled trial to evaluate the intervention of PoCT on the management of patients with either diabetes, hyperlipidaemia or on anticoagulant therapy. A clustered design was chosen to avoid treatment group contamination and for administrative convenience. The Trial commenced in September 2005 and continued for 18 months across 58 general practices based in urban, rural and remote locations across three states in Australia.

The primary research question of the Trial was:

Should PoCT in GP be implemented by the Australian Government?

The Trial evaluated seven key questions:

1. Is it safe to perform PoCT in a GP setting?
2. Is the clinical effectiveness of PoCT the same or better than the same tests using pathology laboratory testing?
3. Is it the same or more cost effective to perform PoCT compared with pathology laboratory testing?
4. Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?

5. Are there differences between urban, rural and remote geographic regions in treatment effects being measured?
6. Would the regulatory environment used for the Trial meet the needs of all the stakeholders if PoCT were to be made more generally available?
7. What would be the appropriate MBS fees be for the PoC tests selected to be in the Trial?

A number of hypotheses were developed in order to answer each of these questions and are shown in Table 1.

A final component was to determine appropriate MBS fees for each PoC test used in the Trial.

**Table 1: Key research questions and associated hypotheses**

<b>Area of key research question</b>	<b>Hypotheses developed</b>	<b>Level of analysis</b>
Safety	All designated staff in the PoCT practices meet the required competency level to perform PoCT	Practice staff level
	All PoCT practices obtain QC results within the acceptable performance range	Practice level
	In terms of accuracy, all PoCT practice results meet the required QA performance levels for the pathology laboratories	Practice level
	In terms of precision, PoCT practice results meet the required QA performance levels for the pathology laboratories	Practice level
	Results obtained from PoCT devices for each patient closely agree with results obtained for the same patient from pathology laboratory testing	Test level
	All Intervention practices meet the standards for PoCT in GP and obtain accreditation	Practice level
	The number of serious adverse events reported in PoCT patients per person-year is the same as or fewer than the number of serious adverse events reported in control patients per person-year	Patient level
	The proportion of PoCT patients who experience one or more serious adverse events is the same as or less than the proportion of control patients who experience one or more serious adverse events	Patient level
Clinical effectiveness	The proportion of PoCT patients who have pathology results within the target range is the same as or greater than the proportion of control patients who have pathology results within the target range	Patient level
	The proportion of total tests within the target range in PoCT practices is the same as or greater than the proportion of total tests within the target range in control practices	Test (within patient) level
	The number of general practitioner visits for PoCT patients per person-year is different to the number of general practitioner visits for control patients per person-year	Patient level
	PoCT patients report the same or greater improvement in compliance with disease management as directed by medical staff as control patients	Time of questionnaire administration (within patient) level
Satisfaction and	The average change in attitudes in GPs from PoCT	Time of

Area of key research question	Hypotheses developed	Level of analysis
attitudes	practices is different to the average change in attitudes in GPs from control practices	questionnaire administration (within GP) level
	The average change in attitudes in patients from PoCT practices is different to the average change in attitudes in patients from control practices	Time of questionnaire administration (within patient) level
	Device Operators report a change in average attitudes	Time of questionnaire administration (within Device Operator) level
	Pathology Providers report a change in average attitudes	Time of questionnaire administration (within pathology provider) level
	The average level of satisfaction with regard to PoCT assisting with disease management in intervention GPs is different to the average level of satisfaction with regard to PoCT assisting with disease management in control GPs	GP level
	The average level of satisfaction with regard to work flow in intervention GPs is different to the average level of satisfaction with regard to work flow in control GPs	GP level
	The average level of satisfaction with testing in intervention GPs is different to the average level of satisfaction with testing in control GPs	GP level
	The average level of satisfaction with regard to the collection process in intervention patients is different to the average level of satisfaction with regard to the collection process in control patients	Patient level
	The average level of confidence in the process in intervention patients is different to the average level of confidence in the process in control patients	Patient level
	The average level of confidence in the results in intervention patients is different to the average level of confidence in the results in control patients	Patient level
	The average level of satisfaction with regard to convenience in intervention patients is different to the average level of satisfaction with regard to convenience in control patients	Patient level
	The average level of satisfaction with regard to cost in intervention patients is different to the average level of satisfaction with regard to cost in control patients	Patient level
	The average level of satisfaction with regard to disease management in intervention patients is different to the average level of satisfaction with regard to disease management in control patients	Patient level
	Device Operators are satisfied with PoCT	Device Operator level
	Pathology Providers are satisfied with PoCT	Pathology Provider level

Area of key research question	Hypotheses developed	Level of analysis
Cost-effectiveness	The value of the resources used in PoCT is different from that of those used in pathology laboratory testing	Patient level

The PoCT Trial had two phases, Phase I lasting six months and Phase II lasting twelve months. In Phase I, patients in practices in the intervention group had pathology testing performed both by the pathology laboratory in the usual manner and by PoCT in the practice. The control group undertook testing by the pathology laboratory.

In Phase II, intervention group patients were tested using only PoCT at the practice, although pathology laboratory testing could be performed at any time at the request of the general practitioner, while control group patients continued to be tested by the pathology laboratory as usual. A summary of the Trial Design is provided in Figure 1.

The Trial Design was developed in partnership with the PoCT Steering Group, a working group of the Quality Use of Pathology Committee PoCT Implementation Subcommittee of the Australian Government (Appendix 1). The original Trial Design was then modified by the Trial Evaluators and the evaluation protocol and statistical analysis plan developed for the adapted Trial Design. This modification related to the equivalency design and is outlined in 1.11 and the reality of implementing the design in a general practice setting.

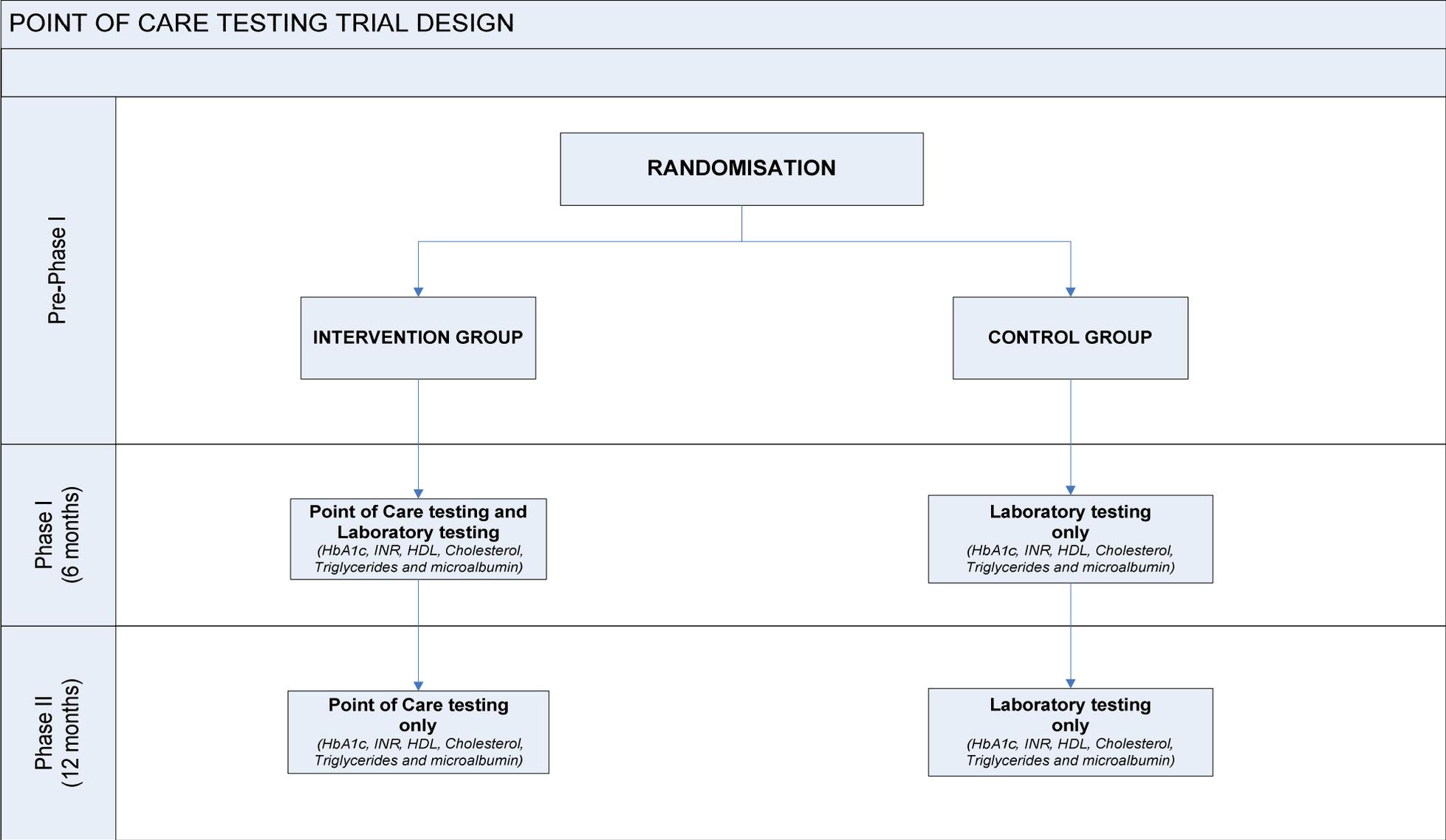
The PoCT Trial involved collaboration between three organisations who administered different aspects of the Trial. Trial Management and Evaluation was undertaken by the Disciplines of General Practice and Public Health at the University of Adelaide. The provision of devices, Device Operator training and QC was undertaken by the Community Point-of-Care Services Unit, Flinders University Rural Clinical School (‘Device Group’) and the external QA (EQA) program was provided by RCPA Quality Assurance Programs Pty Ltd.

### 1.3. STUDY SETTING

The Australian Medicare Program aims to provide equitable access to medical and hospital services for all Australian residents. The Department of Health and Ageing (the Department) has policy responsibility for Medicare, with Medicare Australia being responsible for Medicare administration and the payment of Medicare benefits, which are detailed in the Medicare Benefits Schedule (MBS). The Medical Services Advisory Committee (MSAC) advises the Department on the strength of evidence relating to the safety, clinical effectiveness and cost effectiveness of new and emerging medical services and technologies, and under what circumstances listing on the MBS should be supported.

To enable the payment of Medicare benefits for pathology services, pathology testing must be undertaken by a pathology laboratory that is accredited to provide a particular service. Pathology collection centres must be approved to enable the payment of Medicare benefits for services performed on specimens collected. Patients can either attend an approved collection centre or can have their blood, urine or other samples taken by or on behalf of the general practitioner referring them for the service. The specimen is then delivered to the pathology laboratory for testing. For patients in rural and remote locations, transportation time is critical and turnaround time for results can be longer than in urban settings, with a possible impact on patient management.

Figure 1: Overview of the PoCT Trial



Currently in Australia only a small number of point of care tests, such as pregnancy tests, are funded through the MBS for GP. To claim a broader range of pathology tests a practice must be a Category M (GP) Accredited Pathology Laboratory. This requires that they participate, at a cost, in the inspection and accreditation process implemented by the National Association of Testing Authorities. It has been suggested that the costs associated with accreditation and annual registration currently make it prohibitive for GP to participate, resulting in very few such practices existing in Australia.<sup>23</sup> The outcomes of the PoCT Trial will be used by the Department and its relevant advisory bodies (including MSAC) to determine whether an expanded range of PoCT for GP should be recommended for inclusion in the MBS.

### 1.3.1. GP setting

The Trial took place in a general practice setting. General practice is a component of the Australian health care system which:

*'operates predominantly through private medical practices, which provide universal unreferral access to whole person medical care for individuals, families and communities. General practice care means comprehensive, coordinated and continuing medical care drawing on biomedical, psychological, social and environmental understandings of health'*<sup>24</sup>

The structure of Australian general practice is unique as it is largely provided on a fee-for-service basis by private practitioners. General practice is a core component of primary health care with GPs having an important role in providing structured chronic disease management.

## 1.4. PARTICIPANTS

The Trial aimed to recruit 60 general practices across three geographic locations (urban, rural and remote) in South Australia, New South Wales and Victoria.

Both intervention and control practices were remunerated for their participation in the Trial. The payments were staggered and linked to the completion of milestones. These included signing an agreement to participate, patient recruitment and provision of data. Intervention practices were also remunerated for their participation in the accreditation process.

## 1.5. RRMA CLASSIFICATION

The definitions for the three geographic regions were provided in the Trial Design<sup>25</sup> and are summarised in Table 2.

**Table 2: Geographic regions for the PoCT Trial**

<b>Geographic region</b>	<b>Definition</b>
Urban	RRMA classification Category 1-2
Rural	RRMA classification Category 3-4
Remote	RRMA classification Category 5, 6 & 7

The definitions of the Australian Government's Rural, Remote and Metropolitan Area (RRMA) classification system<sup>26</sup> provided by the Trial Design are not the classifications used in standard practice. All Trial results are reported by geographic region.

## **1.6. RANDOMISATION AND ALLOCATION**

Practices were randomly allocated to the intervention or control arm in the ratio 1:1. Randomisation was stratified by geographic area (urban, rural and remote) and used randomly permuted blocks of size 2, 4 and 6. The random allocation sequence was generated using ralloc.ado version 3.2.5 in Stata 9.0.

Due to the type of intervention, neither participants nor project staff were blinded to the treatment allocation.

## **1.7. INTERVENTION**

Patients recruited in the intervention group had their pathology testing for either HbA1c, microalbumin, lipids (total cholesterol, triglyceride and HDL-C) or INR using PoCT devices in their general practice for 18 months. Patients in the control practices had these same tests undertaken using their usual care – the pathology laboratory.

The practices in the intervention group were provided with three PoCT devices – DCA 2000, CoaguChek S and Cholestech LDx. The selection of devices was based on non-analytical and analytical criteria prior to the commencement of the PoCT Trial. Training was provided to staff members in the use of the devices. At the end of their training, their competency was assessed by the Device and External Quality Assurance (EQA) Groups.

The practices were also required to perform internal QC and external QA testing designed for the PoCT Trial practices. The practices also participated in an accreditation process. The accreditation process and training were based on the (Interim) Standards for Point of Care Testing in General Practice incorporating the Trial Guidelines developed by the Australian Government.<sup>27</sup>

## **1.8. DATA COLLECTION AND OUTCOME MEASURES**

Data were collected at various points throughout the PoCT Trial to answer the four key questions. A schedule of data collection activities is provided in Table 3. In determining the data collection tools and outcome measures, it was necessary to ensure that these were applicable across the three different clinical conditions and could accommodate patients with more than one of the three conditions. Thus, validated tools or measures appropriate to only one condition could not be used. The Evaluation Team developed unique data collection tools and also utilised validated tools where applicable, and these are described below.

### **1.8.1. Safety**

To determine the safety of PoCT, a number of measures were identified. These included: performance in quality management; performance testing; compliance with the (Interim) Standards for PoCT; and serious adverse events reporting.

Internal QC for the intervention practices was assessed using QC materials comprising two levels of HbA1c, microalbumin and lipids and one level for INR. Device Operators forwarded their result to the Device Group for analysis. This was initially undertaken fortnightly and after three months undertaken monthly for the remainder of the Trial. Practices received a feedback report every three months reporting their precision expressed as a coefficient of variation.

The QAP allowed an external assessment of the PoCT device performance and a comparison with all practices in the Trial. Intervention practices were provided with an external QA kit for each test every six months during the Trial. The kit contained samples to be tested by the Device Operators. For the first three months two samples were tested every two weeks and after three months two samples were tested every four weeks for the remainder of the Trial. Practices forwarded results by mail or via the QAP website to RCPA Quality Assurance Programs Pty Ltd and acceptable limits of

**Table 3: Schedule of data collection activities**

Measure	Participant group	Method	Baseline	Continuous	6 months	14 months	18 months
Background data	Patient	Questionnaire	X				
	Practice	Questionnaire	X				
	General Practitioner	Questionnaire	X				
	Device Operator	Questionnaire	X				
	Pathology Provider	Questionnaire	X				
Attitudes to pathology testing	Patient	Questionnaire	X				X
	General Practitioner	Questionnaire	X				X
	Device Operator	Questionnaire	X				X
Comparison of laboratory and PoCT results	Practice	Pathology results PoCT results			X		
Practice costing data	Practice	Medicare Australia					X
		Time and motion study				X	
Patient costing data	Patient	Questionnaire					X
Medication and lifestyle advice compliance	Patient	Questionnaire			X	X	
Incidents		Reporting Form		X			
Serious adverse events		Reporting Form		X			
Process of care actions	General Practitioner	Case note audit					X
Appropriate prescribing	Patient/Practice/General Practitioner	Case note audit/ Medicare Australia					X
Improved therapeutic control	Patient	PoCT/Pathology results	X	X			
Satisfaction survey	Patient	Questionnaire					X
	General Practitioner	Questionnaire					X
	Device Operator	Questionnaire					X
	Pathology Provider	Questionnaire					X

good performance were determined. At the end of each testing cycle, practices were provided with a summary of their performance (precision and accuracy) over the previous six months and a comparison with other participating sites.

### 1.8.2. Clinical effectiveness

To determine the clinical effectiveness of PoCT compared with pathology laboratory testing, the PoCT Trial focused on therapeutic control and impact on patient care.

To measure therapeutic control, two outcomes were considered: firstly, the proportion of patients within target range (prevalence) and secondly the proportion of tests within target range for each type of test. The former was the primary outcome measure for the Trial. The target ranges used for the seven tests are defined in Table 4 and are based on the Australian clinical guidelines for warfarin therapy<sup>28</sup> (Appendix 2), diabetes management<sup>29, 30</sup> (Appendix 3), and lipids management<sup>31</sup> (Appendix 4) as outlined in the Trial design. For intervention practices, patient test results were recorded on a specifically designed request/result form, with copies forwarded to the Trial Manager every month (refer to Appendix 5).

For control practices, test results were collected from the pathology laboratory through either hard copy or weekly electronic downloads of results for those patients identified as participating in the Trial. This was achieved with a PoCT Trial identification sticker adhered to the pathology laboratory test request form.

**Table 4: Target ranges by condition and test**

Condition	Test	Target range
INR <sup>28</sup>	Atrial fibrillation and other conditions	2.0-3.0
	Prosthetic heart valve	2.5-3.5
Diabetes <sup>29, 30</sup>	HbA1c	≤7%
Microalbuminuria <sup>30</sup>	ACR	<3.6 female
		<2.6 male
	Urine albumin	<20µg/min
Hyperlipidaemia <sup>31</sup>	Total cholesterol	<4.0 mmol/L
	Triglycerides	<2.0 mmol
	High density lipoprotein (HDL-C)	>1.0 mmol/L

To measure the impact of PoCT on patient care, a number of outcome measures were determined. These included: number of general practitioner visits per person-year, patient compliance with disease management, pharmaceutical prescribing, and process of care actions undertaken by the general practitioner following a pathology test.

#### 1.8.2.1. General practitioner visits per person-year

Pathology results provided by PoCT as the time of consultation provides GPs with an opportunity to discuss the test results with their patients immediately and implement any changes to improve the management of their condition. Measuring the number of general practitioner visits per person-year for patients in the PoCT Trial will determine if PoCT leads to more or fewer visits. Some research indicates that PoCT results in increased testing<sup>32</sup>, while others have found no significant difference.<sup>33, 34</sup> An increase in the number of tests has the potential to increase the number of patient visits.

In order to assess the number of GP visits during the length of the Trial, data was obtained from Medicare Australia.

#### 1.8.2.2. *Medication compliance*

It has been widely reported in the literature that non-compliance to medication is substantial with an estimated 30-40% of patients failing to take medications as prescribed<sup>35</sup>. It is well known that low compliance to medication compromises the effectiveness of treatment at substantial costs to the patient (to the potential detriment of health), to the health professional (treating morbidity) and to society (economic impact) making it an important area to improve.<sup>36-38</sup> To assess compliance with medication a self-administered questionnaire was sent to all patients twice during the Trial.

Medication compliance was measured using the Medication Adherence Reporting Scale (MARS-5). The MARS-5 is a five-item scale asking participants to rate the frequency with which they engage in each of five components of non-adherent behaviour, e.g. altering the dose or forgetting to take a dose. Since 1996, the MARS-5 has been used in studies across a variety of illnesses and in several countries.<sup>39,40,41, 42</sup> The MARS-5 has been found to have good reliability and validity.<sup>43</sup>

Patients were also asked to comment about their beliefs and attitudes towards medicines in general and medicines prescribed for their condition. Past research has shown that levels of medication compliance are associated with patient beliefs about the necessity of taking medication.<sup>43</sup>

#### 1.8.2.3. *Processes of care and prescribing patterns*

In order to assess the impact of PoCT on general practitioner management of the patient, the PoCT Trial measured the processes of care associated with each pathology test. The availability of a test result during the consultation should assist the general practitioner to treat and manage patients with the three conditions of interest.<sup>44</sup> Grieve et al.<sup>45</sup> found that the provision of immediate test results for HbA1c led to significantly more management changes being made. The minimum number of processes of care for the Trial were based on the guidelines developed for diabetes management, management of patients on anticoagulant therapy and lipids management<sup>28-31, 46</sup> (see Appendix 2 to Appendix 4) and depended on whether the test result was within or outside the target range. The data were collected through a case note audit of a random sample of patient medical records. A total of 18 practices, stratified by treatment group and geographic location, were included in the sample. Sixty-five patients were then randomly selected from each of the chosen practices, or all patients were selected if the practice had less than 65 patients participating in the Trial. Following training, the auditors recorded the number and type of actions relating to each pathology test performed during the Trial. Actions included review of the test result by the general practitioner, medication review, medication changes, lifestyle advice given, referrals, blood pressure readings and requests for follow-up testing.

PoCT has the potential to improve patient compliance with medication and result in more appropriate and timely prescribing by GPs.<sup>4</sup> To assess the influence of PoCT on prescribing patterns, the data from the case note audit were used to identify changes made to prescribed medication for each visit relating to a pathology test. These changes include dosage changes, ceasing of medication and change in type of drug. Prescribing patterns were analysed separately for test results within and outside the target range.

#### 1.8.3. *Cost-effectiveness*

To determine the cost-effectiveness of PoCT versus pathology laboratory testing, comparative cost analysis and cost effectiveness analysis were undertaken, taking a societal perspective. Costs included in the analysis were establishment costs (equipment and training), consumable and maintenance costs, QC and QA costs, accreditation costs, costs associated with the practice consultation, testing costs, patient costs and downstream costs.

Cost data were collected from a number of sources. These included MBS service claims (from Medicare Australia) by participating GPs, general practitioner and Device Operator time through a time and motion study, patient-borne costs collected as part of the baseline and satisfaction questionnaires, industry sources for costs related to PoCT devices, allied health and specialist services from the Medicare Australia database, and hospitalisations from the case note audit.

Cost-effectiveness was measured using the incremental cost-effectiveness ratio. The intermediate outcome indicator for each type of test was the percentage of patients who were maintained within the normal clinical range for that blood level based on the last test result collected during the Trial (adequate control).

#### 1.8.4. Satisfaction

The PoCT Trial assessed the satisfaction of patients, GPs, Device Operators and Pathology Providers with PoCT, and compared this with patient, GP and pathology provider satisfaction with usual pathology testing.

Attitudinal questions were administered at baseline (baseline questionnaires) and at the end of the Trial (satisfaction questionnaires) to patients, GPs, Device Operators and Pathology Providers. Questions covered areas such as preference, convenience, collection of blood, impact on management of conditions, impact of PoCT on the practice and difficulty in the use of PoCT devices.

Additional data relating to satisfaction were also collected through the satisfaction questionnaires. For the intervention group this covered the areas of comparative quality of the process (confidence in the collection process, confidence in the results) and comparative convenience (transport, loss of work time and out-of-pocket expenses). The control group were asked to rate their satisfaction in the same areas as the intervention group, but as it related to pathology laboratories.

For GPs and Device Operators, the satisfaction questionnaire focused on their preference, attitude and stated behaviour around pathology testing. Those in the intervention group had a number of additional questions relating specifically to PoCT. Topics covered in the General Practitioner and Device Operator questionnaires included: training, self-assessed competence, accreditation method, equipment, suitability of PoCT within the consultation, impact on health outcomes, convenience and efficiency to the practice, payment and impact on interaction with Pathology Providers. Pathology Provider attitudes to PoCT were also obtained, covering areas such as analytical quality, accreditation, laboratory involvement and impact on laboratory testing. For all the satisfaction questionnaires, questions were either designed specifically for the Trial or were taken from other studies.<sup>15, 22, 23, 45, 47, 48</sup>

### 1.9. DATA MANAGEMENT AND SAFETY MONITORING

The Data Management and Analysis Centre (DMAC) of the Discipline of Public Health at the University of Adelaide was contracted to design and implement the IT systems for the PoCT Trial. These systems comprised a Management Information System (MIS) and a data entry system. The MIS was web-based and enabled the collection and dissemination of Trial Management information. The database into which management information was collected could also be accessed by Trial Management and Evaluation staff to produce reports as required. Access to the Trial IT systems required log-ins and passwords and all staff received training in its use. Data entry was performed by specialised data entry staff in DMAC following PoCT Trial standard operating procedures.

While the PoCT Trial was deemed low-risk, a Safety Subcommittee was established to monitor serious adverse events (SAEs) and incidents throughout its length and to develop stopping rules. Practices, using a SAE Reporting Form, were required to report any SAEs for recruited patients. The SAEs were categorised as death, life-threatening, permanent or significant disability or incapacity, hospitalisation, newly diagnosed cancer or other important medical event. Each SAE was initially

assessed by the Trial Manager to determine the likelihood of the event resulting from involvement in the PoCT Trial before all events were submitted to the Safety Subcommittee for final assessment. In addition, any Trial related incident was also required to be reported to the Trial Manager for assessment using an Incident Reporting form. Incidents could be patient, operator, device or QC/QA related.

Throughout the PoCT Trial, all participants had access to the three organisations administering the Trial via a free-call telephone number.

#### 1.9.1. CoaguChek S product safety notice

In late October 2006 the Trial Management Group became aware of a Product Safety Notice issued by Roche Diagnostics Australia which involved an international recall by Roche of testing strips for the CoaguChek S INR testing device. The Product Safety Notice identified that the testing strips might occasionally lead to an abnormally high INR test result due to a manufacturing fault. The Therapeutic Goods Association (TGA) and Roche issued a notice (Appendix 6) to users of the CoaguChek S device advising either an upgrade to the new model CoaguChek or to undertake duplicate testing using testing strips from a different batch. An urgent notice was issued by the Device Group (Appendix 7) providing instructions on the duplicate testing procedure to be followed when using testing strips from a different batch. Details of the recall process and subsequent change in Trial protocol are provided in Appendix 8.

### 1.10. STATISTICAL METHODS AND ISSUES

#### 1.10.1. Statistical analysis plan

In order to address the multitude of hypotheses developed for the PoCT Trial, a variety of statistical methods were required. For some hypotheses, the planned analysis was purely descriptive. For other hypotheses, statistical tests were planned. For details of all planned hypotheses and methods of analysis, see the Evaluation Protocol in Appendix 9.

##### 1.10.1.1. *Non-inferiority and comparative tests*

Non-inferiority trials aim to determine whether a new treatment is not worse than the existing treatment/method by more than a specified margin.<sup>49</sup> The new treatment is recommended if the efficacy is similar to or better than the existing treatment, but not if it is worse. The new treatment should have other benefits, such as increased patient and health professional satisfaction, greater convenience or reduced costs. It could also provide an alternative to the standard treatment.<sup>50</sup> The goal of non-inferiority trials is to rule out differences of clinical importance. In these trials, if the new treatment is found to be better, this is an added advantage. To show that the new treatment is better, however, a superiority test must also be performed, as a non-inferiority test can only be used to show that the new treatment is the same or better.

Planned statistical tests fell into two categories; non-inferiority tests and comparative tests.

For non-inferiority tests, the aim is to reject the null hypothesis that PoCT is worse than laboratory testing in relation to the outcome of interest and conclude that PoCT is the same or better (e.g. non-inferior). A non-inferiority margin must be specified, based on clinical considerations, to clarify what is meant by 'the same'. Non-inferiority tests were planned for hypotheses relating to safety and clinical effectiveness, except for the hypothesis relating to the number of GP visits per person-year, since it is unclear whether more or less GP visits would be considered better.

For comparative tests, the aim is to reject the null hypothesis that PoCT is the same as laboratory testing in relation to the outcome of interest and conclude that PoCT is different. Comparative tests were planned for hypotheses relating to cost-effectiveness, satisfaction and the number of GP visits per person-year.

### 1.10.1.2. Intention to treat

An intention to treat approach was planned for all analyses. This type of approach is commonly recommended<sup>51-53</sup> and is generally accepted as the most appropriate analysis approach for comparative tests. There has been some debate about the role of intention to treat and per protocol approaches for tests of non-inferiority; however, an intention to treat approach has also been recommended in this case.<sup>53</sup>

### 1.10.1.3. Baseline covariates

A number of potential confounders were identified *a priori* as important. Both unadjusted and adjusted analyses were pre-specified, with conclusions to be based on the results of the adjusted analyses.

For outcomes relating to patients or individual tests/questionnaires within patients, adjustment was planned for the age and gender of the patient. For outcomes to be analysed separately for each type of test, the potential confounders to adjust for (in addition to age and gender) depended on the type of test. For tests relating to diabetes (HbA1c and microalbuminuria), adjustment was planned for time since diagnosis of diabetes, Aboriginal or Torres Strait Islander status, use of dietary control, prescription tablets and insulin for treating diabetes, and BMI. For HbA1c, adjustment was also planned for baseline HbA1c result. For lipids tests (total cholesterol, HDL-C and triglycerides), adjustment was planned for known heart disease, diabetes, Aboriginal or Torres Strait Islander status, socio-economic status, smoking status and baseline test result. For INR, adjustment was planned for BMI, multiple co-morbidities and baseline INR result (categorised as either above target range, below target range or within target range).

For outcomes relating to GPs, Device Operators and practices, no adjusted analyses were planned.

## 1.11. SAMPLE SIZE CALCULATIONS

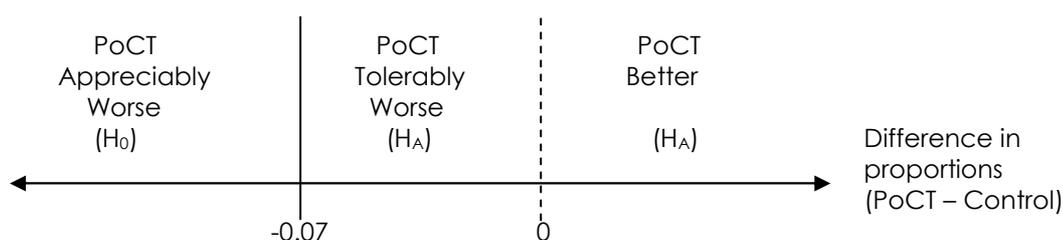
The original Trial Design included details of sample size calculations performed for the Trial. The primary outcome on which the sample size was based was the proportion of patients within target range, a measure of clinical effectiveness.

In the original Trial Design the calculations were performed assuming a comparative test would be used. These types of tests may be used to answer questions about whether PoCT is *better* than laboratory testing in relation to a particular outcome. However, the key question relating to clinical effectiveness asks 'Is the effectiveness of PoCT the *same or better* than for the same tests using pathology laboratory testing?' which cannot be answered using a comparative test. Instead, a non-inferiority test is required. Thus, a non-inferiority margin needed to be specified for the primary outcome so that the sample size could be re-calculated for the Trial.

### 1.11.1. Defining the non-inferiority margin

For the primary outcome of the proportion of patients within target range, the null hypothesis ( $H_0$ ) is that PoCT is worse than laboratory testing in terms of the proportion of patients within target range. The alternative hypothesis ( $H_A$ ) is that PoCT is the same or better (e.g. non-inferior). The PoCT Management Committee considered that PoCT would be non-inferior to pathology laboratory testing if the true difference in the proportion of patients within target range (intervention minus control) was no less than -0.07, or -7% (see Figure 2). In other words, PoCT will be accepted as being the same or better than laboratory testing, provided we can be confident that PoCT is no more than 7% worse than laboratory testing. This non-inferiority margin was chosen as a compromise between clinical significance and the feasibility of recruitment.

**Figure 2: Non-inferiority criteria for proportion of patients within target range**



### 1.11.2. Sample size re-calculations

The sample size was re-calculated separately for each type of test. Where multiple tests are performed for the same condition (e.g. HbA1c and microalbuminuria tests are both performed for diabetic patients), the largest of the estimated sample sizes was used.

Based on information obtained from a pathology laboratory, the proportion of control patients with pathology results within target range was assumed to be 0.12, 0.81, 0.77 and 0.53 for total cholesterol, HDL-C, triglycerides and HbA1c respectively. Since no suitable information was available for INR or microalbuminuria, the proportion of control patients with pathology results within target range was assumed to be 0.5 for each of these tests to give the largest sample size. The difference in the proportion of patients within target range (PoCT – control) was assumed to be zero.

The design effect (DEFF) indicates how many times larger the sample size needs to be for a cluster-randomised trial to achieve the same power as an individual randomised trial, all other things remaining equal. In other words, once the sample size is calculated, assuming individuals will be randomised, this number needs to be multiplied by the DEFF to give the required sample size for a cluster-randomised trial. A DEFF of 2 was suggested in the original Trial Design to allow for correlation between observations arising from the same cluster. The Trial Evaluators investigated DEFFs in the Second Australian National Blood Pressure Study (ANBP2)<sup>54</sup> which suggested that a DEFF of 2 may be an overestimate for a study conducted in a general practice setting. As a conservative approach, however, a DEFF of 2 was still assumed in the sample size calculations to allow for the possibility that the DEFF may be higher for the PoCT Trial than for ANBP2.

Using a one-sided, normal-approximation, non-inferiority test of two proportions, a type 1 error probability of 0.05, 80% power and assuming a DEFF of 2, the number of patients required per group was 1262, 894 and 1262 for anticoagulant therapy, hyperlipidaemia and diabetes respectively.

## 1.12. GENERAL STATISTICAL METHODS

All analyses were performed on an 'intention to treat basis' and took into account clustering at the practice level, as well as the patient/General Practitioner/Device Operator level where appropriate, using mixed effects models or generalised estimating equations. The level of analysis varied depending on the hypothesis (see Table 1). No adjustment was made for multiple tests of hypotheses specified *a priori*. All analyses were carried out using SAS version 9.1.3 (Cary, NC, USA).

Analyses of outcomes relating to patients or individual tests/questionnaires within patients were adjusted for all planned confounders listed in Section 1.10.1, with the exception of Aboriginal or Torres Strait Islander due to the small number of such patients in the Trial. Baseline characteristics were similar between treatment groups. A comparison of baseline covariates by treatment group for each condition is given in Table 5. These comparison indicate that the two treatment groups were similar across most of the variables.

For some hypotheses, the statistical methods used differed from the methods pre-specified in the Trial Evaluation Protocol due to issues with data quality (serious adverse events) or distributions of

**Table 5: Comparison of patient baseline characteristics by condition**

Condition group	Characteristic		Control n(%)	Intervention n(%)	Total n(%)
Diabetes			N=785	N=1182	N=1967
	Male		432 (55.0)	651 (55.1)	1083 (55.1)
	Age (years)	Median (IQ range)	67.0 (59.0-74.0)	66.0 (58.0-73.0)	66.0 (59.0-73.0)
	Aboriginal and Torres Strait Islander	Yes	4 (0.5)	23 (1.9)	27 (1.4)
		No	723 (92.1)	1036 (87.6)	1759 (89.4)
		Missing	58 (7.4)	123 (10.4)	181 (9.2)
	BMI	Underweight	5 (0.6)	3 (0.3)	8 (0.4)
		Normal	121 (15.4)	181 (15.3)	302 (15.4)
		Overweight	243 (31.0)	386 (32.7)	629 (32.0)
		Obese	334 (42.5)	464 (39.3)	798 (40.6)
		Missing	82 (10.4)	148 (12.5)	230 (11.7)
	HbA1c %	Median (IQ range)	7.1 (6.3-8.0)	6.9 (6.2-7.7)	7.0 (6.3-7.8)
		Missing	64 (8.2)	90 (7.6)	154 (7.8)
	Diabetes management:				
	Dietary control	Yes	446 (56.8)	604 (51.1)	1050 (53.4)
		No	309 (39.4)	503 (42.6)	812 (41.3)
		Missing	30 (3.8)	75 (6.3)	105 (5.3)
	Insulin	Yes	145 (18.5)	204 (17.3)	349 (17.7)
		No	610 (77.7)	903 (76.4)	1513 (76.9)
		Missing	30 (3.8)	75 (6.3)	105 (5.3)
	Prescription tablets	Yes	541 (68.9)	729 (61.7)	1270 (64.6)
		No	214 (27.3)	378 (32.0)	592 (30.1)
		Missing	30 (3.8)	75 (6.3)	105 (5.3)
	Years since first diagnosed	< 1 year	39 (5.0)	67 (5.7)	106 (5.4)
		1-5 years	256 (32.6)	403 (34.1)	659 (33.5)

Condition group	Characteristic	Control n(%)	Intervention n(%)	Total n(%)
	6-10 years	201 (25.6)	235 (19.9)	436 (22.2)
	> 10 years	230 (29.3)	311 (26.3)	541 (27.5)
	Missing	59 (7.5)	166 (14.0)	225 (11.4)
Hyperlipidaemia		N=1463	N=2356	N=3819
	Male	753 (51.5)	1277 (54.2)	2030 (53.2)
	Age (years)	Median (IQ range)	68.0 (60.0-74.0)	66.0 (59.0-74.0)
	Aboriginal and Torres Strait Islander	Yes	9 (0.6)	26 (1.1)
		No	1342 (91.7)	2102 (89.2)
		Missing	112 (7.7)	228 (9.7)
	Index of Relative Socio-Economic Disadvantage	1 <sup>st</sup> quartile	251 (17.2)	575 (24.4)
		2 <sup>nd</sup> quartile	476 (32.5)	756 (32.1)
		3 <sup>rd</sup> quartile	390 (26.7)	663 (28.1)
		4 <sup>th</sup> quartile	346 (23.7)	362 (15.4)
	Co-morbid conditions:			
	Known heart disease	Yes	540 (36.9)	812 (34.5)
		No	869 (59.4)	1398 (59.3)
		Missing	54 (3.7)	146 (6.2)
	Diabetes		509 (34.8)	853 (36.2)
	Smoking status	Current	103 (7.0)	201 (8.5)
		Ex-smoker	644 (44.0)	1001 (42.5)
		Never smoked	654 (44.7)	990 (42.0)
		Missing	62 (4.2)	164 (7.0)
	Total cholesterol	Median (IQ range)	4.7 (4.0-5.4)	4.6 (4.0-5.4)
		Missing	99 (6.8)	186 (7.9)
	Triglyceride	Median (IQ range)	1.6 (1.1-2.2)	1.6 (1.2-2.2)
		Missing	185 (12.6)	204 (8.7)
	HDL-C	Median (IQ range)	1.3 (1.1-1.6)	1.3 (1.1-1.5)

Condition group	Characteristic	Control n(%)	Intervention n(%)	Total n(%)	
	Missing	239 (16.3)	515 (21.9)	754 (19.7)	
Anticoagulant therapy		N=372	N=572	N=944	
	Male	217 (58.3)	326 (57.0)	543 (57.5)	
	Age (years)	Median (IQ range)	73.0 (66.0-79.0)	73.0 (65.0-79.0)	
	BMI	Underweight	7 (1.9)	5 (0.9)	12 (1.3)
		Normal	90 (24.2)	165 (28.8)	255 (27.0)
		Overweight	130 (34.9)	190 (33.2)	320 (33.9)
		Obese	111 (29.8)	132 (23.1)	243 (25.7)
		Missing	34 (9.1)	80 (14.0)	114 (12.1)
	Multiple co-morbidities	Yes	170 (45.7)	285 (49.8)	455 (48.2)
		No	186 (50.0)	259 (45.3)	445 (47.1)
		Missing	16 (4.3)	28 (4.9)	44 (4.7)
	INR	Below target range	73 (19.6)	115 (20.1)	188 (19.9)
		Within target range	197 (53.0)	316 (55.2)	513 (54.3)
		Above target range	37 (9.9)	63 (11.0)	100 (10.6)
		Missing	65 (17.5)	78 (13.6)	143 (15.1)

outcomes differing from assumed distributions (medication compliance and satisfaction). Further details relating to statistical methods and any deviations from the Trial Protocol will be given in subsequent chapters in relation to specific hypotheses (Appendix 9).

### 1.12.1. Geographic location

In order to determine whether there were differences between urban, rural and remote geographic regions in any of the treatment effects measured, analyses were repeated with a geographic location effect as well as an interaction between treatment group and geographic location to test for evidence of effect modification by geographic location. *Post hoc* tests were performed to examine the effect of treatment separately within each geographic region. Where there was evidence of effect modification, this suggested that PoCT was having a different effect on the outcome, depending on the geographic location. In this case, the results of the *post hoc* tests were used to determine where the differences were. If there is no evidence of effect modification, the results of the *post hoc* tests should be interpreted with caution since there is no evidence to suggest that PoCT is having a different effect on the outcome by geographic location.

### 1.12.2. Missing data

Missing data were a general problem for the PoCT Trial. Data were missing for a variety of reasons, including withdrawal, death, relocation, failure of participants to return questionnaires and failure by practices to follow Trial procedures.

The form and extent of the missing data on both outcomes and potential confounders were considered separately for each analysis (see subsequent chapters for further details in relation to specific analyses). Where there was evidence to suggest the missing data were not missing completely at random, 10 completed data sets were generated for analysis using multiple imputation.<sup>55</sup>Under-reporting of test results

Data collected through the case note audit provide evidence of under-reporting of test results. The percentage of test results for case note audit patients that were discovered through the case note audit, rather than reported by the practice or downloaded electronically from the pathology laboratory, are presented in Table 6. These figures indicate that there is evidence of under-reporting of test results across both treatment groups, with a higher rate of under-reporting occurring in the control group. Possible reasons for the under-reporting include non-adherence to Trial protocol by GPs and patients and test request by specialists.

**Table 6: Percentage of test results for case note audit patients that were discovered through the case note audit by treatment group and type of test**

Test	Intervention (%)	Control (%)
INR	18.07	36.37
Total Cholesterol	32.05	34.38
HDL Cholesterol	30.32	34.46
Triglycerides	32.05	34.52
HbA1c	28.47	32.45
Urine Albumin	28.06	46.12
Albumin/Creatinine Ratio	24.18	41.67

This under-reproting has implications for several areas of the analysis which are outlined below. The implications of under-reporting for SAEs are outlined in section 8.4.1.

### *Implications for Costing Analysis*

For the costing analysis, two data sources were available for determining the number of tests performed; the test results collected for the Trial from the practices and pathology laboratories, and the Medicare Australia data. While both data sources have their limitations, the Medicare data was considered a more reliable source of the number of tests performed for the purposes of comparing costs between treatment groups. If the number of tests used in the costing analysis was based on the number of test results collected for the Trial, the cost of the tests performed for the Trial would be substantially underestimated due to the under-reporting of test results. This would be more of a problem for the control group where the under-reporting was greater (Table 6).

### *Implications for the Clinical Effectiveness Analysis*

The assessment of clinical effectiveness in relation to target ranges was based on both the last test result and all test results. It is important to consider the potential impact of the under-reporting of test results on the results of these analyses. For patients who did not have a test result due to either under-reporting or failure to have a test, a single result was imputed so all patients were included in the analysis. For patients who had fewer test results than they should have had due to under-reporting, only the available test results were included in the analysis. Failure to include the test results that were not reported means a reduction in power to show that PoCT is non-inferior to pathology laboratory testing in terms of the proportion of test results within target range. It could also lead to bias in the clinical effectiveness analyses relating to both the last test result and all test results if the missing test results were more likely to be within or outside the target range compared to the test results that were reported. However, this is considered to be unlikely since reasons for missing test results include: failure by the GP to attach a pink sticker to a pathology request which occurs before the test result is known and hence cannot be influenced by the test result; problems with the electronic download of pathology laboratory results which may result in a batch of results not being received depending on the date the tests were performed rather than the test results.

## **1.13. CASE NOTE AUDIT SAMPLE SELECTION AND WEIGHTS**

Data relating to a number of hypotheses were collected through a case note audit of a sample of Trial patients. Only 34 practices (3352 patients) were eligible for selection for the case note audit. The remaining practices were excluded due to either practice withdrawal or inability to provide any space for the auditor. Each eligible practice was given a score depending on factors such as accessibility and space within the practice to conduct the audit. A total of 18 practices (three from each stratum determined by treatment group and geographic location) were randomly selected and practices with a higher score were given a higher probability of selection.

From each selected practice, 65 patients were randomly selected, with equal probability of selection applying to all patients within a given practice. For practices with less than 65 patients, all patients were selected. A total of 1126 patients were selected for the case note audit. Sampling weights were calculated from the probabilities of selection for practices and patients to allow estimation of parameters of interest relating to the 3352 patients who were eligible for case note audit selection based on data from the 1126 patients who were audited.

Baseline characteristics of patients who were selected for the case note audit and patients who were eligible for selection but who were not selected is shown in Table 7. The two groups are similar, except for the percentage in each geographic location. This difference was expected, since the selection process was designed to select approximately equal patient numbers from each geographic location and this was accounted for in the sampling weights.

A comparison of baseline characteristics of patients who were eligible for selection for the case note audit and patients who were not eligible is given in Table 8. The two groups are fairly similar, except for the percentage in each geographic location which was due to the relatively large number of remote practices excluded from the case note audit selection process. Thus, sampling weights were adjusted within each stratum (defined by treatment group and geographic location) to allow estimation of parameters of interest relating to all 4968 Trial patients based on data from

the 1126 patients who were audited. Where analysis has been performed based on data from the case note audit, all figures are weighted estimates which apply to all patients in the Trial.

**Table 7: Baseline patient characteristics by case note audit selection status among eligible patients**

Characteristic	Not selected for case note audit	Selected for case note audit	Total
	N=2226	N=1126	N=3352
Gender: n (%)			
Female	1021 (45.9)	560 (49.7)	1581 (47.2)
Male	1205 (54.1)	566 (50.3)	1771 (52.8)
Age Group: n (%)			
18-39	25 (1.1)	18 (1.6)	43 (1.3)
40-49	133 (6.0)	61 (5.4)	194 (5.8)
50-59	403 (18.1)	195 (17.3)	598 (17.8)
60-69	715 (32.1)	362 (32.1)	1077 (32.1)
70-79	707 (31.8)	361 (32.1)	1068 (31.9)
80+	243 (10.9)	129 (11.5)	372 (11.1)
Age (Years): median (IQ range)	67.0 (59.0-75.0)	68.0 (60.0-75.0)	68.0 (60.0-75.0)
Geographic Location: n (%)			
Urban	1178 (52.9)	389 (34.5)	1567 (46.7)
Rural	701 (31.5)	308 (27.4)	1009 (30.1)
Remote	347 (15.6)	429 (38.1)	776 (23.2)
Anticoagulant Therapy: n (%)			
No	1796 (80.7)	878 (78.0)	2674 (79.8)
Yes	430 (19.3)	248 (22.0)	678 (20.2)
Diabetes: n (%)			
No	1305 (58.6)	689 (61.2)	1994 (59.5)
Yes	921 (41.4)	437 (38.8)	1358 (40.5)
Hyperlipidaemia: n (%)			
No	497 (22.3)	270 (24.0)	767 (22.9)
Yes	1729 (77.7)	856 (76.0)	2585 (77.1)
Number of Conditions: n (%)			
1	1429 (64.2)	736 (65.4)	2165 (64.6)
2	740 (33.2)	365 (32.4)	1105 (33.0)
3	57 (2.6)	25 (2.2)	82 (2.4)

**Table 8: Baseline patient characteristics by eligibility for case note audit selection**

Characteristic	Eligible for case note audit selection	Ineligible for case note audit selection	Total
	N=3352	N=1616	N=4968
Gender: n (%)			
Female	1581 (47.2)	739 (45.7)	2320 (46.7)
Male	1771 (52.8)	877 (54.3)	2648 (53.3)
Age Group: n (%)			
18-39	43 (1.3)	30 (1.9)	73 (1.5)
40-49	194 (5.8)	114 (7.1)	308 (6.2)
50-59	598 (17.8)	310 (19.2)	908 (18.3)
60-69	1077 (32.1)	542 (33.5)	1619 (32.6)
70-79	1068 (31.9)	479 (29.6)	1547 (31.1)
80+	372 (11.1)	141 (8.7)	513 (10.3)
Age (Years): median (IQ range)	68.0 (60.0-75.0)	66.0 (58.0-74.0)	67.0 (59.0-75.0)
Geographic Location: n (%)			
Urban	1567 (46.7)	170 (10.5)	1737 (35.0)
Rural	1009 (30.1)	355 (22.0)	1364 (27.5)
Remote	776 (23.2)	1091 (67.5)	1867 (37.6)
Anticoagulant Therapy: n (%)			
No	2674 (79.8)	1309 (81.0)	3983 (80.2)
Yes	678 (20.2)	266 (16.5)	944 (19.0)
Missing	0 (0.0)	41 (2.5)	41 (0.8)
Diabetes: n (%)			
No	1994 (59.5)	966 (59.8)	2960 (59.6)
Yes	1358 (40.5)	609 (37.7)	1967 (39.6)
Missing	0 (0.0)	41 (2.5)	41 (0.8)
Hyperlipidaemia: n (%)			
No	767 (22.9)	341 (21.1)	1108 (22.3)
Yes	2585 (77.1)	1234 (76.4)	3819 (76.9)
Missing	0 (0.0)	41 (2.5)	41 (0.8)
Number of Conditions: n (%)			
Missing	0 (0.0)	41 (2.5)	41 (0.8)
1	2165 (64.6)	1072 (66.3)	3237 (65.2)
2	1105 (33.0)	472 (29.2)	1577 (31.7)
3	82 (2.4)	31 (1.9)	113 (2.3)

#### 1.14. ETHICAL APPROVAL AND REGISTRATION

The PoCT Trial was approved by five relevant independent Australian Human Research Ethics Committees:

The University of Adelaide Human Research Ethics Committee

- Departmental Ethics Committee, Department of Health and Ageing
- Human Research Ethics Committee, The University of Sydney
- The Standing Committee on Ethics in Research Involving Humans, Monash University and
- National Research and Evaluation Ethics Committee, Royal Australian College of General Practitioners (RACGP).

The Trial was registered with the Australian Clinical Trial Registry, Number 12612605000272695.<sup>56</sup>

## 1.15. DISCUSSION

The PoCT Trial was a complex study taking place in a GP setting. The issues facing the implementation and design of the Trial emphasised the difficulties of undertaking a RCT in a GP setting and why RCTs in GP are often termed 'pragmatic' RCTs. As with the PoCT Trial, pragmatic RCTs are suitable to evaluate effectiveness rather than to measure efficacy.<sup>57</sup> Such trials determine the benefit of a treatment within routine clinical care rather than under ideal conditions. Results reflect the variation that occurs in the real world and are particularly suitable for interventions that inform policy decisions.

A key methodological issue in pragmatic RCTs is balancing internal validity and external validity. This issue was addressed for the PoCT Trial in the study design and evaluation protocol. External validity was maintained by minimising the exclusion criteria, allowing the GPs to implement PoCT in their own manner within the practice and allowing patients to choose not to have PoCT at any time during the Trial. Internal validity was maintained through cluster randomisation of practices to reduce contamination issues.

### *Evaluation protocol design*

In developing the evaluation protocol and the data collection tools, three participant groups were considered – GPs and their practices, patients and Pathology Providers. The approach taken needed to balance data quality with the pragmatic aspects necessary when undertaking a RCT in a GP setting.

### *Limitations*

Unfortunately, the PoCT Trial was not able to recruit sufficient patients in two of the three conditions to obtain desired power. The Trial Design required the recruitment of practices in three geographic locations – urban, rural and remote. However, the original Trial Design did not consider the possibility that practices in rural or remote locations would not have sufficient patient population to meet the required sample size and hence the amended design allowed practices to be recruited knowing that they could not meet the minimum requirement of patients.

With any trial, ensuring adherence to the evaluation and treatment protocol by participants is difficult, although this is of less importance in a pragmatic RCT.<sup>57</sup> This difficulty was amplified for the PoCT Trial because of the large number of participants and their geographic spread. One of the aims of establishing Node Support Officers (NSOs) in each region was to provide a local link for practices and for the NSO to monitor adherence to the protocol, which worked to some extent. However, it was reliant on the relationship between the NSO and the practices and the geographic spread of practices meant that it was not possible for the NSO to visit practices on a regular basis.

Due to both time and cost constraints, the case note audit of patient records could only be undertaken for a sample of patients. However, descriptive analysis suggests that the sample of patients included in the CNA was representative of the entire patient population of the PoCT Trial in

terms of baseline characteristics and hence results based on analysis of CNA data are applicable to all Trial patients.

## **1.16. CONCLUSION**

The PoCT Trial was one of the largest and most comprehensive RCTs to evaluate the impact of PoCT in a GP setting. There have been few RCTs in this area and none have investigated all the areas covered in this Trial or at the scale of this Trial either in terms of the number of practices, the number of patients or the number of pathology tests included.<sup>8, 18, 33, 34, 58-60</sup> No past trials and very few observational studies<sup>16, 17</sup> have investigated the influence of geographic location on PoCT. The results of the PoCT Trial should provide a sound evidence base as to whether PoCT (for the three conditions) should be implemented by the government in Australian general practice.

## 2. SYSTEMATIC REVIEW OF PoCT IN GENERAL PRACTICE

### SUMMARY OF THE CHAPTER

This chapter describes the systematic review of the literature conducted to assess whether the available evidence relating to the safety, clinical effectiveness, cost and patient and health professional satisfaction supports the introduction of PoCT for diabetes, hyperlipidaemia and patients requiring anticoagulant therapy on a population-wide basis in Australian GP.

Studies of adults 18 years and older treated for diabetes, hyperlipidaemia and anticoagulant therapy in a GP setting in either an urban, rural or remote geographic location were included. The studies included in the review were aimed at determining the safety, clinical effectiveness, cost and satisfaction of patients and health professionals with PoCT compared to usual care (pathology laboratory testing). All study designs were included in the search. All titles and abstracts were independently assessed by two review authors. All randomised controlled trials were assessed independently by two review authors and all other study designs were assessed individually.

The key findings of the chapter are:

- 29 studies were included in the review
- there were six randomised controlled trials (three RCTs produced two papers)
- in terms of clinical effectiveness, the review showed that only one study found a significant difference between PoCT and usual care (pathology laboratory testing)
- studies relating to the safety or quality of PoCT by comparing agreement of PoCT results to pathology laboratory results were limited, with variable analytical methods used to show the agreement between the methods, making conclusions difficult to draw
- conclusions about the costs of PoCT were also difficult to draw because of limited studies with variable analyses and findings
- patient and health professional satisfaction towards PoCT was generally positive. However, small participant numbers and no comparative analyses completed in most of the studies were limitations that needed to be considered.

The key conclusion:

- this systematic review of the PoCT literature in GP does not provide good evidence that PoCT improves patient health outcomes, that it has comparable analytical quality to pathology laboratory testing or that it is cost-effective compared to usual care. Most studies found that patients and health professionals were satisfied and found PoCT to be acceptable.

### 2.1. INTRODUCTION

Point of Care Testing (PoCT) is defined as any test taken by or on behalf of the treating doctor on-site, at the time of consultation allowing the test result to be used to make immediate decisions about patient treatment.<sup>1</sup> PoCT is sometimes referred to as near patient testing or bedside testing. Many laboratory tests such as the testing of glucose in urine were first developed at the bedside and in effect PoCT pre-dated the concept of the centralised laboratory as we know it today. Recently there has been a trend back to performing tests at the bedside or at least closer to the patient.

The growing interest in PoCT has come about partly through technological advances which have enabled smaller and simpler analytical devices to be manufactured. However, there are also clinical reasons why the use of PoCT is growing around the world particularly in primary care. Hobbs et al.<sup>3</sup> cites a number of challenges that face the primary care physician such as intolerance of a late diagnosis, an increasing need to filter access to specialist care, the earlier discharge of patients from hospitals, and demands to manage the surveillance of long-term disease. It can be appreciated that PoCT might offer assistance with meeting all of these challenges.

In 1999 Hobbs et al.<sup>3</sup> published the first major systematic review of PoCT in primary care. The aim was to 'identify publications relating to 'near patient' testing, the use of alternative delivery systems between laboratory and general practice, including electronic data interchange and computerised diagnostic decision support, in the primary care setting'.<sup>3</sup> They concluded that there was little evidence to support the general introduction of PoCT in general practice in preference to laboratory services. Yet it was suggested that PoCT could provide value to patients particularly in monitoring of chronic disease. The review found that in general the quality of the methods reported in the literature was poor and that issues such as patient acceptability and patient outcomes were not adequately addressed. There was also little published on the cost-effectiveness of PoCT in GP. Overall Hobbs et al.<sup>3</sup> suggested that further research in the primary care setting was required to determine whether PoCT would be valuable. They also recommended that future systematic reviews should be focused, subject-specific and include all aspects of PoCT such as analytical performance, effectiveness and stakeholder satisfaction.

Since the systematic review by Hobbs et al.<sup>3</sup> Vitro Diagnostics industry statistics show that PoCT has grown substantially both in volume and in terms of the types of available tests. In addition there have been numerous publications in the peer-reviewed and grey literature relating to PoCT. Given that nearly 10 years have elapsed since the Hobbs et al.<sup>3</sup> review it appears timely to review the PoCT literature relating to the use of PoCT in GP, and in particular to systematically assess the evidence for this type of testing. This systematic review was conducted in parallel to a larger randomised controlled trial to inform policy decisions relating to the implementation of PoCT in the management of patients with established diabetes, hyperlipidaemia and patients on anticoagulant therapy in an Australian general practice setting.

## **2.2. AIMS AND OBJECTIVES**

To assess whether the available evidence relating to the safety, clinical effectiveness, cost, and patient and health professional satisfaction supports the introduction of PoCT for diabetes (HbA1c, urine ACR), anticoagulant therapy (INR) and hyperlipidaemia (total cholesterol (TC); high density lipoproteins (HDL-C); low density lipoproteins (LDL-C) and triglycerides (TG)) on a population-wide basis in Australian GP.

## **2.3. METHODS**

### **2.3.1. Types of participants and setting**

Studies of adults 18 years and older treated for diabetes, hyperlipidaemia and anticoagulant therapy in a GP setting in either an urban, rural or remote geographic location were included (Table 9). Studies involving PoCT among hospital inpatients/hospital outpatients, pharmaceutical settings, self-management and home visitations were excluded.

### **2.3.2. Types of intervention**

The intervention was defined as PoCT and studies were included in the review when PoCT was compared to usual care which was defined as testing in a conventional laboratory setting.

### **2.3.3. Types of outcomes**

Outcome measures included:

- safety as indicated by a comparison of the analytical performance of the PoCT to the equivalent laboratory test and the results of quality control (QC) and quality assurance (QA) testing
- clinical effectiveness as indicated by improvements in patient health outcomes (e.g. increase in the proportion of patients in therapeutic range) or change in patient management due to the provision of a PoC test result
- cost
- patient satisfaction and acceptability
- health professional (General Practitioner, Device Operator) satisfaction and acceptability.

#### 2.3.4. Types of studies

All study designs irrespective of any language restrictions were included in the search. Letters, reviews, commentaries, conference abstracts and editorials were excluded. All papers published before January 1995 were not included in the current review as these were part of Hobbs et al's<sup>3</sup> comprehensive systematic review and they are of doubtful relevance given the changes in PoCT technology since 1995.

**Table 9: Inclusion criteria for the systematic literature review**

Population/setting	Intervention	Comparison	Outcome
Adults Diabetes (type 1 and 2) Anticoagulant therapy Hyperlipidaemia HbA1c Urine ACR TC, HDL-C, LDL-C, TG (lipid studies)	PoCT	Usual care (laboratory testing)	Safety Clinical effectiveness Cost Patient and health professional satisfaction and acceptability
General Practice Urban, Rural and Remote geographic settings			

## 2.4. SEARCH STRATEGY

### 2.4.1. Electronic searches

The medical literature was searched to identify relevant studies for the period between 1966 and 2007. The medical subject librarian at The University of Adelaide provided assistance with the database MeSH search terms. The electronic database searches and the period covered are shown in Table 10. Searching commenced in November 2006 and was completed in March 2007. The electronic database search terms are presented in Appendix 10 .

**Table 10: Electronic databases used in the search strategy**

Database	Period covered
Medline (using PubMed)	1966 - 31 November 2006
EMBASE	1980 – 2 January 2007
CINAHL	1982 – 14 February 2007
Current Contents	1998 – 1 March 2007
BIDS	1992 – 7 March 2007
Cochrane Library (all Cochrane products)	1900 – 21 March 2007

#### 2.4.2. Hand searching

One author (AG) was electronically sent monthly updates from PubMed (December 2006 – November 2007) for any new articles for the search terms used in the electronic database search. Hand searches of four key journals were completed on the 5<sup>th</sup> of November 2007. The *British Medical Journal* and journal of *Clinical Chemistry* were identified as containing more than 10% of the relevant publications in Hobbs et al.<sup>3</sup> systematic review and *The Journal of Near Patient Testing & Technology* and *British Journal of General Practice* were included as the review team believed that key articles could be submitted to those journals (Table 11)

**Table 11: Hand search of journals**

Journal	Issues hand searched
<i>British Medical Journal</i>	6 January 2007 334 (7583) - 3 November 2007 335 (7626)
<i>Clinical Chemistry</i>	1 January 2007 (53) 1 - 1 November 2007 53 (11)
<i>Point of Care: The Journal of Near-Patient Testing &amp; Technology</i>	All issues since March 2002
<i>British Journal of General Practice</i>	January 57 (534) - November 2007 57 (544)

#### 2.4.3. Reference lists

The reference lists of all articles included in the review and Hobbs et al.<sup>3</sup> systematic review were appraised to identify any studies that were not detected through the electronic searches. The Point-of-Care Testing book edited by Price et al.<sup>1</sup> was also appraised for missed articles.

#### 2.4.4. Correspondence with primary investigators of PoCT trials

Primary investigators of identified trials were contacted for details of any unpublished studies or studies currently taking place in PoCT for diabetes, anticoagulant therapy or hyperlipidaemia in a GP setting, in the last 12 months. The email sent to primary investigators can be found in Appendix 11.

## 2.5. METHODS OF THE REVIEW

#### 2.5.1. Selection of studies

Due to time constraints only articles in English were reviewed. All titles and abstracts were independently assessed by two review authors (AG and ASJ) to determine which articles should be included in the systematic review. All assessments on which there were disagreements between

reviewers were discussed by the two reviewers in the context of the inclusion and exclusion criteria. In all cases, agreement was achieved. If there was any uncertainty regarding an abstract's relevance, it was discussed and a decision made regarding inclusion. Where a decision could not be determined from the abstract, the full article was retrieved for consideration.

## 2.5.2. Data extraction and management

Articles included in the systematic review were entered into End Note version 6.0.2. All review authors independently extracted data from the articles onto a paper data collection form based on the tools developed by the Critical Appraisal Skills Programme (CASP). The data collection forms were piloted on two papers. A copy of the data collection forms can be found in Appendix 12.

## 2.5.3. Assessment of methodological quality

All randomised controlled trials were assessed independently by two review authors (AG and TB). Discrepancies were resolved by discussion. All other study designs were assessed by individual review authors (AG, ASJ, CL, TB) with any uncertainty discussed within the review team. We assessed the methods and reporting of each of the studies for internal/external validity and relevance.

## 2.5.4. Data synthesis

The data were summarised from the studies in text and table format, before providing a descriptive synthesis of findings.

## 2.6. DESCRIPTION OF THE STUDIES

### 2.6.1. Studies identified from the searches

The studies identified and used in the review are summarised in Figure 3. Studies were eligible for inclusion if they included PoCT as the intervention in a GP setting for diabetes, hyperlipidaemia or anticoagulant therapy and that safety, clinical effectiveness, cost and patient and health professional satisfaction and acceptability were reported as outcome measures. Twenty nine of the 76 studies met these criteria.

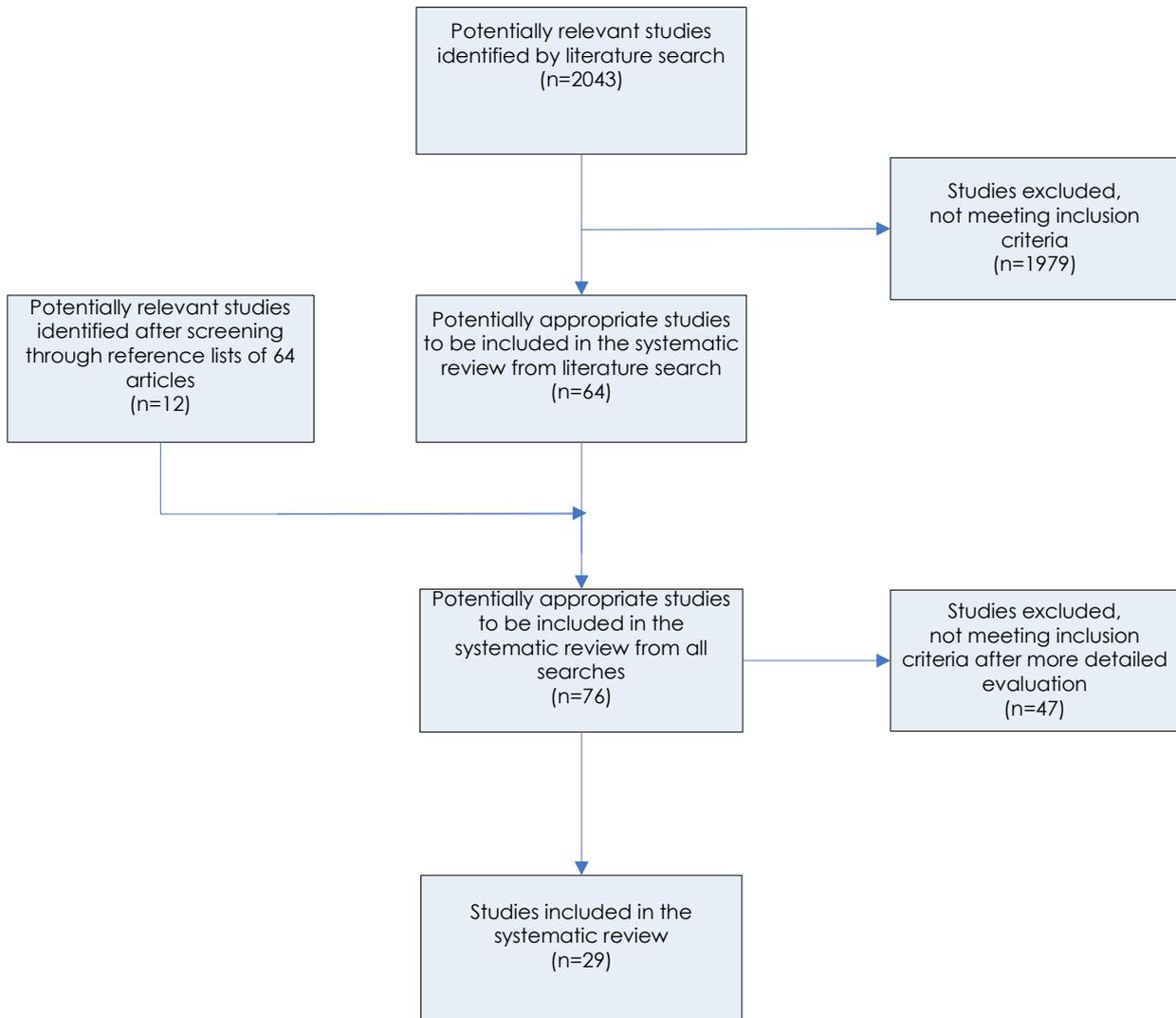
### 2.6.2. Excluded studies

Forty seven of the 76 potentially appropriate studies were excluded after being assessed in further detail (Table 12). Characteristics of papers excluded from the review can be found in Appendix 13.

**Table 12: Reasons for study exclusion**

Reason for exclusion	Number	Percent (%)
No PoCT	16	34.0
Published before January 1995	8	17.0
PoCT not in a general practice setting	7	14.9
PoCT performed by laboratory or pharmacy staff	6	12.7
No PoCT for condition of interest	4	8.5
Foreign paper (time constraints)	3	6.3
Commentary	1	2.1
Conference abstract	1	2.1
No PoCT for outcome of interest	1	2.1
<b>Total Number</b>	<b>47</b>	<b>100</b>

**Figure 3: Studies identified and used in the systematic review**



### 2.6.3. Included studies

Of the 29 studies six were RCTs generating a total of nine papers<sup>8, 18, 21, 33, 34, 44, 58-60</sup>, with the remainder being non-randomised studies. Three of the RCTs investigated INR PoCT<sup>8, 18, 34, 59, 21</sup>, two investigated diabetes PoCT<sup>33, 58, 60</sup> and one hyperlipidaemia PoCT.<sup>44</sup> Four of the RCTs investigated PoCT with another intervention.<sup>8, 18, 21, 34, 58, 59</sup> The geographical setting included the United Kingdom (n=13)<sup>8, 16, 18, 21, 33, 60-67</sup>, Australia (n=7)<sup>17, 23, 47, 68-71</sup>, USA (n=5)<sup>44, 58, 72-74</sup>, Belgium (n=2)<sup>34, 59</sup>, Sweden (n=1)<sup>75</sup> and Ireland (n=1).<sup>76</sup> A description of the 29 studies included in the review is reported in Table 13 and Table 14.

**Table 13: Randomised controlled trials**

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test & Device	Duration	Outcome(s)	Main findings	Limitations
<b>INR RELATED RCTS</b>												
Claes <sup>34</sup>	2005	Belgium	Primary Care	Four interventions Education; Education + Feedback; Education + PoCT; Education + Computer Decision Support	RCT	Anti-coagulant therapy	834 patients	INR Coagu Chek	12 mths (6 mths retrospective and 6 mths prospective)	Clinical effectiveness	All four interventions resulted in significant increase in % time spent within 0.5 INR from target (49.5% at baseline to 60% after intervention). No difference in % in target range or event rates between different interventions.	No baseline characteristics of patients and GPs participating in the trial Follow-up of patients was short (median follow-up was 4.8 months)
Claes <sup>59</sup>	2006	Belgium	Primary Care	Four interventions Education; Education + Feedback; Education + PoCT; Education + Computer Decision Support	RCT	Anti-coagulant therapy	834 patients 16 GP interviews 5 persons involved in the organisation of study interviewed	INR Coagu Chek	Not Relevant	Cost-effectiveness	PoCT + education resulted in net savings and quality improvement. The cost per test was reduced to €14.13 and accounted for €36.74 per patient per month. The Incremental Cost-effectiveness Ratio for education + PoCT were dominant over usual care. In a sensitivity analysis when overhead costs were varied the dominance of this intervention versus usual care was lost (at an overhead cost of €8 instead of €10.05).	Cost calculations based on estimates rather than actual time
Fitzmaurice <sup>8</sup>	2000	UK	Primary Care	PoCT Computer Decision Support	RCT	Anti-coagulant therapy	367 patients	INR Thrombotrak	12 mths	Clinical effectiveness	No difference in level of control of INR (Point prevalence) between groups. PoCT group had an improvement in the proportion of time in INR range (as did all groups) but not significantly different from the control practices. Intervention patients had fewer serious adverse events (1.14 serious bleeding incidents and 2.28 serious thrombotic events per 100 patient-years).	Recruitment is unclear Study was powered as an equivalence trial but comparative analysis completed Effectiveness relates to PoCT and Computer Decision Support
Parry <sup>21</sup>	2000	UK	Primary Care	PoCT Computer	RCT	Anti-coagulant	224 patients	INR Thromb	Not Relevant	Cost-effectiveness	Costs of PoCT per patient per year was £170 (95% CI £149-190)	Costs relate to PoCT +

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test & Device	Duration	Outcome(s)	Main findings	Limitations
				Decision Support		therapy		otrak			vs. £69 (95% CI £57-81) in primary care (p<0.01). Cost per visit and follow up visits were significantly less in hospital arm compared to primary care £13.89 vs. £25.41 and £6.62 vs £20.18 Sensitivity analysis indicated cost of PoCT could be reduced to below £100.	Computer Decision Support
Shiach <sup>18</sup>	2002	UK	Community Clinic	PoCT Computer Decision Support	Randomised Cross over trial	Anti-coagulant therapy	46 patients	INR Coagu Chek	12 mths	Clinical effectiveness Patient satisfaction Safety	No significant difference in time spent in INR target range between groups (60.9% PoCT vs. 59.3% laboratory). Patients had greater satisfaction with PoCT. Bland Altman plot of INR with the 2 methods showed that the INR difference increased as the average INR increased. No significant difference between geometric mean INR with PoCT and laboratory systems (2.48 versus 2.50 p=0.08). INR values >4.0 were less reliable. No difference in the dependability of the two INR systems.	No baseline characteristics of patients participating in the trial reported No statistical analyses performed on patient satisfaction Low study power
<b>DIABETES RELATED RCTS</b>												
Khunti <sup>33</sup>	2006	UK	Primary Care	PoCT	Prospective RCT	Diabetes	681 patients	HbA1c Bayer DCA 2000	12 mths	Clinical effectiveness Cost	Proportion of patients with HbA1c <7.0% not statistically different between two groups at 12 months. Difference in cost of care in two groups not statistically different.	Patients but not practices were randomised Borderline statistical difference of baseline HbA1c between groups
Stone <sup>60</sup>	2007	UK	Primary Care	PoCT	Prospective RCT	Diabetes	410 patients 11 practice personnel 15 patient	HbA1c Bayer DCA 2000	12 mths	Patient satisfaction GP and Device operator satisfaction	Survey results failed to confirm increased patient satisfaction in PoCT group. Interviews showed that nurses found equipment easy to use. GPs saw the cost of equipment	Patient time on PoCT was one year – many patients only had one PoCT visit

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test & Device	Duration	Outcome(s)	Main findings	Limitations
							interviews Participants part of a larger trial <sup>(2)</sup>				and consumables as a disadvantage. Usefulness of having an immediate result differed between practices (reflecting the manner PoCT in which PoCT was set up and the nurse's level of responsibility for making management changes).	Sample size for health professional satisfaction was small
Miller <sup>58</sup>	2003	USA	Primary Care	PoCT GP education re: diabetes before start of study	Prospective RCT	Diabetes	597 patients	HbA1c Bayer DCA 2000	188 days	Clinical effectiveness	PoCT led to more intensification of therapy in patients with HbA1C $\geq 7.0$ at baseline (51 versus 32, $p=0.01$ ), more so when HbA1C $> 8.0$ . In PoCT group HbA1C fell from 8.4 to 8.1% ( $p=0.04$ ) but not in routine group – 8.1 to 8.0 ( $p=0.31$ ). No statistically significant changes in HbA1c between groups.	Patients came from one practice with the majority Afro-American females Patient follow-up was short (6 months)
<b>HYPERLIPIDAEMIA RELATED RCTS</b>												
Ruffin <sup>44</sup>	1997	USA	Primary Care Outpatient Centre	PoCT	Randomised Parallel Group Control Design	Hyperlipidaemia	35 patients	TC HDL-C LDL-C TG Cholesterol LDX	Unknown	Clinical effectiveness	Significantly more CHD risk assessments were documented in the PoCT (68%) group than the control group (19%) ( $p=0.0001$ ). No difference in therapeutic interventions between groups ( $p=0.183$ ). No difference in the process of care (with regard to hypercholesterolemia) among study doctors ( $p=0.3027$ ).	Pilot study Only one practice Length of patient follow-up not stated. It appears that GPs reviewed 1 result

**Table 14: Non-randomised studies**

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device	Duration	Outcome(s)	Main findings	Limitations
<b>INR RELATED NON-RANDOMISED STUDIES</b>												
Wurster <sup>73</sup>	2006	USA	Primary Care	PoCT Computer Decision Support Workflow redesign	Case Series	Anti-coagulant therapy	40 patients	INR Coagu Chek	12 mths (6 mths retrospective)	Clinical effectiveness Costs	Significant improvement in the percentage of visits in which patient's INR is in target range (34% versus 67% (p<0.01). Relative risk reduction during the intervention phase was 91%, odds ratio = 0.057 (95% CI =0.0067, 0.490). Increased revenue for practice (\$35,317.00 in new revenue). Labour related overhead costs for administration of INR care decreased (from \$12,584 to \$3,032). Costs of equipment and consumables \$7,581.	Recruitment not described Small patient sample Short follow-up (6 months) Patients came from one practice No cost-effectiveness
Jackson <sup>17</sup>	2004	Australia	Primary Care	PoCT	Case Series	Anti-coagulant therapy	169 patients 19 operators	INR Coagu Chek S	Unknown	Safety Health professional satisfaction	PoCT INR values were significantly correlated with the laboratory values (r=0.89 p<0.0001). PoCT devices were more likely to underestimate the INR value compared to the laboratory (especially for results >3.5). 88% of dual measurements were within 0.5 INR units of each other. Most thought that PoCT was useful to clinical practice, easy to use, preferred PoCT to the laboratory and were confident in the results.	Bland Altman comparison of results not reported Uncertain of who & how many PoCT device users completed the satisfaction questionnaire
Chaudry <sup>74</sup>	2004	USA	Community Clinic	PoCT Face-to-face counselling	Case Series	Anti-coagulant therapy	385 patients	INR Device not reported	1 mth	Patient satisfaction	Significantly more patients preferred the PoCT INR service compared to usual care (p<.001). Patients reported improved capacity to make appointments, spent less time at the appointment, experienced less pain, improved communication regarding medication dosage (p<.001).	Self-selection of patients No baseline characteristics Short follow-up (one mth) Patients not surveyed before PoCT
Daly <sup>76</sup>	2004	Ireland	Primary Care	PoCT	Case Series	Anti-coagulant therapy	122 patients	INR CoaguCh ek	12 mths	Safety Clinical effectiveness	No significant difference between mean PoCT (2.34 (0.95 SD)) and laboratory results (2.40 (SD 0.97)) (p=0.53). Mean difference between paired	No baseline characteristics of patients Unclear practice and patient

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device &	Duration	Outcome(s)	Main findings	Limitations
											PoCT and laboratory tests was -0.061 (95% CI -1.14, 1.02). PoCT slightly under-estimated INR values. 48% of results were within the target therapeutic range. Number of tests in range varied from 32-76%	recruitment Selection bias High practice withdrawal Missing data
Fitzmaurice <sup>64</sup>	1998	UK	Primary Care	PoCT Computer Decision Support	Case Series	Anti-coagulant Therapy	29 patients	INR Thrombotrak	12 mths	Clinical effectiveness Costs incurred	Mean percentage of total patients in therapeutic range was 72%. Mean percentage of patients in therapeutic range of 2.0-3.0 was 71% and therapeutic range of 3.0-4.5 was 75%. 53.4% of INR results were within therapeutic range. No adverse events in 12 month period. Actual costs to the practice were £1751.	No patient baseline characteristics Cost evaluation has its limitations – not clear what was included in the overhead costs
Fitzmaurice <sup>61</sup>	2001	UK	Primary Care	PoCT Computer decision support	Concurrent control or cohort	Anti-coagulant therapy	452 patients	INR CoaguChek Thrombotrak	18 mths	Clinical effectiveness	No significant difference between PoCT and hospital based care in percentage time in range (69% PoCT vs. 64% laboratory). Proportion of tests in range was significantly higher in the PoCT group compared to hospital based care (61% vs. 57% p=0.015). No differences between groups for the number of clinical outcomes per patient.	The effectiveness of the intervention relates to PoCT and computer decision support
Murray <sup>62</sup>	1999	UK	Primary Care	PoCT	Case Series	Anti-coagulant therapy	19 patients	INR CoaguChek TAS Protime	6 mths	Safety Relative costs	No statistical/clinical differences in terms of correlation coefficients or Bland Altman Plots found between results of 3 PoCT devices and laboratory results. PoCT showed slightly higher mean INR values than the laboratory. 19% of TAS and CoaguChek PoCT devices and 24% of Protime PoCT device results would have resulted in a change in patient management compared to the laboratory. No mechanical problems experienced with PoCT devices. Costs varied for the 3 different PoCT devices.	Unclear what variables were used in the costing analysis Unclear what percentage of results were within the limits of agreement

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device	Duration	Outcome(s)	Main findings	Limitations
Hobbs <sup>63</sup>	1998	UK	Primary Care	PoCT	Case Series	Anti-coagulant therapy	296 patients	INR Thrombotrak	12 mths	Clinical effectiveness Safety	No difference in the proportion of results in therapeutic range between groups (54% of PoCT results were within the individual therapeutic range compared to 54% lab 1, 52% lab 2 and 54% lab 3). Correlation between practice (PoCT) results and laboratory ranged from 0.86 to 0.92. Small positive bias of 0.28 on average in PoCT results (range of 0.28 to 1.55). INR values are consistently higher for PoCT results compared to the laboratory results. Bias was greater as the INR increased. 53% of tests would have resulted in change in Warfarin dose.	Unclear practice and patient recruitment No patient/practice baseline characteristics
Seamark <sup>16</sup>	1997	UK	Primary Care	PoCT	Analytical	Anti-coagulant Therapy	Not Relevant	INR CoaguChek	306 blood samples	Safety	Correlation between the PoCT method and control results was $r=0.850$ , $p<0.0001$ . Mean difference of PoCT results from control results was $-0.32$ INR units ( $\pm 2$ SD $+0.55$ and $-1.20$ ).	Clinical significance of Bland Altman results interpreted incorrectly
Parry <sup>67</sup>	2001	UK	Primary Care	PoCT Computer Decision Support	Concurrent control or cohort	Anti-coagulant therapy	49 patients in primary care 104 patients in secondary care	INR Thrombotrak	Not Relevant	Cost-effectiveness	Patient cost per visit was significantly higher in the secondary care arm (£14.58 (£9.08) versus £6.78 (£5.04)). Primary care patients spent less time in the clinic compared to secondary care patients (23 minutes (8.62minutes SD) vs. 34 minutes (13.86 minutes SD)). No statistically significant difference between primary and secondary care in the overall cost per patient per year.	Data not from a RCT - biases
<b>DIABETES RELATED NON-RANDOMISED STUDIES</b>												
Shephard <sup>68</sup>	2006	Australia	Primary Care	PoCT	Case Series	Diabetes	74 patients with clinical outcomes 161 patient satisfaction	HbA1c Bayer DCA 2000	12 mths	Clinical effectiveness Patient satisfaction GP satisfaction Device operator satisfaction	In the group of 74 patients monitored at baseline and at 12 months after the introduction of PoCT there was a statistically significant reduction of 0.7% in HbA1c ( $p=0.003$ ). Percentage of diabetes patients who achieved optimal glycaemic control (<10%) increased by 12%. Patients were satisfied with the	Only Aboriginal patients Patients were assisted in completing satisfaction questionnaires

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device	Duration	Outcome(s)	Main findings	Limitations
							n 41 GPs 65 Device Operators				convenience of PoCT and improved self motivation to manage their condition. Patients more satisfied with diabetes service (p=0.007). Most GPs cited convenience and immediacy of test result as advantages. Confident in the accuracy and reliability of results, perceived that patients more disease compliant. Most Device Operators were confident in using the device, satisfaction with diabetes service improved but did not reach statistical significance (p=0.271).	
Shephard <sup>69</sup>	2006	Australia	Primary Care	PoCT	Analytical	Diabetes	Not Relevant	HbA1c Urine ACR Bayer DCA 2000	HbA1C - 13 six monthly testing cycles ACR- 6 six monthly testing cycles	Safety	Median imprecision (CV*) of external QA samples for HbA1C over 6 years was 3.6% ( $\pm 0.52$ ) and not significantly different to median CV* achieved by laboratories (3.4% $\pm 0.42$ ) p = 0.21. Median imprecision (CV*) of external QA samples for urine ACR over 2 years was 2.9% with median bias of 0.42% (range 0.28-0.62).	No data on accuracy of HbA1C data. No statistical assessment of significance of change of HbA1C or ACR data over time
Shephard <sup>71</sup>	2005	Australia	Primary Care	PoCT	Analytical	Diabetes	Not Relevant	Urine ACR Bayer DCA 2000	4 six monthly testing cycles	Safety	Median imprecision of external QA program for urine ACR over 24 months was 5.4% which was within stated analytical guidelines.	No confidence levels given with data and no statistical assessment of significance of change of ACR data over time
Schwartz <sup>72</sup>	2005	USA	<b>Primary Care</b>	PoCT	Case Series	Diabetes	156 patients (147 paired blood samples) 9 operators	HbA1c  BIORADM icromat II	One blood test	Safety Device operator acceptability	PoCT correlated well with all laboratory methods (ranging from 0.71 – 0.92). The laboratory method produced a significantly higher mean HbA1c than that from the PoCT device (p<0.001). The time required for individual analysis was a limitation noted by operators.	Small sample to demonstrate operator acceptability

**DIABETES AND HYPERLIPIDAEMIA RELATED NON-RANDOMISED STUDIES**

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device &	Duration	Outcome(s)	Main findings	Limitations
Grodzinsky <sup>75</sup>	2004	Sweden	Primary Care	PoCT	Case Series	Diabetes Hyperlipidaemia	Not Relevant	HbA1c TC HDL-C LDL-C TG Device not reported	3542 samples	Clinical effectiveness	When tests were analysed using PoCT approximately 30% of patients were notified about the test result during the test visit. This varied depending on the type of test – CRP test result (74%) more likely to be given to the patient compared to HbA1c (52%), TC (9%), HDL-C, LDL-C and TG (7%).	
Shephard <sup>47</sup>	2005	Australia	Primary Care	PoCT	Case Series	Diabetes Hyperlipidaemia	54 patients with established diabetes 3 GPs 3 nurses	HbA1c Urine ACR TC Bayer DCA 2000 Cholesterol LDX	12 mths	Clinical effectiveness Safety Patient satisfaction GP and Device operator satisfaction	The mean HbA1c decreased from 7.6% to 7.1% (p=0.03). The mean TC decreased from 4.6mmol/L to 4.28mmol/L (p=0.01). The precision of internal QC testing for HbA1c, urine ACR, urine albumin and urine creatinine met the analytical performance specifications. The precision for TC did not reach the recommended analytical goal. Overall patient satisfaction with the diabetes service was significantly greater after the introduction of the program (p=0.01). GPs were confident with PoCT results and that the program improved patient care. Nurses satisfied with training in PoCT devices and confident in the results.	Only Aboriginal patients Small sample size Short follow-up (mean = 10mths)
Shephard <sup>70</sup>	2006	Australia	Primary Care	PoCT	Case Series	Diabetes Hyperlipidaemia	45 patients in service 1 36 patients in service 2 12 GPs 13 Device Operators 58 patients re satisfaction	HbA1c Urine ACR TC HDL-C LDL-C TG Bayer DCA 2000 Cholesterol LDX	12 mths	Clinical effectiveness GP satisfaction Device operator satisfaction Patient satisfaction Safety	Service 1: Significant reduction in HbA1c at 12 months after the introduction of PoCT (p=0.02). After categorising patients into those who achieved target glycaemia (HbA1c <7% and <8%) and those who had an HbA1c >10% the statistical significance was lost. Service 2: Patients were categorised into those self-managing well (SMW) and those having difficulties with self-management (SMD). Significant decrease in mean HbA1c of the SMW group (p=0.0001). Mean HbA1c in SMD group increased (p=0.097). Significant reduction in mean total and LDL-C of 1.0 and 0.7 mmol/L (p=0.02)	Only Aboriginal patients Small sample size

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device &	Duration	Outcome(s)	Main findings	Limitations
											and 0.03) in the SMW group. Higher in the SMD group. PoCT reported by GPs and Device Operators as convenient with confidence in the accuracy and reliability of results. All patients reported that PoCT encouraged them 'to look after their health better', PoCT was convenient, less anxiety having a fingerpick than vene-puncture. Patients more satisfied with diabetes service after the introduction of PoCT (p=0.03). Within-site imprecision achieved for external QA HbA1c and urine ACR met the minimum precision goals recommended by the standards. External QA program not available for lipid testing. Used average imprecision for QC testing. Results met minimum precision goals.	
<b>HYPERLIPIDAEMIA RELATED NON-RANDOMISED STUDIES</b>												
Cohen <sup>23</sup>	1998	Australia	Primary Care	PoCT	Case Series	Hyperlipidaemia	206 patients 13 GPs	TC Reflotron analyser Abott Vision Kodak analyser	One blood test	Clinical effectiveness Costs Patient satisfaction GP satisfaction	Mean cholesterol results for 161 patients showed a reduction in cholesterol levels over time (highest 7.44mmol/L; most recent 6.33mmol/L and current value 6.12mmol/L). Potential cost savings for patients identified (fewer visits, transport cost savings not having to travel to external laboratory). Lower costs for the HIC with PoCT compared to laboratory. GP annual operating costs, registration and accreditation and costs to be an approved pathology provider are large (mean operating cost of \$30,500). Patients and GPs reported a preference for PoCT in all questions regarding convenience, patient care, factors relating to GP management. GPs expressed concern with the cost of PoCT (registration costs, quality	Not a full economic analysis No follow-up of patients Recruited practices were Category 5 pathology laboratories (already using PoCT devices)

Author and Reference	Year of publication	Country	Setting	Intervention	Study Design	Condition	No of subjects	Test Device	Duration	Outcome(s)	Main findings	Limitations
											assurance fees). Also thought that compulsory QA was time consuming and not appropriate for general practice.	
Gillam <sup>65</sup>	1998	UK	Primary Care	PoCT	Case Series	Hyperlipidaemia	Not reported clearly	TC Kodak	Blood samples tested over 6 month period	Safety Clinical effectiveness GP satisfaction Patient satisfaction Practice costs	40% of cholesterol testing impacted on GP decision making. The PoCT device was less precise than the laboratory method (CV* laboratory - 2.0%, Kodak PoCT - 3.9% and Spotchem PoCT - 2.9%). GPs found PoCT convenient but it was not considered important to have test results immediately. Quality control was seen as onerous and GPs were concerned with legal action due to inaccurate results. 87% of patients preferred tests done at the practice with most patients citing convenience and time saving advantages. PoCT is more expensive than conventional testing with the volume of demand the key component driving the cost.	Included PoCT for diagnosis as well as monitoring of disease for a range of diseases Number of GPs participating is unclear
Summerton <sup>66</sup>	1995	UK	Primary Care	PoCT	Analytical	Hyperlipidaemia	10 practices with PoCT devices 29 QC samples	TC Lipotrend	Analysis of 2 QC samples	Safety	QC - CV* for 2 QC samples were 18% and 20%. Half of the results were within 0.5mmol/l of the mean result and 20.6% differed from the mean by more than 1 mmol/l. 4/10 practices had received no training in the PoCT device. Maintenance of devices was variable. 5/10 devices had never been cleaned. QC rarely completed by practices.	No description of the practices Number of users not specified

\*CV - Coefficients of variation

## 2.7. RESULTS

The studies included in this review were aimed at determining the safety, clinical effectiveness, cost and satisfaction of patients and health professionals with PoCT. Papers were grouped based on outcome and condition as follows (Table 15):

**Table 15: Studies by condition and outcome**

Outcome	Condition	RCT references	Observational study references	Total number of studies by outcome
Safety	INR	Schiach 2002 <sup>18</sup>	Jackson 2004 <sup>17</sup> ; Daly 2003 <sup>76</sup> ; Murray 1999 <sup>62</sup> ; Hobbs 1999 <sup>63</sup> ; Seamark 1997 <sup>16</sup>	6
	Diabetes		Schwartz 2005 <sup>72</sup> ; Shephard 2006 <sup>69</sup> ; Shephard 2005 <sup>71</sup>	3
	Hyperlipidaemia		Gillam 1998 <sup>65</sup> ; Summerton 1995 <sup>66</sup>	2
	Diabetes and Hyperlipidaemia		Shephard 2005 <sup>47</sup> ; Shephard 2006 <sup>70</sup>	2
	All conditions			<b>13</b>
Clinical effectiveness	INR	Claes 2005 <sup>34</sup> ; Fitzmaurice 2000 <sup>8</sup> ; Schiach 2002 <sup>18</sup>	Wurster 2006 <sup>73</sup> ; Daly 2003 <sup>76</sup> ; Fitzmaurice 2001 <sup>61</sup> ; Hobbs 1999 <sup>63</sup> ; Fitzmaurice 1998 <sup>64</sup>	8
	Diabetes	Khunti 2006 <sup>33</sup> ; Miller 2003 <sup>58</sup> ;	Shephard 2006 <sup>68</sup>	3
	Hyperlipidaemia	Ruffin 1997 <sup>44</sup>	Gillam 1998 <sup>65</sup> ; Cohen 1998 <sup>23</sup>	3
	Diabetes and Hyperlipidaemia		Shephard 2005 <sup>47</sup> ; Grodzinsky 2004 <sup>75</sup> ; Shephard 2006 <sup>70</sup>	3
	All conditions			<b>17</b>
Cost	INR	Claes 2006 <sup>59</sup> ; Parry 2000 <sup>21</sup>	Wurster 2006 <sup>73</sup> ; Murray 1999 <sup>62</sup> ; Fitzmaurice 1998 <sup>64</sup> ; Parry 2001 <sup>67</sup>	6
	Diabetes	Khunti 2006 <sup>33</sup>		1
	Hyperlipidaemia		Cohen 1998 <sup>23</sup> ; Gillam 1998 <sup>65</sup>	2
	Diabetes and Hyperlipidaemia			0
	All conditions			<b>9</b>
Patient satisfaction	INR	Schiach 2002 <sup>18</sup>	Chaudhry 2004 <sup>74</sup>	2
	Diabetes	Stone 2007 <sup>60</sup>	Shephard 2004 <sup>68</sup>	2
	Hyperlipidaemia		Cohen 1998 <sup>23</sup> ; Gillam 1998 <sup>65</sup>	2
	Diabetes and Hyperlipidaemia		Shephard 2005 <sup>47</sup> ; Shephard 2006 <sup>70</sup>	2
	All conditions			<b>8</b>
Health professional satisfaction	INR		Jackson 2004 <sup>17</sup>	1
	Diabetes	Stone 2007 <sup>60</sup>	Schwartz 2005 <sup>72</sup> ; Shephard 2004 <sup>68</sup>	3
	Hyperlipidaemia		Cohen 1998 <sup>23</sup> ; Gillam 1998 <sup>65</sup>	2
	Diabetes and Hyperlipidaemia		Shephard 2005 <sup>47</sup> ; Shephard 2006 <sup>70</sup>	2
	All conditions			<b>8</b>

\*Total number of studies by condition and outcome (N=55) is more than the total number of studies (N=29) as more than one outcome was reported in some studies

## 2.7.1. Randomised controlled trials

### 2.7.1.1. *INR related RCTs*

Claes et al.<sup>34, 59</sup> studied the clinical effectiveness and cost-effectiveness of four interventions of which one included PoCT + education for the management of oral anticoagulation in 834 patients. A significant increase in percent time spent within 0.5 INR from target (from 46% at baseline to 57% at the end of the study,  $p < 0.0001$  after PoCT + education intervention implemented) was detected for all interventions. There were no differences in percent in target range or event rates between the different interventions. For the cost-effectiveness analysis (Claes et al.<sup>59</sup>), clinical data were used from 834 patients and structured interviews from 16 GPs (randomly selected from the 66 practices) and five persons involved in the organisation of the study. PoCT + education resulted in net savings and quality improvement. Due to savings at the laboratory level the cost per test was reduced to €14.13 and accounted for €36.74 per patient per month (which is the continuous cost for the intervention). The Incremental Cost-effectiveness Ratio (ICER) for education + PoCT were dominant over usual care. At an overhead cost of €8 rather than €10.05, the dominance of education + PoCT was lost.

Fitzmaurice et al.<sup>8</sup> studied the clinical effectiveness and Parry et al.<sup>21</sup> the cost-effectiveness of INR PoCT and the use of computerised decision support software in 367 patients. For clinical effectiveness, Fitzmaurice et al.<sup>8</sup> found no significant difference in the level of control (point prevalence) between the intervention and control groups. A significant difference in percentage of time spent in range was detected in the intervention group during the study period ( $p < 0.01$ ) with significant improvement in proportion of time spent in range ( $p = .008$ ) but this was not significantly different from the control groups. Intervention group patients had fewer serious adverse events (1.14 serious bleeding incidents and 2.28 serious thrombotic events per 100 patient years). For Parry et al.<sup>21</sup> cost-effectiveness study, 224 patients from the same RCT were used in the analysis. The costs per patient per year in the intervention group (PoCT) were significantly higher, £170 [95% CI £149-190] versus £69 [95% CI £57-81] than in the control group ( $p < 0.001$ ).

Schiach et al.<sup>18</sup> studied the safety, clinical effectiveness and patient satisfaction of INR PoCT and computer decision support software in a sample of 46 patients. There were no significant differences in time spent in the INR target range between the intervention and control groups (60.9% PoCT versus 59.3% laboratory). The Bland Altman plot of PoCT INR versus laboratory method showed that the INR difference increased as the average INR increased. There was no significant difference between the geometric mean INR with PoCT and laboratory methods (2.48 versus 2.50 respectively, [CI -2.1, 0.1]  $p = 0.08$ ). There were also no differences in the dependability of the PoCT and laboratory systems (PoCT= 1.0% and 5.5% at the beginning and end of trial; laboratory= 1.0% and 3.1% for the two time periods). However, INR values  $> 4.0$  were less reliable (mean relative difference of 12.6%). Patients had significantly greater satisfaction with PoCT (no statistical comparisons reported).

### 2.7.1.2. *Diabetes related RCTs*

Khunti et al.<sup>33</sup> studied the clinical and cost-effectiveness of PoCT in 681 patients with Type 2 diabetes mellitus. The percentage of intervention patients who achieved an HbA<sub>1c</sub>  $< 7.0\%$  at 12 months did not vary significantly from the control patients (37% versus 38%, OR 0.95 [95% CI 0.69 to 1.31]). The total cost of diabetes related care per patient in the intervention group was £370 and £390 for the control group which was not statistically significant. As part of the same RCT, Stone et al.<sup>60</sup> studied the patient acceptability and satisfaction with PoCT by sending a questionnaire to 344 patients, and interviewing 15 patients, and health professional satisfaction and acceptability by interviewing 11 practice personnel. Questionnaire results did not find an increase in patient satisfaction in the intervention (PoCT) group. Interviews showed that nurses found the PoCT equipment easy to use. GPs saw the cost of equipment and consumables as a disadvantage of PoCT. The usefulness of having an immediate test result differed between practices (reflecting the manner PoCT is organised and nurse's level of responsibility for making management changes).

Miller et al.<sup>58</sup> studied the clinical effectiveness of PoCT in 597 patients with Type 2 diabetes, of whom the majority were Afro-American females. The intervention group had more intensification of

therapy when the HbA1c was  $\geq 7.0\%$  at baseline (51% versus 32% of patients,  $p=0.01$ ) and more significantly when the HbA1c was  $>8.0\%$  (HbA1c 8.0-8.9%, PoCT group 51% versus 23%,  $p=0.007$ ; HbA1c  $\geq 9.0\%$  PoCT group 65% versus 46%,  $p=0.006$ ). Within-group analyses showed that the HbA1c decreased significantly in the intervention group by the end of the study (8.4 to 8.1%,  $p=0.04$ ) but not in the control group (8.1 to 8.0%,  $p=0.31$ ). There were no statistically significant changes in HbA1c between the intervention and control group (results not reported).

### 2.7.1.3. *Hyperlipidaemia related RCTs*

Ruffin et al.<sup>44</sup> studied the clinical effectiveness of PoCT in 35 patients with hypercholesterolemia. The trial sought to determine whether providing cholesterol results during a patient GP visit had any effect on GPs process of care actions. There were no significant differences in therapeutic interventions between groups ( $p=0.183$ ). There was no difference in the process of care (with regard to hypercholesterolemia) among study GPs ( $p=0.3027$ ). There was significantly more coronary heart disease (CHD) risk assessments in the intervention group (68%) compared to the control group (19%) ( $p=0.0001$ ).

### 2.7.2. *Observational studies*

#### 2.7.2.1. *INR related non-randomised studies*

Wurster et al.<sup>73</sup> studied the clinical and cost-effectiveness of PoCT, computer decision support software and workflow redesign in 40 patients treated with anticoagulation therapy. There was a significant improvement in the percentage of visits in which a patient's INR result was in the target range (34% at baseline versus 67% in the PoCT phase,  $p<0.01$ ). Complications due to anticoagulation therapy were reduced by 91% (OR 0.057, [95% CI 0.0067, 0.490]). Practice revenue increased (\$35,317.00) due to practices being able to charge patients for practice visits and increases in testing. The overhead costs for administration of INR care decreased (from \$12,584.00 to \$3,032.00). Costs for equipment and consumables were \$7,581.00.

Jackson et al.<sup>17</sup> studied the safety of INR PoCT for 169 patients and health professional satisfaction with the service. The paper does not report number of health professionals but notes 19 questionnaires were used in the analysis. PoCT INR values were significantly correlated with the laboratory values ( $r=0.89$ ,  $p<0.0001$ ). PoCT devices were more likely to under-estimate the INR value compared to the laboratory, especially for results  $>3.5$ . Eighty eight percent of dual measurements were within 0.5 units of each other (mean INR PoCT 2.39 versus 2.54 for the laboratory). The majority of PoCT users preferred to use PoCT, they thought that PoCT was useful to clinical practice, it was easy to use and were confident in the results.

Chaudhry et al.<sup>74</sup> studied the patient satisfaction of PoCT in 385 patients who were receiving long-term anticoagulant therapy. Significantly more patients preferred the PoCT INR service compared to usual care (79.1% versus 11.8%,  $p<0.01$ ). Patients reported improved capacity to make appointments, spent less time at the appointment, experienced less pain and there was improved communication regarding medication dosage ( $p<0.01$ ).

Daly et al.<sup>76</sup> studied the safety and clinical effectiveness of PoCT in 122 patients receiving anticoagulant therapy. There was no significant variation between mean PoCT and laboratory results (2.34 PoCT versus 2.40 lab  $p=0.53$ ). The mean difference between paired PoCT and laboratory tests was -0.061 [95% CI -1.14, 1.02]. PoCT tended to slightly under-estimate INR values compared to the laboratory. Forty eight percent of INR results were within the target therapeutic range.

Fitzmaurice et al.<sup>64</sup> studied the clinical effectiveness and costs incurred from PoCT and computer decision support software used in 29 patients receiving anticoagulant therapy. This study took place after a larger scale RCT (Fitzmaurice et al.<sup>8</sup>) had been conducted to determine whether the model of care tested in the RCT was successful outside of trial conditions. The mean percentage of total patients in the therapeutic range was 72% (INR range of 2.0-3.0 - 71%; INR range of 3.0-4.5 - 75%) and 53% of INR values were within therapeutic range. There were no adverse events reported in the 12 month study period. The actual costs to the practice were £1751.

Fitzmaurice et al.<sup>61</sup> studied the clinical effectiveness of PoCT and computerised decision support in 452 patients receiving anticoagulant therapy. This study was a follow-up from Fitzmaurice et al.'s<sup>8</sup> RCT to determine the effectiveness of this model in routine care. There was no significant difference in percentage of time in the therapeutic range between PoCT and hospital based care (69% versus 64% respectively). The proportion of tests in range was significantly higher in the intervention group compared to the control group (61% versus 57%,  $p=0.015$ ). There was no significant difference between groups for the number of clinical outcomes per patient (four deaths in intervention group versus 13 deaths in the control group). There were no deaths related to Warfarin therapy.

Murray et al.<sup>62</sup> studied the safety and relative costs of PoCT in 19 patients receiving anticoagulant therapy. Three PoCT devices were compared to the laboratory in this study. The mean PoCT results were higher than the laboratory results (CoaguChek mean bias  $-0.10$  [0.05 SE], TAS mean bias  $-0.10$  [0.06 SE], Protime mean bias  $-0.28$  [0.06 SE]). Correlation coefficients for the three devices were  $r=0.96$  for CoaguChek,  $r=0.92$  for Protime and  $r=0.92$  for the TAS. Bland Altman plots of the PoCT and laboratory results were reported to show no significant differences but the paper did not present the results. Nineteen percent of PoCT (CoaguChek and TAS devices) and 24% of (Protime device) results would have resulted in a change in patient management compared to the laboratory. There were no mechanical problems experienced with the PoCT devices. The costs of the devices were CoaguChek £730, Protime £900 and £2000 for TAS while the costs of tests were CoaguChek £2.50, Protime £3.50 and TAS £2.50.

Hobbs et al.<sup>63</sup> studied the safety and clinical effectiveness of PoCT in 296 patients receiving anticoagulant therapy. Fifty four percent of PoCT results were within the individual therapeutic range (compared to 54%, 52% and 54% in laboratories 1-3). The correlation coefficient between PoCT and laboratory results ranged from 0.86 - 0.96. The PoCT results had a mean positive bias of 0.28 (range 0.28 to 1.55) which was greater as the INR increased. Up to 53% of tests would have resulted in a change in medication dosage and was dependent on the site and method of testing.

Seamark et al.<sup>16</sup> studied the safety of PoCT for patients receiving anticoagulant therapy. Complete data were obtained for 306 blood samples. The correlation between the PoCT method and laboratory method was  $r=0.850$ ,  $p<0.0001$ . The mean difference of PoCT results from the control results was  $-0.32$  INR units (SD  $+0.55$  and  $-1.20$ ).

Parry et al.<sup>67</sup> studied the cost-effectiveness of PoCT and computer decision support software for patients treated with anticoagulant therapy ( $n=153$ ). The patient mean cost per visit was significantly higher in the control arm (secondary care) versus the intervention or PoCT arm - £14.58 (9.08 SD) versus £6.78 (5.04 SD). Intervention group patients spent less time in the clinic compared to control group patients (23 minutes, [SD 8.62 minutes] versus 34 minutes, [SD 13.86 minutes]). There were no statistically significant differences between primary and secondary care in the overall cost per patient per year.

#### 2.7.2.2. *Diabetes related non-randomised studies*

Shephard et al.<sup>68</sup> studied the clinical effectiveness (74 patients) and patient satisfaction (161 patients) of PoCT for Aboriginal patients with Type 2 diabetes and health professional satisfaction of the service (41 GPs and 65 Device Operators). In the group of 74 patients at 12 months after the introduction of PoCT there was a statistically significant reduction of 0.7% in HbA1c ( $p=0.003$ ) and the percentage of diabetes patients who achieved glycaemic control increased by 12%. Patients were satisfied with the convenience of PoCT, improved their self-motivation to manage their condition and were more satisfied with the PoCT service ( $p=0.007$ ). Most GPs cited convenience and immediacy of test results as advantages of PoCT. GPs were confident in the accuracy and reliability of results and believed patients were more disease compliant. Most Device Operators were confident in using the device. Device Operators were satisfied with the PoCT service but this did not reach statistical significance ( $p=0.271$ ).

Shephard et al.<sup>69</sup> studied the safety of PoCT for diabetes (HbA1c and urine ACR) by reviewing 13 six monthly QA testing cycles for HbA1c PoCT and 6 six monthly QA testing cycles for urine ACR PoCT. Median imprecision (CV) of external QA samples for HbA1c over 6 years was 3.6% ( $\pm 0.52$ ). This was

not significantly different to the median CV achieved by laboratories - 3.4 ( $\pm 0.42$ )  $p=0.21$ . Median imprecision (CV) of external QA samples for urine ACR over 2 years was 2.9% with a median bias of 0.42% (range 0.28-0.62).

Shephard et al.<sup>71</sup> studied the safety of PoCT for diabetes by reviewing four six monthly QA testing cycles for urine ACR. Median imprecision for urine ACR over 24 months was 5.4% which was within the stated analytical guidelines.

Schwartz et al.<sup>72</sup> studied the safety and patient satisfaction with PoCT for 156 patients having an HbA1c test and the acceptability and satisfaction of PoCT in nine health professionals. PoCT was well correlated with three laboratory methods ( $r=0.773$ ,  $r=0.713$  and  $r=0.927$ ,  $p<0.01$  in all cases) but the three different laboratory methods produced a significantly higher mean HbA1c than that from the PoCT device ( $p<0.001$  in all cases). The time required for PoCT was a limitation noted by operators.

#### 2.7.2.3. *Hyperlipidaemia related non-randomised studies*

Cohen et al.<sup>23</sup> studied the clinical effectiveness, cost-effectiveness and patient satisfaction with PoCT in 206 patients with hyperlipidaemia and health professional satisfaction of PoCT through PoCT use by 13 GPs. Mean cholesterol results for 161 patients showed a reduction in cholesterol levels over time (highest 7.44mmol/L; most recent 6.33mmol/L and current value 6.12mmol/L) but no statistical analyses were reported. The potential cost savings for patients and the Health Insurance Commission were identified as \$47.65 compared to \$61.30. The costs to GPs for PoCT were high with an estimated mean annual operating cost of \$30,500. Patients and GPs reported a preference for PoCT in all questions relating to convenience, patient care and factors relating to GP management. GPs expressed concerns with the cost of PoCT and thought that quality assurance was not required in the primary care setting.

Gillam et al.<sup>65</sup> studied the safety, clinical effectiveness and patient satisfaction of PoCT for a sample of patients (number not clearly stated in the study) and health professional satisfaction (number not reported) and practice costs. The study investigated a number of PoCT tests including cholesterol testing. The PoCT device was less precise than the laboratory method (CV laboratory - 2.3% vs CV Kodak PoCT device - 3.9% and CV Spotchem PoCT device - 2.9%). Forty percent of PoC cholesterol testing impacted on GP decision making, while 87% of patients preferred tests done at the practice. GPs found PoCT convenient but they did not believe that having an immediate result was important. Quality control was seen as onerous and GPs were concerned about medico-legal action due to inaccurate results. PoCT was more expensive than testing in the hospital laboratory or phlebotomy at the practice compared with testing at the laboratory.

Summerton et al.<sup>66</sup> studied the safety of PoCT through enrolling 10 practices that had a PoCT device in a QC scheme for cholesterol testing and the main PoCT Device Operator completed a questionnaire about the use of devices (number of operators not reported). Coefficients of variation for the two QC samples were 18% and 20% with half of the results within 0.5mmol/L of the mean result and 20.6% differing from the mean by 1mmol/L. Forty percent of PoCT Device Operators had received some training. Maintenance of the PoCT device was variable with 50% of devices never cleaned and QC was rarely completed by practices (data not reported).

#### 2.7.2.4. *Diabetes and hyperlipidaemia related non-randomised studies*

Grodzinsky et al.<sup>75</sup> studied the clinical effectiveness of PoCT by investigating 1615 blood tests including 374 for TC, 321 for HDL-C, 317 for LDL-C, 329 for TG and 274 for HbA1c. The study aimed to investigate the time from blood sampling to an available result and the time from sampling to when the patient was informed about the test result. Thirty percent of patients were notified about the test result during the test visit, varying from 52% in the case of HbA1c, 9% for TC and 7% for HDL-C, LDL-C and TG results.

Shephard et al.<sup>47</sup> investigated the safety, clinical effectiveness (54 patients) and patient satisfaction (36 patients) with PoCT tests for HbA1c, urine ACR, TC, HDL-C, LDL-C and TG in an Aboriginal population with established diabetes. Health professional satisfaction with PoCT was studied in

three GPs and three nurses. The mean HbA1c decreased from 7.6% to 7.1% ( $p=0.03$ ) while the mean TC decreased from 4.6 mmol/L to 4.28 mmol/L ( $p=0.01$ ). The precision of internal quality control testing for HbA1c, urine ACR, urine albumin and urine creatinine met the analytical performance specifications but this performance was not achieved for TC. Patient satisfaction with the diabetes service was significantly greater after the introduction of the PoCT program ( $p=0.01$ ). GPs were confident with the results and thought that the PoCT program improved patient care. Nurses were satisfied with the PoCT device training and were confident in the results (no results reported).

Shephard et al.<sup>70</sup> studied the clinical effectiveness (81 patients) and patient satisfaction (58 patients) with PoCT for Aboriginal patients with Type 2 diabetes, the health professional satisfaction of the service (12 GPs and 13 Device Operators) and the safety of PoCT. Patients were either in Service 1 (N=45) or Service 2 (N=36). At Service 1, there was a significant reduction in HbA1c at 12 months after the introduction of PoCT ( $p=0.02$ ). When patients were categorised into those who achieved target glycaemia (HbA1c <7% and HbA1c <8%) and those who had an HbA1c >10% the statistical significance was lost. At Service 2, patients were categorised into self-managing well (SMW) and those who had difficulties in self-management (SMD). There was a significant decrease in mean HbA1c in the SMW group ( $p=0.0001$ ) and a significant reduction in mean total and LDL-C of 1.0 and 0.7mmol/L ( $p=0.02$  and  $p=0.03$ ). The mean HbA1c in the SMD group increased ( $p=0.097$ ) and there was no significant reduction in TC or LDL-C. All patients reported that PoCT encouraged them to 'look after their health better', it was convenient and there was less anxiety having a finger prick than venepuncture. Also patients were more satisfied with the PoCT diabetes service ( $p=0.03$ ). The within-site imprecision achieved for external QA HbA1c and urine ACR met the minimum precision goals recommended by previously published standards. The external QA program was not available for lipid testing but the average imprecision for QC testing met the minimum precision goals.

### 2.7.3. Results from contact with primary investigators of PoCT Trials

Six primary investigators identified as authors of key PoCT studies and those interested in the field were emailed and asked of their awareness of any unpublished studies or studies currently taking place in PoCT for anticoagulant therapy, diabetes or hyperlipidaemia in a GP setting in the last 12 months. Overall, 50% of emails were answered with no investigator aware of any such studies taking place in a GP setting.

## 2.8. SUMMARY OF DATA

### 2.8.1. PoCT and safety

#### 2.8.1.1. Overall findings

Thirteen studies reported safety as an outcome. Of these, seven studies investigated safety by comparing results obtained by PoCT to those obtained by the laboratory. The correlation between PoCT and laboratory methods was reported to be good in all seven studies. The mean difference in results was completed in all seven studies. Four of the seven studies showed that the mean PoCT results were higher than laboratory results while three studies showed lower values with the PoCT device. Bland Altman plots were completed in four of the seven studies yet only two studies reported the 95% limits of agreement between PoCT and laboratory and only one reported that PoCT under-estimated the results compared to the laboratory.

Six studies (1 HbA1c/ACR, 1 ACR, 2 lipids, and 2 HbA1c/ACR/lipids) investigated safety through the results of quality control and quality assurance procedures. Four studies which investigated QC/QA for HbA1c and urine ACR found that the imprecision goals met the desired standards while three of the four studies of QC/QA results for lipid tests showed the PoCT device to be less precise than the laboratory method.

### 2.8.1.2. INR

Six studies investigated INR PoCT and safety one of which was a RCT.<sup>18</sup> The mean bias between PoCT and laboratory values was assessed in all six studies with three<sup>18, 62, 63</sup> detecting an overestimate of the PoCT INR result compared to the laboratory and three<sup>16, 17, 76</sup> found an underestimate. Four of the six studies investigated the correlation between PoCT and laboratory values with all concluding that the results were adequate<sup>16, 17, 62, 63</sup>. In four studies Bland Altman plots were performed<sup>16-18, 62</sup> but only two studies<sup>16, 62</sup> reported the 95% limits of agreement between PoCT and laboratory and only Seamark et al<sup>16</sup> reported the actual results indicating that the mean difference of PoCT results from control results was -0.32 INR units ( $\pm 2$  SD +0.55 and -1.20).

### 2.8.1.3. Diabetes and Hyperlipidaemia

Three studies<sup>69, 71, 72</sup> reported the safety of PoCT diabetes testing. Schwartz et al<sup>72</sup> showed the mean HbA1c result of the PoCT device to be significantly higher compared to the laboratory. The remaining two studies<sup>69, 71</sup> conducted in the Australian indigenous setting showed that the HbA1c and urine albumin creatinine ratio (ACR) met the desired goals for imprecision.

Gillam et al and Summerton et al<sup>65, 66</sup> reported the safety of hyperlipidaemia testing through QC/QA assessment and both studies showed the PoCT device to be less precise than the laboratory method.

Two studies<sup>47, 70</sup> investigated the safety of both diabetes and hyperlipidaemia testing through QC/QA PoC testing. HbA1c and urine ACR PoCT results met the analytical goals in both studies but only Shephard et al<sup>70</sup> found that hyperlipidaemia PoCT met the analytical goal.

## 2.8.2. PoCT and clinical effectiveness

### 2.8.2.1. Overall findings

There were 17 studies reporting clinical effectiveness as an outcome measure. Some studies reported more than one clinical effectiveness outcome. Four of the studies investigated differences between groups, five investigated within-group differences after the introduction of PoCT, three investigated both between and within-group differences, three determined the impact a PoCT result had on clinical decisions and two reported the proportion of results in therapeutic range.

### 2.8.2.2. In therapeutic/target range between-groups

Four studies investigated between group differences, that is was there significant differences between PoCT and usual care (laboratory testing) with one study finding improved patient health outcomes in the PoCT group compared to the laboratory group.

### 2.8.2.3. In therapeutic/target range within-group

Five studies investigated whether there were significant differences within the PoCT group. All studies found that PoCT was associated with significant improvement in test results at follow up.

### 2.8.2.4. In therapeutic/target range between and within-group

Three studies investigated both between and within-group differences in the study sample. There were no between-group differences (intervention and control); however, all three studies found within-group differences, with an improvement in patient health outcomes after the introduction of PoCT.

### 2.8.2.5. Impact on GP clinical decisions

Three studies investigated the impact PoCT had on clinical decision making but only one study found an association.

#### 2.8.2.6. *Therapeutic range*

Two studies provided descriptive data relating to the percentage of results in therapeutic range. One study reported that 53% of INR PoCT results were in therapeutic range and the other reported that 48% were in therapeutic range with no between or within-group statistical analysis undertaken in either study.

#### 2.8.2.7. *INR*

Eight studies <sup>8, 18, 34, 61, 63, 64, 73, 76</sup> investigated the clinical effectiveness of INR PoCT, three of which were RCTs <sup>18, 34, 8</sup>. Three of these <sup>18, 61, 76</sup> investigated between-group differences, with only Fitzmaurice et al <sup>61</sup> showing a significant improvement in the PoCT group compared to the control group in terms of the proportion of tests in range. Wurster et al <sup>73</sup> looked at within-group changes and found a significant improvement in the percentage of visits in which a patient's INR result was in target range in the PoCT group. Fitzmaurice et al and Claes et al <sup>8, 34</sup> measured both between and within-group differences and found a significant improvement in the PoCT group at the end-of-study (within-group analysis) but no differences were found between the intervention and control groups. Fitzmaurice et al <sup>64</sup> and Daly et al <sup>63</sup> showed that 53% and 48% of PoCT results respectively were in therapeutic range but no between or within-group statistical analysis were undertaken in either study.

#### 2.8.2.8. *Diabetes and Hyperlipidaemia*

Two RCTs <sup>33, 58</sup> and one observational study <sup>68</sup> investigated the clinical effectiveness of diabetes PoCT. Khunti et al <sup>33</sup> showed there was no significant difference in the HbA1c value in the intervention compared to the control groups while Shephard et al <sup>68</sup> showed through within-group differences that there was a significant improvement in HbA1c 12 months after PoCT was introduced. Miller et al <sup>58</sup> showed there were no between-group differences (intervention and control) but within-group analysis demonstrated an improvement in the mean HbA1c value and more intensification of therapy after the introduction of PoCT.

Of the three studies <sup>23, 44, 65</sup> investigating the clinical effectiveness of hyperlipidaemia PoCT only Ruffin et al <sup>44</sup> was an RCT. Cohen et al <sup>23</sup> showed an improvement in within-group differences of total cholesterol levels after the introduction of PoCT. Two studies <sup>44, 65</sup> examined the impact of PoCT on clinical decisions with Ruffin et al <sup>44</sup> finding that PoCT made a significant impact on clinical decisions with more coronary heart disease interventions in the PoCT group compared to the control group.

Shephard et al <sup>47, 70</sup> in two studies of diabetes and hyperlipidaemia PoCT showed through within-group differences of HbA1c and Total Cholesterol that there were significant improvements in glycaemic control and reduction in cholesterol levels after the introduction of PoCT. Grodzinsky et al <sup>75</sup> looked at the impact of PoCT on clinical decisions and found that patients were notified of an HbA1c test result at the test visit 52% of the time, 9% of the time for total cholesterol and high density lipoproteins and 7% of the time for triglycerides. No statistical analyses were undertaken.

### 2.8.3. *PoCT and cost*

#### 2.8.3.1. *Overall findings*

Nine studies reported cost as an outcome. A cost-effectiveness analysis was undertaken in three of the nine studies, two from a health care provider's perspective and one from a patient perspective. One study found PoCT to be cheaper for the health care provider and another more expensive than usual care, while from the patient perspective PoCT was cheaper than usual care.

Overall five of the nine studies investigating cost found PoCT to be cheaper, or that cost savings could be achieved compared to usual care, while two found PoCT more expensive than usual care. One study found no statistical difference in costs and another study only looked at relative costs.

### 2.8.3.2. INR PoCT

There were two RCTs<sup>59, 21</sup> and four observational studies<sup>62, 73, 64, 67</sup> of INR PoCT and cost. Three undertook a cost-effectiveness analysis (two from a health care provider perspective<sup>21, 59</sup> and one from a patient perspective<sup>67</sup>); two reported the practice costs incurred<sup>64, 73</sup> and one study<sup>62</sup> reported costs of the device and test. Claes et al<sup>59</sup> found that PoCT provided net savings for the health care provider while Parry et al<sup>21</sup> found PoCT costs to be greater than usual care to the health care provider. One study<sup>67</sup> found PoCT to provide lower patient costs, two studies<sup>64, 73</sup> which determined practice costs found PoCT to be cheaper and the one study<sup>62</sup> investigating PoCT device and test costs found that these varied depending on the device.

### 2.8.3.3. Diabetes and Hyperlipidaemia

The RCT of Khunti et al<sup>33</sup> measured the total cost for diabetes-related care and found no statistical differences between PoCT and usual care. Two studies reported on the cost of PoCT for hyperlipidaemia, with Gillam et al<sup>65</sup> studying the costs of PoCT compared to testing in the laboratory or blood testing at the practice using a laboratory, while Cohen et al<sup>23</sup> measured estimated costs to patients, to the health care provider and costs of PoCT to GPs. Gillam et al<sup>65</sup> found PoCT to be more expensive while Cohen et al<sup>23</sup> found potential cost savings to the health care provider and patients.

## 2.8.4. PoCT and patient satisfaction and acceptability

### 2.8.4.1. Overall findings

Eight studies investigated patient satisfaction and acceptability of PoCT. Increased patient satisfaction and acceptability of PoCT was found in four of the eight studies in which it was reported. One study found no increase in satisfaction and the remaining three did not statistically investigate differences within or between-groups. Overall descriptive data indicated that patients perceived an improvement in communication with their GP after the introduction of PoCT; they also thought that PoCT was convenient and preferred tests being done at the practice.

### 2.8.4.2. INR

Of the two studies<sup>18, 74</sup> only Chaudry et al<sup>74</sup> undertook statistical analyses and found significantly more patients preferred the PoCT INR service compared to usual care. They reported that patients had improved capacity to make appointments, spent less time at the appointment, experienced less pain and received improved communication regarding medication dosage.

### 2.8.4.3. Diabetes and Hyperlipidaemia

Two studies<sup>60, 68</sup> investigated diabetes PoCT and patient satisfaction. Stone et al<sup>60</sup> in an RCT found no significant difference between treatment group (intervention and control) and patient satisfaction while Shephard et al<sup>68</sup> found a significant increase in patient satisfaction after PoCT, with patients reporting that they thought PoCT was convenient and they were motivated to manage their condition better.

Cohen et al and Gilliam et al<sup>23, 65</sup> investigated PoCT for hyperlipidaemia and patient satisfaction with both finding a patient preference for PoCT but no statistical analyses were undertaken. The areas of satisfaction ranged from patients reporting PoCT was convenient, patients preferring their own GP to do the test and their anxiety was alleviated by the immediacy of results.

Two studies<sup>47, 70</sup> investigated patient satisfaction for both diabetes and hyperlipidaemia PoCT. Both showed that there was a significant increase in patient satisfaction after the introduction of the PoCT service. Patients reported that they thought PoCT was convenient and improved patient self-motivation.

## 2.8.5. PoCT and health professional satisfaction and acceptability

### 2.8.5.1. Overall findings

Seven of the eight studies reporting health professional satisfaction and acceptability of PoCT did not investigate whether there were statistically significant differences between or within-groups. One of the eight studies in which statistical tests were completed found no association between PoCT and increase in satisfaction with the service. Overall descriptive data showed that most health professionals found PoCT useful, reliable, accurate, convenient and easy to use, but had concerns regarding costs and the time taken to complete tests.

### 2.8.5.2. INR

Jackson et al<sup>17</sup> reported the satisfaction of the INR PoCT user and descriptive results showed that the users of the device found PoCT useful to clinical practice, easy to use, preferred PoCT to laboratory testing and were confident in the results.

### 2.8.5.3. Diabetes and Hyperlipidaemia

Three studies<sup>60, 68, 72</sup> reported on diabetes PoCT and health professional satisfaction with only Shephard et al<sup>68</sup> completing statistical analysis and showing no statistically significant improvement in health professional (Device Operators) satisfaction with the diabetes service after the introduction of PoCT. All three studies provided descriptive data with two<sup>60, 68</sup> showing that the nurses' found PoCT easy and convenient to use but another<sup>72</sup> reporting nurses' concern around the time required for PoCT. Clinicians in one study<sup>68</sup> reported confidence with the accuracy and reliability of the PoCT result and thought PoCT positively impacted on patient care; however, Stone et al<sup>60</sup> cited GPs' concerns around the cost of equipment and consumables.

No statistical analyses were performed in either of the studies of Cohen et al<sup>23</sup> and Gilliam et al<sup>65</sup> but both studies found that there was a reported preference for PoCT, that it was convenient, useful and reliable. However, there were concerns about various factors including the cost, pressures of time to complete QC and medico-legal action related to inaccuracy of results.

Two studies using descriptive data only showed that health professionals believed the immediacy of results as beneficial. In addition they had confidence in the accuracy and reliability of the PoCT result, as well as finding it convenient and an acceptable alternative to the laboratory.<sup>47, 70</sup>

## 2.9. DISCUSSION

Despite the increase in the use of PoCT since the publication more than a decade ago of the last systematic review of PoCT in GP, there remains a dearth of well-designed studies to determine the outcomes from this type of testing. Thus the overwhelming conclusion now remains the same as that of Hobbs et al.<sup>3</sup>, namely there is insufficient evidence to support the introduction of PoCT in a general practice setting.

A minority of the studies published in the literature since Hobbs et al.<sup>3</sup> are randomised controlled trials and none of these is sufficiently similar to be combined in a meta-analysis. There is also great variability in the remaining observational studies which make it difficult to draw any firm conclusions about the influence of PoCT on a number of different outcomes. Deficiencies in both randomised controlled trials and observational studies included few studies examining the same outcomes and many studies considering multiple outcomes. The participant numbers examined were generally small and the duration of the PoCT intervention was usually short.

In terms of clinical effectiveness, our review showed that only one study found a significant difference in the number of patients having tests in the therapeutic or target range compared to usual care. Of importance is that making comparisons between studies was difficult as there was no consistency in how outcome measures were reported. This was of particular importance when reviewing INR clinical outcomes with a range of methods used to measure INR control. Further to this, five of the seven studies evaluating between-group (intervention and control) differences did

not investigate PoCT separately but with another intervention making it difficult to determine whether treatment differences were masked because of multiple interventions. Our review showed that eight studies found within-group improvements in test results after the introduction of PoCT. However, there are limitations to this finding particularly in generalising the results to the broader population. Four of the eight studies conducted PoCT in specific populations (three studies took place in an Aboriginal community setting and one study had a majority of Afro-American females from one practice). Furthermore the results of these studies could be explained by the Hawthorne effect. The Hawthorne effect describes a change to behaviour, usually the response being an improvement, simply by participating in a study or trial. By not having a control group the Hawthorne effect cannot be rejected.

Studies relating to the safety or analytical quality of PoCT by comparing agreement of PoCT results to laboratory results are limited, with the majority of studies devoted to INR testing. Most studies were characterised by poor design and the use of statistics such as correlation coefficients which are inadequate to show the degree of agreement between two analytical methods.<sup>77</sup> Most studies focused on the bias between PoCT and laboratory results with only one study investigating the 95% limits of agreement. Drawing conclusions from studies using better statistics such as Bland Altman plots is also difficult because of the different measurement technologies used for both PoCT and in the laboratory. Nevertheless the studies by Shephard et al<sup>69</sup> show sound long term analytical performance for HbA1c and urine ACR PoCT.

Conclusions about the costs of PoCT are also difficult to draw because of limited studies with variable analyses and findings. Only three studies looked at cost-effectiveness, two from the cost to society (health care provider) and one from a patient perspective. As noted above, the results were not consistent other than the results being sensitive to particular costs and altering these changed the outcome. The quality of these cost studies was also low with little detail on how cost data was collected and allocated to the intervention and control groups.

The literature relating to patient and health professional satisfaction was generally positive but different questions and research methodology were used in the majority of studies. This deficiency combined with small patient and health professional numbers and no comparative analyses completed in most of the studies could have led to an over-estimate of satisfaction.

## **2.10. CONCLUSION**

This systematic review of the PoCT literature does not provide good evidence that PoCT provides better patient health outcomes than usual care with no consistent and significant differences found. There were inconsistent and limited data available on safety and cost outcomes making conclusions difficult to infer. However, most studies found that patients and health professionals were satisfied and found PoCT acceptable. Yet this may need to be interpreted with caution as many studies were not of high quality and many did not statistically analyse differences.

There are some limitations to this review that need to be considered. Despite the comprehensive search strategy used for this review, publication bias was still possible as many small, descriptive studies may not have been published and only English articles were reviewed. This review only focused on seven point of care tests for the management of patients with established chronic disease in general practice which may result in some bias in results. However, the review provides a relevant and meaningful summary to help inform decisions around the implementation of these point of care tests in the GP setting.

Three foreign language articles were identified as part of the review but were not appraised due to time constraints. These papers were not RCTs and the review team did not believe that the results of these papers would have changed the outcome of this review. Also, since there is no standard definition of PoCT it is possible that some published papers could have been missed. This limitation was noted in Hobbs et al.<sup>3</sup> systematic review and remains the case today.

Further research is required to inform policy decisions of whether PoCT should be implemented in the GP setting. As it is not intended for PoCT to replace laboratory testing in the current setting but rather to provide a practical and timely alternative of equivalent quality, future studies for the

three conditions evaluated in this review should focus on conducting non-inferiority trials to determine the safety and clinical effectiveness of PoCT. This type of analysis would allow the identification of whether PoCT is as effective as the standard procedure of laboratory testing so the two methods can be used interchangeably in the GP setting. The PoCT Trial has been designed to address the limitations reported in the literature and should provide a sound evidence base which underpins decisions about whether PoCT should be implemented by the Australian government.

### **3. RECRUITMENT OF PARTICIPANTS**

#### **SUMMARY OF THE CHAPTER**

This chapter reports on the methods utilised to recruit Trial participants and provides descriptive data on those recruited. Recruitment of practices and patients was overseen by the PoCT Recruitment Subcommittee.

Practices were recruited through the support of local Node Support Officers and Divisions of General Practice. Randomisation and allocation to treatment group occurred prior to the initial training on use of PoCT devices, the Trial protocols and data collection processes.

The key findings of the chapter are:

- a total of 58 practices were recruited, two less than the target of 60
- 26 practices were randomised to the control group and 32 practices were randomised to the intervention group
- 5234 patients were recruited from the practices, 944 patients having anticoagulant therapy, 1967 patients with diabetes and 3819 with hyperlipidaemia
- 247 GPs participated
- 80 practice staff were trained as Device Operators – five GPs and the rest being other practice staff
- 23 pathology providers/laboratories representing 10 parent companies were linked to the practices recruited for the Trial
- retention rates of practices and patients were 84% and 86% respectively.

The key conclusion:

- interest from all stakeholders in participating in the Trial was high and the Trial achieved excellent retention rates.

#### **3.1. INTRODUCTION**

The recruitment of practices and patients was overseen by the PoCT Recruitment Subcommittee. This sub-committee approved the recruitment strategy developed by the Trial Management Team and the strategy was implemented by the Node Support Officers (NSOs) with support from the Trial Management Team.

#### **3.2. AIMS AND OBJECTIVES**

The aim was to recruit a total of 60 practices (30 intervention and 30 control), twenty from each of the three geographic areas – urban, rural and remote as outlined in the Trial Design.<sup>25</sup>

#### **3.3. METHODS**

##### **3.3.1. Practices**

Divisions of General Practice (Divisions) were approached to assist in recruiting practices through various channels. A letter was sent to those Divisions in the regions in which the Trial sought to recruit practices, explaining the Trial and requesting their support. Divisional databases were used to develop a list of practices and GPs who would be approached to participate in the Trial, following which an individual letter of invitation was sent to all GPs in these practices.

Once a GP or practice had expressed an interest in being involved in the Trial, further information was sought in the form of a practice checklist. If the practice as a whole continued to display

interest as indicated by the return of the checklist, the NSO followed up by telephone to organise a practice visit to discuss the Trial in more detail. At this visit the NSO provided information regarding the accreditation process, frequency of testing, quality control and other requirements for participation in the Trial. Communication links with the practice's primary contact person were also established.

Each practice was required to enter into an agreement with Adelaide Research and Innovation Pty Ltd (ARI), the University's commercialisation arm. The agreement was in the form of a 'Letter of Participation' which detailed the terms and conditions of involvement in the Trial.

### 3.3.1.1. Selection and eligibility criteria

In order to maximise the chances of achieving the Trial outcomes, the criteria used for selection of practices is shown in Table 16 as outlined in the Trial Design.<sup>25</sup>

Practices were initially screened by their NSO using the weighted scoring matrix. Practices were excluded if they were already involved in other primary care pathology trials.

**Table 16: Criteria for practice selection, PoCT Trial**

1	Practice has current accreditation under 2 <sup>nd</sup> Edition of RACGP Standards for General Practice
2	A signed Contract from the practice entity and from the designated GP will also be required
3	Associated pathology practice agreement on provision of QAP (obtained by Trial Manager but practice must identify the pathology provider routinely used)
4	The practice has a minimum patient load from all disease groups and is prepared to undertake PoCT for each of the tests. The minimum load has been set at approximately 50% of the expected patient load for an 'average' practice:  Anticoagulant therapy – 20 tests per month  Hyperlipidaemia – 10 tests per month  Diabetes – 5 tests per month
5	The practice has suitable facilities for PoCT including premises, appropriately qualified staff and suitable medical record systems
6	The practice can demonstrate a commitment to the Trial and its objectives
7	There has been previous involvement of the practice in projects and/or in on-site pathology testing
8	There is a willingness to direct bill the PoCT items to Medicare

Criteria 1-3 were mandatory while criteria 4–8 were weighted as detailed in weighted scoring matrix in Appendix 14.

### 3.3.1.2. Randomisation

The unit of randomisation for the Trial was the practice. Central randomisation by the Data Management & Analysis Centre (DMAC) was undertaken by phone or email after consent was obtained from participating practices. The recruiters (Trial Management) did not know the

sequence. The random allocation sequence was generated using ralloc.ado version 3.2.5 in Stata 9.0<sup>78-81</sup>. Practices were randomly allocated to the intervention or control arm in the ratio 1:1. Randomisation was stratified by geographic area (urban, rural and remote) and used randomly permuted blocks of size 2, 4 and 6. The randomisation key has been kept for random sequence allocation should it be required.

### 3.3.2. Patients

#### 3.3.2.1. Selection and eligibility criteria

Selection and eligibility criteria were based on general criteria as well as condition-specific criteria. Patients were required to have one or more of the following established diseases – anticoagulant therapy, hyperlipidaemia and diabetes. The eligibility criteria for each condition are provided in Table 17.

#### Exclusion criteria

Patients meeting one or more of the following criteria were excluded from the Trial:

- < 18 years of age
- patients whose condition is not stabilised
- patients who have dementia
- patients deemed by their GP as not able to comply with the requirements of the Trial and/or
- patients who are unable to understand the instructions written in English.

**Table 17: Eligibility criteria for patients by condition**

Condition	Eligibility criteria	
	Patient	Range
Anticoagulant therapy	Patient has been prescribed warfarin	INR test result within the therapeutic range for at least one month (e.g. stabilised) <sup>28</sup>
Diabetes	Fasting plasma glucose $\geq 7.0$ mmol/L or 2-hour post glucose load $\geq 11.1$ mmol/L <sup>82</sup>	
Hyperlipidaemia	Patients with one or more of the following:- <ul style="list-style-type: none"> <li>• existing coronary heart disease</li> <li>• symptomatic cerebrovascular disease</li> <li>• symptomatic peripheral vascular disease</li> <li>• diabetes mellitus in patients aged 40 years or more</li> </ul>	cholesterol > 3.5 mol/L
	Other patients at high risk with one or more of the following: <ul style="list-style-type: none"> <li>• diabetes mellitus in patients aged less than 40 years</li> <li>• familial hypercholesterolaemia</li> <li>• family history of coronary heart disease (first degree relative less than 60 years of age)</li> <li>• Hypertension</li> </ul>	cholesterol > 6.5 mol/L or cholesterol > 5.5 mol/L and HDL-C < 1 mmol/L
	Patients with HDL-C < 1 mmol/L	cholesterol > 6.5 mmol/L
	Patients not eligible under the above: <ul style="list-style-type: none"> <li>• men 35 to 75 years of age</li> <li>• post-menopausal women up to 75 years of age</li> </ul>	cholesterol > 7.5 mmol/L or triglyceride > 4 mmol/L
	Other patients not included in the above	cholesterol > 9 mmol/L or triglyceride > 8 mmol/L

Patients were initially recruited in the first three months of the Trial. Eligible patients were those aged 18 years and over who had established and stabilised diabetes, or hyperlipidaemia or who were taking anticoagulant medication such as warfarin. The initial recruitment phase was extended beyond the three months to four months because insufficient patients had been recruited in this timeframe. This was further extended for another two months to specifically recruit additional patients with diabetes and those requiring anticoagulant therapy. This brought the total recruitment period to six months (1 September 2005 to 28 February 2006).

Eligibility criteria for patients was established and provided to practices. Eligible patients were then identified through a search of the practice's electronic patient records, undertaken either by the GP, nurse, or Practice Manager with support from the NSO. A software program was designed by DMAC which allowed practices to generate a random list of 150 – 200 patients per disease group from their list of eligible patients and which also removed duplicate names.

A patient list was then established and a decision made by the key GP on those patients who met further selection criteria including competency to consent. Each practice then prepared a mail out to those patients on the list, which included a patient information sheet and consent form. Once patients had consented, their information was entered on the PoCT Management Information System (MIS) and those in the intervention group began PoCT.

### 3.3.3. General Practitioners

All General Practitioners (GPs) from each practice were invited to participate in the Trial. Those wishing to participate were required to sign a consent form, letter of participation and provide proof of having current Medical Malpractice Insurance cover.

### 3.3.4. Device Operators

Practices randomised to the intervention group were required to nominate at least one person (preferably a practice nurse) to undertake training on using the PoCT devices and Trial processes and procedures.

### 3.3.5. Pathology Providers

All practices recruited to participate in the Trial identified the Pathology Provider/s they used for the tests specified in the Trial. These Pathology Providers were then approached by the Trial Manager, inviting their participation in the Trial.

The role of the Pathology Providers recruited for the Trial included:

- provision of pathology results for the tests utilised in the Trial for each patient who consented to participate for the duration of the Trial (for both control and intervention practices)
- provision of the quality assurance reports for the tests utilised for the duration of the Trial
- provision of ongoing clinical advice where it was required by the General Practitioners and
- participation in an evaluation process with the Trial Evaluators to obtain their attitudes to and satisfaction with PoCT in general practice.

In order to identify the patients participating in the Trial, the Trial Manager, following consultation with the Pathology Providers, provided practices with identifying stickers for pathology request forms. The majority of Pathology Providers provided patient data electronically directly to DMAC.

### 3.4. RESULTS

The clusters and the various participants' progress throughout the Trial is shown as a CONSORT<sup>83</sup> diagram in Figure 4. Details of each participant's recruitment and progress are provided in detail in the following sections.

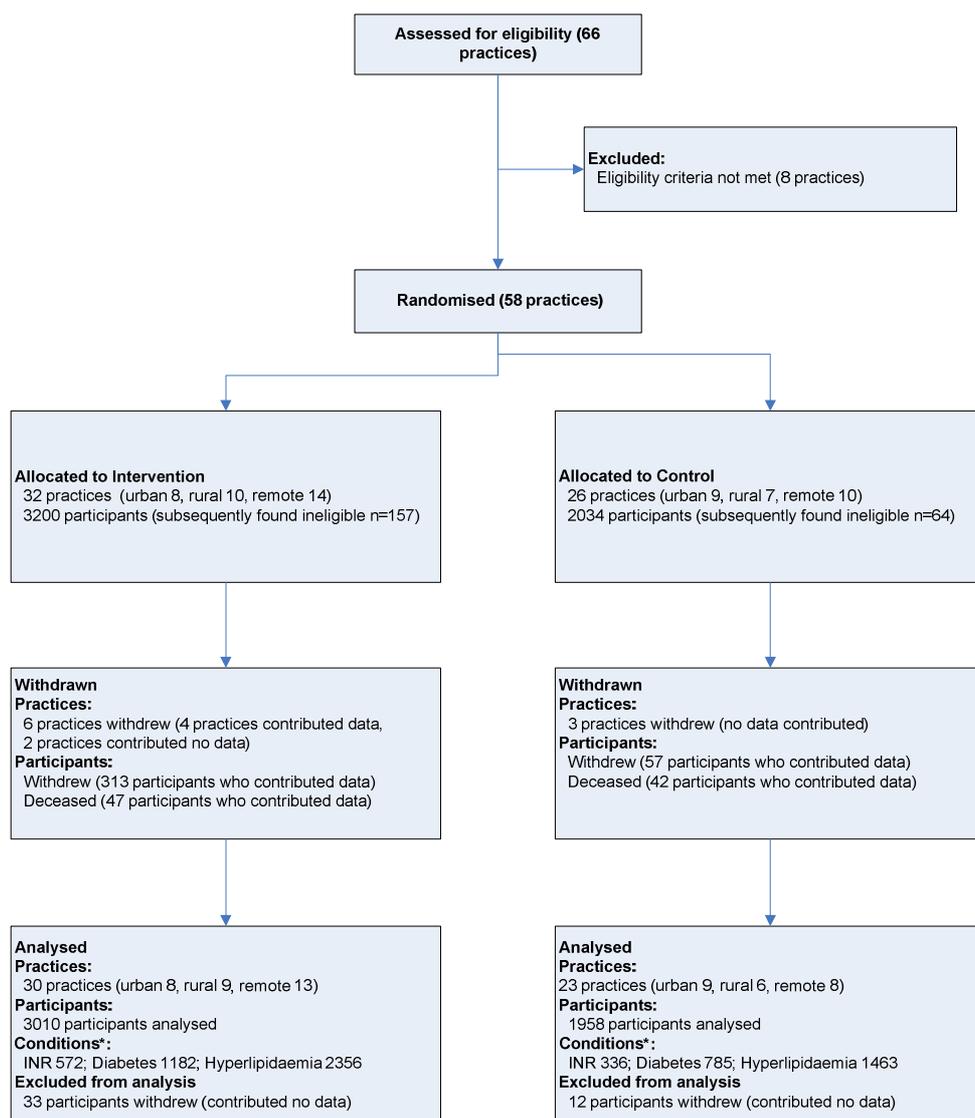
#### 3.4.1. Practices

The result of recruitment of practices by geographic region is summarised in Table 18 and their location is shown in Figure 5. Practices were deemed withdrawn if they had signed an agreement to be part of the Trial and subsequently withdrew.

A total of 66 practices expressed an interest in participating in the Trial and met the selection criteria. Of the practices approached, 58 agreed to participate and signed on to be part of the Trial (Table 18). Subsequently, nine practices withdrew from the Trial (Table 18). Practices that withdrew were located in rural or remote areas, while no urban based practices withdrew from the Trial (Table 18).

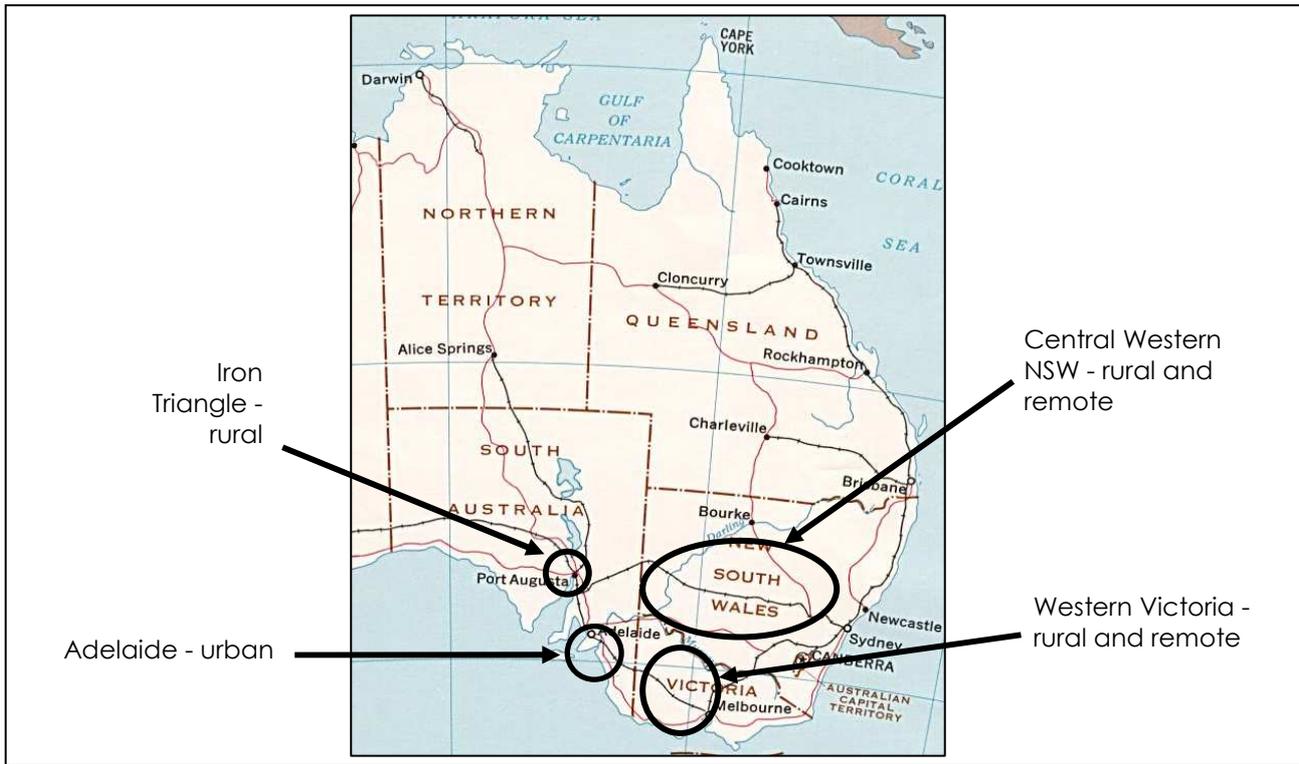
Of the practices which completed the Trial, 36.73% were located in remote areas, 28.57% in rural areas and 34.69% in urban areas (Table 18).

**Figure 4: Flow diagram showing flow of clusters and participants' progress through the Trial**



\* Patients could have one or more conditions

**Figure 5: Location of practices recruited for the PoCT Trial**



**Table 18: Summary of practice recruitment by status and region**

Geographic region	Practice status				Total	
	Completed study		Withdrew			
	N	%	N	%	N	%
Urban	17	34.69	0	0	17	29.31
Rural	14	28.57	3	33.33	17	29.31
Remote	18	36.73	6	66.67	24	41.38
Total	49	100.00	9	100.00	58	100.00

Of the 58 practices recruited for the Trial, a total of 26 practices were randomised to the control group and 32 practices were randomised to the intervention group (Table 19). There was an imbalance of six in the number of practices allocated to each treatment group. Based on the method of randomisation used, the maximum imbalance in treatment allocation that could have occurred was nine (though an imbalance of this size would have been highly unlikely). The possibility of an imbalance in the number of practices allocated to each treatment group was necessary, however, in order to ensure that the treatment allocation of the next practice to be randomised could not be predicted.

A total of nine practices (six intervention and three control) withdrew after the Trial commenced (Table 19). Of the 32 practices randomised to the intervention group, two withdrew after randomisation but before the start of the Trial, therefore 30 practices commenced the intervention. Of the practices that withdrew there was a higher percentage from the intervention group (66.67%) than from the control group (33.33%).

**Table 19: Summary of practice recruitment by status and treatment group**

Treatment group & geographical region		Practice status				Total	
		Completed study		Withdrew			
		N	%	N	%	N	%
Intervention	Urban	8	16.33	0	0	8	13.79
	Rural	8	16.33	2	22.22	10	17.24
	Remote	10	20.41	4	44.44	14	24.14
	Subtotal	26	53.06	6	66.67	32	55.17
Control	Urban	9	18.37	0	0	9	15.52
	Rural	6	12.24	1	11.11	7	12.07
	Remote	8	16.33	2	22.22	10	17.24
	Subtotal	23	46.94	3	33.33	26	44.83
Total		49	100.00	9	100.00	58	100.00

*Reasons for withdrawal*

Practices that withdrew from the Trial were asked to complete a brief questionnaire to ascertain their reason for withdrawing. A total of seven practices completed this questionnaire and their results are summarised in Table 20.

**Table 20: Reasons provided by practices for withdrawal from the Trial**

Reason(s) for withdrawing	Frequency (N=7)	% of responses
The practice has inadequate resources to assist the Trial	3	43
Do not have enough time available to participate in the Trial	2	29
Do not want to participate in control arm of Trial only intervention arm	1	14
The practice is not able to recruit the required number of patients	1	14
Total	7	100

Missing data = 2

These practices identified the lack of resources in terms of staff and administration and time for the GP to participate in the Trial as the main reasons for withdrawing.

### 3.4.2. Patients

As at the 28<sup>th</sup> February 2007, 5234 patients had been recruited for the Trial as summarised in Table 21. Of these patients, 221 were deemed ineligible, that is, while the patients had consented to participate in the Trial, they did not meet the Trial selection criteria and subsequently revoked their consent. In addition, 45 patients withdrew from the Trial and on revoking their consent asked that their data not be used. Patients who were ineligible and who withdrew and indicated that their data could not be used have been excluded from all further analyses. The majority of ineligible patients were from the remote region (64.25%) – 11.31% in the control group and 52.94% in the intervention group. This was likely to be the result of an error in the process used by practices to search for eligible patients.

A total of 370 patients withdrew from the Trial after having given consent but indicated that their data already collected could be used. A higher percentage of withdrawn patients were from the intervention group (84.59%) with most being from remote regions. In the control group, withdrawal was evenly distributed across all three regions. Just over half of the withdrawn patients (50.84%) were from practices that withdrew from the Trial. Other reasons for withdrawal included moving, changing practice attended or no longer wishing to participate in the Trial.

During the Trial 89 patient deaths were reported. Within the control group there were more deaths of patients in the urban area (1.02%) while in the intervention group the majority of deaths occurred in the remote area (0.79%). (For a more detailed analysis see Serious Adverse Events and Incidents Section).

A total of 4968 patients completed the Trial, 39.41% in the control group and 60.59% in the intervention group (Table 21). The distribution of participating patients was fairly even across the three geographic regions, with a slightly smaller percentage of patients from rural areas participating in the Trial (27.46%) (Table 21).

It should be noted that the recruited number of patients by condition was greater than the total number of patients recruited as shown in Table 22, as patients were registered for one or more conditions. More than half of the participants were registered as having only one condition, while a third were registered as having two conditions and a small proportion had all three conditions (Table 22). Conditions for 41 patients were unobtainable due to a change in practice management and subsequent withdrawal from participating in the Trial.

**Table 21: Summary of patient recruitment by treatment group and geographic regions**

Treatment group & geographic region		Excluded*						Included								Total	
		Ineligible		Withdrew (data not used)		Subtotal		Completed study		Deceased (data collected prior to death used)		Withdrew (data collected prior to withdrawal used)		Subtotal			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%		
Intervention	Urban	30	13.57	9	20.00	39	14.66	855	18.96	9	10.11	33	8.92	897	18.06	936	17.88
	Rural	10	4.52	12	26.67	22	8.27	855	18.96	14	15.73	48	12.97	917	18.46	939	17.94
	Remote	117	52.94	12	26.67	129	48.50	940	20.85	24	26.97	232	62.70	1196	24.07	1325	25.32
	Subtotal	157	71.04	33	73.33	190	71.43	2650	58.77	47	52.81	313	84.59	3010	60.59	3200	61.14
Control	Urban	23	10.41	6	13.33	29	10.90	797	17.68	20	22.47	23	6.22	840	16.91	869	16.60
	Rural	16	7.24	2	4.44	18	6.77	423	9.38	7	7.87	17	4.59	447	9.00	465	8.88
	Remote	25	11.31	4	8.89	29	10.90	639	14.17	15	16.85	17	4.59	671	13.51	700	13.37
	Subtotal	64	28.96	12	26.67	76	28.57	1859	41.23	42	47.19	57	15.41	1958	39.41	2034	38.86
Total		221	100.00	45	100.00	266	100.00	4509	100.00	89	100.00	370	100.00	4968	100.00	5234	100.00

\*Patients who were ineligible or who withdrew and indicated their data could not be used have been excluded from all analyses.

**Table 22: Summary of patient conditions by treatment group**

Conditions (%)		Intervention	Control	Total
		N=3010	N=1958	N=4968
Anticoagulant Therapy	Yes	572 (19.0)	372 (19.0)	944 (19.0)
	Missing	41 (1.4)	0 (0.0)	41 (0.8)
Diabetes	Yes	1182 (39.2)	785 (40.1)	1967 (39.6)
	Missing	41 (1.4)	0 (0.0)	41 (0.8)
Hyperlipidaemia	Yes	2356 (78.3)	1463 (74.7)	3819 (76.9)
	Missing	41 (1.4)	0 (0.0)	41 (0.8)
Number of Conditions	1	1904 (63.3)	1333 (68.1)	3237 (65.2)
	2	989 (32.9)	588 (30.0)	1577 (31.7)
	3	76 (2.5)	37 (1.9)	113 (2.3)
	Missing	41 (1.4)	0 (0.0)	41 (0.8)

The following tables show recruitment of patients by treatment group and geographic region for each of the three conditions – anticoagulant therapy (Table 23), diabetes (Table 25) and hyperlipidaemia (Table 27).

3.4.2.1. *Anticoagulant therapy*

A total of 944 patients on anticoagulant therapy were eligible for the Trial, this included 38 who died and 70 who withdrew, leaving 836 who completed the Trial (Table 23). Of the 944 patients, 572 (60.59%) were in the intervention group and 372 (39.41%) were in the control group. This number was substantially below the recruitment target of 2524.

**Table 23: Patients included in the analysis by treatment group and geographic regions - anticoagulant therapy**

Treatment group & geographic region		Patient status						Total	
		Completed study		Deceased		Withdrew			
		N	%	N	%	N	%	N	%
Intervention	Urban	188	22.49	4	10.53	9	12.86	201	21.29
	Rural	143	17.11	9	23.68	20	28.57	172	18.22
	Remote	166	19.86	5	13.16	28	40.00	199	21.08
	Subtotal	497	59.45	18	47.37	57	81.43	572	60.59
Control	Urban	153	18.30	10	26.32	7	10.00	170	18.01
	Rural	61	7.30	2	5.26	1	1.43	64	6.78
	Remote	125	14.95	8	21.05	5	7.14	138	14.62
	Subtotal	339	40.55	20	52.63	13	18.57	372	39.41
Total		836	100.00	38	100.00	70	100.00	944	100.00

GPs, Device Operators and practices (usually the Practice Manager) were asked, through the Satisfaction Questionnaire, to give reasons why they thought low numbers of patients on anticoagulant therapy were recruited and the results are shown in Table 24. In all cases the highest rated reason (21% to 32%) was 'patients did not want to participate in the Trial'. The next highest rated reason provided by Device Operators and practices (16% – 23%) was 'insufficient patients with condition'. Interestingly GPs did not rate this as highly and indicated that 'patients did not want to change their management process for the length of the Trial' as an important reason (14%). In addition, 20% of GPs said they did not know why the recruitment was low.

**Table 24: Reasons given by GPs, practices and device operators for low recruitment of INR patients**

INR recruitment	GPs		Practice		Device operator	
	N	%	N	%	N	%
Insufficient patients with condition	25	9.0	15	15.8	8	23.5
Patients did not want to participate	58	20.9	24	25.3	11	32.4
Patients too old	24	8.7	13	13.7	3	8.8
Patients did not want to change their management process	39	14.1	11	11.6	5	14.7
GP did not wish patient to participate	10	3.6	2	2.1	1	2.9
GP did not wish to change patient's management	8	2.9	0	0	0	0
Trial selection criteria too narrow	15	5.4	3	3.2	0	0
Unable to identify patients meeting selection criteria	10	3.6	2	2.1	0	0
Patient managed by Specialist	9	3.2	87	7.4	0	0
Don't know	56	20.2	108	8.4	0	0
Other	23	8.3	10	10.5	6	17.6
Total	277	100	95	100	34	100

*Note: more than one reason could be given.*

#### 3.4.2.2. Diabetes

A total of 1967 patients who had diabetes were eligible for the Trial (Table 25). This included 39 who died and 120 who withdrew, leaving 1808 who completed the Trial. Of the 1967 patients, 1182 (60.09%) were in the intervention group and 785 (39.91%) were in the control group. The number was below the recruitment target of 2524.

Again GPs, Device Operators and practices were asked, through the Satisfaction Questionnaire, to give reasons why they thought low numbers of patients with diabetes were recruited (Table 26). In all cases, again, the most frequently given reason (25% – 38%) was that patients did not want to participate in the Trial. While Device Operators and practices gave 'insufficient patients in the

practice with diabetes' as their next highest rated reason, practices also rated 'patients did not want to change their management process for the length of the Trial' just as highly and this was supported by GPs, who also rated it highly (15%). Of the GPs, over 25% indicated they did not know why there were low recruitment numbers of patients with diabetes.

**Table 25: Patients included in the analysis by treatment group and geographic regions - diabetes**

Treatment group & geographic region		Patient status						Total	
		Completed study		Deceased		Withdrew			
		N	%	N	%	N	%	N	%
Intervention	Urban	343	18.97	3	7.69	17	14.17	363	18.45
	Rural	375	20.74	5	12.82	24	20.00	404	20.54
	Remote	343	18.97	16	41.03	56	46.67	415	21.10
	Subtotal	1061	58.68	24	61.54	97	80.83	1182	60.09
Control	Urban	349	19.30	8	20.51	10	8.33	367	18.66
	Rural	155	8.57	1	2.56	7	5.83	163	8.29
	Remote	243	13.44	6	15.38	6	5.00	255	12.96
	Subtotal	747	41.32	15	38.46	23	19.17	785	39.91
Total		1808	100.00	39	100.00	120	100.00	1967	100.00

**Table 26: Reasons by GPs, practices and device operators for low recruitment of diabetes patients**

Diabetes recruitment	GP		Practice		Device Operator	
	N	%	N	%	N	%
Insufficient patients with condition	11	4.2	11	12.6	6	17.6
Patients did not want to participate	65	24.7	25	28.7	13	38.2
Patients too old	12	4.6	9	10.3	2	5.9
Patients did not want to change their management process	40	15.2	11	12.6	4	11.8
GP did not wish patient to participate	9	3.4	3	3.4	1	2.9
GP did not wish to change patient's management	7	2.7	2	2.3	0	0
Trial selection criteria too narrow	6	2.3	1	1.1	0	0
Unable to identify patients meeting selection criteria	5	1.9	1	1.1	0	0
Patient managed by Specialist	19	7.2	6	6.9	4	11.8
Don't know	67	25.5	10	11.5	1	2.9
Other	22	8.4	8	9.2	3	8.8
Total	263	100	87	100	34	100

Note: more than one reason could be given.

### 3.4.2.3. Hyperlipidaemia

A total of 3819 patients who had hyperlipidaemia were recruited for the Trial (Table 27). This included 54 who died and 244 who withdrew, leaving 3521 who completed the Trial. Of the 3819 patients, 2356 (61.69%) were in the intervention group and 1463 (38.31%) were in the control group. This number was well above the recruitment target of 894.

**Table 27: Patients included in the analysis by treatment group and geographic regions - hyperlipidaemia**

Treatment group & geographic region		Patient status						Total	
		Completed study		Deceased		Withdrew			
		N	%	N	%	N	%	N	%
Intervention	Urban	631	17.92	4	7.41	20	8.20	655	17.15
	Rural	685	19.45	9	16.67	34	13.93	728	19.06
	Remote	806	22.89	17	31.48	150	61.48	973	25.48
	Subtotal	2122	60.27	30	55.56	204	83.61	2356	61.69
Control	Urban	623	17.69	10	18.52	18	7.38	651	17.05
	Rural	313	8.89	5	9.26	12	4.92	330	8.64
	Remote	463	13.15	9	16.67	10	4.10	482	12.62
	Subtotal	1399	39.73	24	44.44	40	16.39	1463	38.31
Total		3521	100.00	54	100.00	244	100.00	3819	100.00

### 3.4.3. General Practitioners

A total of 247 GPs participated, of which 53 withdrew, leaving 194 who completed the Trial. Of the 247 GPs, 153 (61.94%) were in the intervention group and 94 (38.06%) were in the control group (Table 28). All GPs were included in the data analysis, as those GPs who withdrew consented to use of their data following withdrawal. The two main reasons given for GP withdrawal were relocation (45.28%) and practice withdrawal (35%).

**Table 28: GP status by treatment group and geographic region**

Treatment group & geographic region		GP status				Total	
		Completed study		Withdrew			
		N	%	N	%	N	%
Intervention	Urban	44	22.68	10	18.87	54	21.86
	Rural	47	24.23	18	33.96	65	26.32
	Remote	23	11.86	11	20.75	34	13.77
	Subtotal	114	58.76	39	73.58	153	61.94
Control	Urban	48	24.74	5	9.43	53	21.46
	Rural	12	6.19	1	1.89	13	5.26
	Remote	20	10.31	8	15.09	28	11.34
	Subtotal	80	41.24	14	26.42	94	38.06
Total		194	100.00	53	100.00	247	100.00

*Note: Five GPs were employed in two Trial practices and have each been counted twice in this table.*

#### 3.4.4. Device Operators

A total of 80 staff were selected by the practices to be trained as Device Operators. Seventy nine were involved at the commencement of the Trial. Of these, 18 withdrew leaving a total of 61 who completed the Trial (Table 29). Device Operator withdrawal was mainly in remote and rural locations and was largely (61%) due to practice withdrawal.

**Table 29: Device Operator status by geographic region**

Geographic region	Device operator status				Total	
	Completed study		Withdrew			
	N	%	N	%	N	%
Urban	16	26.23	2	11.11	18	22.78
Rural	22	36.07	6	33.33	28	35.44
Remote	23	37.70	10	55.56	33	41.77
Total	61	100.00	18	100.00	79	100.00

### 3.4.5. Pathology Providers

All identified Pathology Providers agreed to participate in the Trial and a summary of those involved is provided in Table 30. A total of 23 providers/laboratories participated in the Trial, representing 10 parent pathology companies. Most practices had more than one Pathology Provider with, on average, each practice using 1.5 Pathology Providers. For practices located in rural or remote areas, the pathology laboratory may be located outside their town or region.

Pathology laboratories 10186 and 10200 had the largest percentage of participating practices using their pathology services (20.7% each). During the Trial a number of Pathology Providers amalgamated and one closed down.

**Table 30: Participating pathology providers by treatment group and parent company**

Pathology providers		Associated practices					
		Intervention		Control		Total	
Parent company ID	Pathology provider/laboratory ID	N=32	%	N=26	%	N=58	%
10155	10178	2	4.4	0	0.0	2	3.4
	10179	1	2.2	0	0.0	1	1.7
	10180	4	8.9	4	11.1	8	13.8
10156	10181	2	4.4	0	0.0	2	3.4
	10182	3	6.7	0	0.0	3	5.2
	10184	1	2.2	3	8.3	4	6.9
	10185	0	0.0	1	2.8	1	1.7
	10186	5	11.1	7	19.4	12	20.7
10157	10189	4	8.9	1	2.8	5	8.6
10158	10190	1	2.2	0	0.0	1	1.7
10159	10191	1	2.2	2	5.6	3	5.2
10160	10192	4	8.9	2	5.6	6	10.3
10161	10193	3	6.7	3	8.3	6	10.3
	10194	1	2.2	0	0.0	1	1.7
	10196	2	4.4	0	0.0	2	3.4
	10197	1	2.2	0	0.0	1	1.7
	10198	1	2.2	2	5.6	3	5.2
	10231	1	2.2	0	0.0	1	1.7
10162	10220	0	0.0	1	2.8	1	6.9
10163	10199	2	4.4	2	5.6	4	1.7
10164	10200	4	8.9	8	22.2	12	20.7
	10204	2	4.4	0	0.0	2	3.4
	10205	1	2.2	0	0.0	1	1.7

### 3.5. DISCUSSION

Strong interest in PoCT was evident in the large number of participants, both practices and patients, and high retention rates (84.5% and 86.1% respectively). The high retention rate was likely due also to the efforts made by the Trial team to minimise the impact on both practices and patients. Various support strategies known to improve recruitment and compliance<sup>84</sup> were implemented including support provided from local Node Support Officers, a free telephone support line and regular newsletters.

Unfortunately, the Trial was not able to recruit sufficient patients in two of the three conditions to obtain desired power. The Trial Design required the recruitment of practices in three geographic locations – urban, rural and remote. However, the original Trial Design did not consider the possibility that practices in rural or remote locations would not have sufficient patient population to meet the required sample size and hence the amended design allowed practices to be recruited knowing that they could not meet the minimum requirement of patients. In addition the Trial Evaluation team needed to re-calculate the sample sizes as those provided by the Trial Design were incorrectly based on a comparative rather than a non-inferiority study.

A total of 58 practices (32 intervention and 26 control) initially agreed to participate in the Trial. The treatment group imbalance was largely due to the randomisation method applied. The practices were located in urban (30%), rural (30%) and remote (40%) locations across three states in Australia.

During the Trial a small number of practices withdrew and consequently the patients of these practices were lost. The withdrawn practices were from rural and remote areas and cited time constraints and inadequate resources as reasons for not continuing to participate.

A total of 5234 patients (3200 intervention and 2034 control) were initially recruited through the practices. Of the 4968 that were included in the final analysis, 3819 had hyperlipidaemia, 1967 had diabetes and 944 were on anticoagulant therapy (patients could be registered in the Trial with one or more condition).

At the end of the recruitment period, targets were exceeded for hyperlipidaemia, not quite met for diabetes, and fell far short for anticoagulant therapy. This was likely to be related to the severity and scope of the particular condition. The high number of patients recruited with hyperlipidaemia may reflect the high proportion of the population on lipid lowering drugs<sup>46, 85</sup> and the ease of identifying these patients on practice databases. These patients are by-and-large self-managed and at times require little intervention. Although it is known that a high proportion of the population has diabetes target numbers for this condition were not reached. There were multiple reasons why the recruitment of patients on anticoagulant therapy was low. The characteristics of the patients on anticoagulant therapy may make them reluctant to participate in a Trial. For example, patients with this condition tend to be older and the instability of INR may cause them to be hesitant to participate in a Trial that could potentially alter their management process. However, this may only be part of the answer, as the recruitment rate of participating patients was also low for the control group, where there was no change to the patient's usual care. It is likely that the population on anticoagulant therapy may originally have been over-estimated and there were not enough patients within the geographic regions to recruit to the Trial. GPs may also have deterred patients from participating in the Trial due to perceived interference with their management.

A review of other INR studies indicates that recruitment of patients on anticoagulant therapy is difficult. The recently completed study on a community pharmacy-based anticoagulant management service in Sydney<sup>86</sup> was unable to recruit their required 100 patients, which resulted in a change to their trial protocol.

In addition, GPs, Device Operators and practices (usually the Practice Manager) were asked, through the Satisfaction Questionnaire, why they thought recruitment numbers were low for patients with diabetes or on anticoagulant therapy. In both cases, the most cited reason was that patients did not want to participate in the Trial. The next most given reason by practice staff was insufficient patients in the practice with either condition. Interestingly GPs did not rate this as high

and indicated that patients did not want to change their management process for the length of the Trial as an important reason.

GP interest was high with a total of 247 participating in the Trial. Reasons why GPs withdrew from the Trial were mainly due to relocation and practice withdrawal. The low number of rural control GPs may be due to the smaller number of practices in this area and reflect the characteristics of the practices (see Baseline Characteristics section).

Most practices allocated at least two staff members to participate in the Trial and be trained as Device Operators. Device Operator withdrawal was mainly in remote and rural locations and was largely due to practice withdrawal.

### **3.6. CONCLUSION**

Despite target numbers not being reached this was the largest PoCT RCT in general practice. Interest in participating in the Trial was high and excellent retention rates were achieved.

It is estimated that over half of RCTs fail to reach their recruitment numbers. Reasons include poor trial design or over-estimating the potential study population.<sup>84</sup>



## 4. PARTICIPANT BASELINE DESCRIPTION

### SUMMARY OF THE CHAPTER

This chapter provides a description of the baseline characteristics of the four participant groups involved in the PoCT Trial – patients, GPs, Device Operators and Pathology Providers. It also provides a description of the practices recruited to the Trial.

Data was collected through baseline questionnaires to each group, with a high response rate obtained for all groups except Pathology Providers.

The key findings of the chapter are:

- the practices based in rural and remote locations tended to be solo (48%), bulk billed (100%), had smaller patient numbers and an older patient profile
- a higher percentage of urban practices used their computer systems for disease register (82%) and recall systems (100%)
- the characteristics of the GPs in the Trial were similar to those found across the GP workforce. The majority were vocationally registered (89%), with a median number of years in general practice of 16 years, worked between five and nine sessions per week and were male (63%)
- Device Operators were mainly female (93%), with a median age of 45 years and were qualified as nurses
- patients recruited to the Trial tended to be older (75%), male (53%), married (72%), born in Australia (77%) and most had retired (54%)
- the most common co-morbidities for patients (other than the conditions in the Trial) include heart attack (15%), coronary heart disease (15%), and depression or anxiety (14%)
- atrial fibrillation was the most common reason for patients being on anticoagulant therapy (38%)
- the Pathology Providers recruited for the Trial had similar characteristics. They serviced a mixture of private and public patients, provided laboratory and collection services, with technicians and scientists forming the majority of staff.

The key conclusions are:

- on the whole, participants in each treatment group had similar characteristics, although when analysed by geographic location, a number of rural/urban differences were found
- the characteristics and patterns found in the baseline descriptions reflected the GP workforce profile, the practice structure and the GP nursing workforce found in Australian GP. The characteristics of patients reflected the conditions being evaluated.

### 4.1. INTRODUCTION

The Trial had four key groups who participated in various parts of the Trial. These included patients, GPs, Device Operators and Pathology Providers. At their enrolment in the Trial, data was collected that provided a description of the various participant groups and also determined if the characteristics were similar across the treatment groups.

### 4.2. METHODS

To obtain baseline information for the participant groups in the Trial, data was collected through questionnaires. Baseline questionnaires were designed for the following participants in the Trial:

- practices through either the GP or Practice Manager
- General Practitioners
- Device Operators
- Patients
- Pathology Providers associated with the Trial

These questionnaires were designed to cover demographic characteristics of participants, attitudes to pathology testing including PoCT, health service utilisation, costs associated with practice and pathology attendance and information relevant to the management of the Trial. Copies of the questionnaires are provided in Appendix 15.

#### 4.2.1. Baseline pilot

Six practices took part in the pilot of the baseline questionnaires. All were located in South Australia, four in the South East and two on the Yorke Peninsula. Practice personnel and patients were invited to complete the questionnaire and provide feedback regarding any item that was either unclear or confusing, or that could be improved on. The results of the baseline pilot were as follows:

- five practices completed the practice baseline questionnaire and feedback sheet
- six GPs completed the baseline questionnaire and feedback sheet
- five practice nurses completed the Device Operator baseline questionnaire and feedback sheet and
- eight patients with diabetes, hyperlipidaemia or cardiovascular disease requiring anticoagulant therapy completed the patient baseline questionnaire and feedback sheet.

Members of the Trial Management Committee were also invited to provide feedback regarding the questionnaire and any modifications were made prior to mail out.

The questionnaires were also approved by the University of Adelaide Human Research Ethics Committee, Department of Health and Ageing Departmental Ethics Committee, the RACGP Ethics Committee, and the University of Sydney and Monash University Ethics Committees.

The baseline questionnaires were disseminated to participants upon their recruitment to the Trial and receipt of consent documentation.

#### 4.2.2. Response rate

The response rates for each group of questionnaires are outlined in Table 31. The response rate was calculated on all participants who were sent the questionnaire and excludes participants who withdrew or died prior to dissemination of the baseline questionnaire. A total of 23 Pathology Provider/laboratories representing 10 parent companies were associated with the Trial. The Pathology Provider baseline questionnaire was sent to 25 pathology organisations deemed to be representative of the total involved.

An overall response rate of 93.89% was achieved. The lowest response rate was from Pathology Providers, followed by General Practitioners.

**Table 31: Response rate for baseline questionnaires**

Participant Group	No. of questionnaires disseminated	No. of questionnaires received	Response rate based on no. of questionnaires disseminated (%)
Practices	53	53	100.00
General Practitioners*	241	221	91.70
Device Operators	78	76	97.44
Patients (excludes ineligible)	5055	4755	94.07
Pathology Providers	25	14	56.00
Total	5452	5119	93.89

\*Excludes 6 GPs from practices that withdrew prior to the questionnaire being sent. Five GPs were employed in two Trial practices and have each been counted twice in this table.

The response rates were achieved by using the following strategy, based on Dillman<sup>87</sup>:

- initial mail out to all participant groups with baseline questionnaire
- follow-up reminder using a flyer to all participants
- final reminder to participants with a copy of the questionnaire

Node Support Officers were used to follow-up outstanding practice, GP and Device Operator questionnaires.

### **4.3. RESULTS**

The following sections report the baseline characteristics of the five groups of participants. The data is presented by treatment group and geographic area. Additional results are provided in the appendices. The patient results described below refer to those patients who were eligible to participate in the Trial and therefore the total numbers differ from the number who received the baseline questionnaire.

#### **4.3.1. Practices**

The following tables provide a description of the practices participating in the Trial including: key characteristics, practice size, Information Technology (IT) characteristics, patient register/recall use and pathology arrangements at commencement of the Trial. Details on the number of practices recruited are provided in Section 3.4.1 and are not repeated here.

##### *4.3.1.1. Practice characteristics*

A summary of the key characteristics of practices is provided in Table 32 and Table 33. The most common practice structures were partnerships (32.1%) or solo practices (28.3%) and this pattern was similar across treatment groups (Table 32). Nearly half of the practices based in a remote location were solo (47.6%), while partnerships were the most common structure in urban locations (58.8%) (Table 33). Nearly all the practices were managed by a non-GP manager and this was the same across treatment group (Table 32) and geographic location (Table 33)).

Over 90% of practices in both control and intervention groups bulk billed (Table 32), although a smaller percentage of practices in rural areas bulk billed (85.7%) (Table 33). Practices reported a range of circumstances in which they bulk-billed, with 64.2% bulk-billing at professional discretion, 54.7% bulk-billing pensioners and 45.3% bulk-billing Health Care Card holders. Only 22.6% of practices bulk-billed all patients. The percentage of practices bulk-billing all patients was higher in the intervention group (26.7%) compared to the control group (17.4%), while a higher percentage of practices in this treatment group bulk-billed pensioners (60.9%) and Health Care Card holders (52.2%).

Practices located in a remote area were more likely to bulk-bill all patients (42.9%) compared to practices in rural (20.0%) and urban areas (0%) (Table 33). However, a higher percentage of practices located in urban areas were more likely to bulk-bill Health Care Card holders, pensioners, patients requiring long-term care, children, and at professional discretion, than practices located in rural or remote areas (Table 33).

**Table 32: Key characteristics of practices in the PoCT Trial by treatment group**

Practice characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=23	N=30	N=53
Practice structure	Associateship	4 (17.4)	5 (16.7)	9 (17.0)
	Corporate	1 (4.3)	1 (3.3)	2 (3.8)
	Other	3 (13.0)	5 (16.7)	8 (15.1)
	Partnership	9 (39.1)	8 (26.7)	17 (32.1)
	Solo	5 (21.7)	10 (33.3)	15 (28.3)
	Missing	1 (4.3)	1 (3.3)	2 (3.8)
Non GP Practice Manager	Yes	19 (82.6)	27 (90.0)	46 (86.8)
	No	4 (17.4)	3 (10.0)	7 (13.2)
Bulk-billing practice	Yes	21 (91.3)	29 (96.7)	50 (94.3)
	No	2 (8.7)	1 (3.3)	3 (5.7)
Type of billing* (only includes practices that bulk-billed)	All patients	4 (17.4)	8 (26.7)	12 (22.6)
	Health Care Card holders	12 (52.2)	12 (40.0)	24 (45.3)
	Pensioners	14 (60.9)	15 (50.0)	29 (54.7)
	Patient requiring long-term care	6 (26.1)	8 (26.7)	14 (26.4)
	Professional discretion	16 (69.6)	18 (60.0)	34 (64.2)
	Children under 16 years	9 (39.1)	13 (43.3)	22 (41.5)
	Other	2 (8.7)	3 (10.0)	5 (9.4)
Accredited practice	Yes	22 (95.7)	27 (90.0)	49 (92.5)
	In the process	1 (4.3)	3 (10.0)	4 (7.5)

\*Multiple responses

A total of 49 practices (92.5%) were RACGP accredited, with the remaining 4 practices (7.5%) in the process of being accredited. All practices in urban locations were accredited, while 85.7% of remote practices were not accredited and consequently formed the larger percentage of practices in the process of being accredited (14.3%) (Table 33).

**Table 33: Key practice characteristics by geographic location**

Practice size characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=17	N=15	N=21	N=53
Practice structure	Associateship	1 (5.9)	4 (26.7)	4 (19.0)	9 (17.0)
	Corporate	0 (0.0)	0 (0.0)	2 (9.5)	2 (3.8)
	Other	5 (29.4)	1 (6.7)	2 (9.5)	8 (15.1)
	Partnership	10 (58.8)	5 (33.3)	2 (9.5)	17 (32.1)
	Solo	1 (5.9)	4 (26.7)	10 (47.6)	15 (28.3)
	Missing	0 (0.0)	1 (6.7)	1 (4.8)	2 (3.8)
Non GP Practice Manager	Yes	14 (82.4)	14 (93.3)	18 (85.7)	46 (86.8)
	No	3 (17.6)	1 (6.7)	3 (14.3)	7 (13.2)
Bulk-billing practice	Yes	16 (94.1)	13 (86.7)	21 (100)	50 (94.3)
	No	1 (5.9)	2 (13.3)	0 (0.0)	3 (5.7)
Type of billing* (only includes practices that bulk-billed)	All patients	0 (0.0)	3 (20.0)	9 (42.9)	12 (22.6)
	Health Care Card holders	11 (64.7)	4 (26.7)	9 (42.9)	24 (45.3)
	Pensioners	11 (64.7)	7 (46.7)	11 (52.4)	29 (54.7)
	Patient requiring long-term care	7 (41.2)	2 (13.3)	5 (23.8)	14 (26.4)
	Professional discretion	13 (76.5)	10 (66.7)	11 (52.4)	34 (64.2)
	Children under 16 years	10 (58.8)	4 (26.7)	8 (38.1)	22 (41.5)
	Other	2 (11.8)	1 (6.7)	2 (9.5)	5 (9.4)
Accredited practice	Yes	17 (100)	14 (93.3)	18 (85.7)	49 (92.5)
	In the process	0 (0.0)	1 (6.7)	3 (14.3)	4 (7.5)

\*Multiple responses

#### 4.3.1.2. Practice size and patient profile

Nearly two-thirds of practices had a patient list size greater than 5000 patients and this was similar across the treatment groups (Table 34). When viewed in terms of geographic location, more differences in the size of the patient list were found. A lower percentage of practices in rural (60.0%) and remote (47.6%) locations had patient list sizes of greater than 5000 compared to urban practices (82.4%) (Table 34). Practices in the Trial had a larger percentage of female patients (53.5%) and this pattern was the same by treatment group (Table 34) and geographic location (Table 35). The percentage of patients by age was similar for both the control and intervention groups. A larger percentage of practices had patients aged 40 years or below (Table 34).

Most practices in the study had between 1-3 full-time equivalent (FTE) GPs working in the practice, with 39.7% of practices having more than 3 FTE GPs. A larger percentage of practices in the intervention had 1-3 FTE GPs and >5 FTE GPs, but there were fewer medium size practices (3-5 FTE GPs) in the intervention group (16.7% versus 21.7%) (Table 34). The majority of practices employed more than 5 FTE staff (37.7%), although there were differences between the treatment groups. A larger percentage of control practices (43.5%) compared to intervention practices (33.3%) employed more than 5 FTE staff (Table 34).

**Table 34: Practice size and patient profile by treatment group**

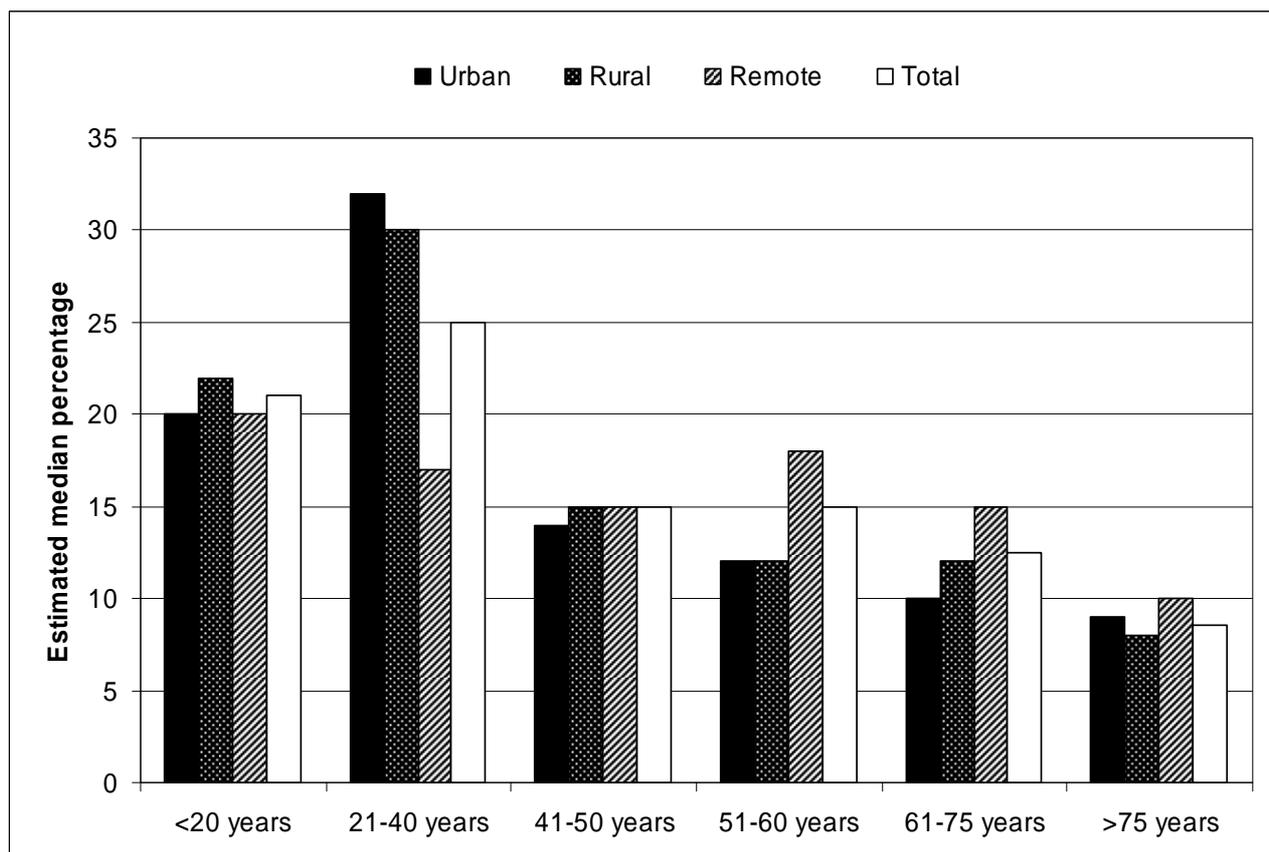
Practice characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=23	N=30	N=53
Number of patients	501 – 1000	1 (4.3)	1 (3.3)	2 (3.8)
	1001-2000	2 (8.7)	4 (13.3)	6 (11.3)
	2001-3000	1 (4.3)	3 (10.0)	4 (7.5)
	3001-4000	1 (4.3)	1 (3.3)	2 (3.8)
	4001-5000	3 (13.0)	3 (10.0)	6 (11.3)
	>=5001	15 (65.2)	18 (60.0)	33 (62.3)
Estimated percentage of patients – median (IQ range)	Male	44.0 (40.0-50.0)	47.0 (43.0-50.0)	46.5 (40.0-50.0)
	Female	56.0 (50.0-60.0)	53.0 (50.0-57.0)	53.5 (50.0-60.0)
	<20 years	20.0 (15.0-22.0)	22.5 (20.0-26.0)	21.0 (15.0-26.0)
	21-40 years	25.0 (20.0-32.0)	24.5 (18.0-30.0)	25.0 (18.0-31.0)
	41-50 years	15.0 (14.0-20.0)	15.0 (13.0-17.0)	15.0 (13.0-18.0)
	51-60 years	15.0 (11.0-20.0)	14.0 (12.0-18.0)	15.0 (12.0-20.0)
	61-75 years	12.0 (9.0-17.0)	13.0 (11.0-15.0)	12.5 (10.0-15.0)
	>75 years	6.0 (3.0-10.0)	10.0 (7.0-14.0)	8.5 (5.0-12.0)
Number of FTE GPs	>0-1 GPs	2 (8.7)	3 (10.0)	5 (9.4)
	>1-3 GPs	10 (43.5)	15 (50.0)	25 (47.2)
	>3-5 GPs	5 (21.7)	5 (16.7)	10 (18.9)
	>5 GPs	4 (17.4)	7 (23.3)	11 (20.8)
	Missing	2 (8.7)	0 (0.0)	2 (3.8)
Other staff	>0-1 staff	0 (0.0)	1 (3.3)	1 (1.9)
	>1-3 staff	8 (34.8)	10 (33.3)	18 (34.0)
	>3-5 staff	5 (21.7)	9 (30.0)	14 (26.4)
	>5 staff	10 (43.5)	10 (33.3)	20 (37.7)

**Table 35: Practice size and patient profile by geographic location**

Practice size and characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=17	N=15	N=21	N=53
Number of patients	501 – 1000	0 (0.0)	0 (0.0)	2 (9.5)	2 (3.8)
	1001-2000	1 (5.9)	1 (6.7)	4 (19.0)	6 (11.3)
	2001-3000	0 (0.0)	3 (20.0)	1 (4.8)	4 (7.5)
	3001-4000	0 (0.0)	0 (0.0)	2 (9.5)	2 (3.8)
	4001-5000	2 (11.8)	2 (13.3)	2 (9.5)	6 (11.3)
	>=5001	14 (82.4)	9 (60.0)	10 (47.6)	33 (62.3)
Estimated percentage of patients – median (IQ range)	Male	45.0 (40.0-48.0)	47.0 (42.0-50.0)	49.0 (40.0-50.0)	46.5 (40.0-50.0)
	Female	55.0 (52.0-60.0)	53.0 (50.0-58.0)	51.0 (50.0-60.0)	53.5 (50.0-60.0)
	<20 years	20.0 (18.0-24.0)	22.0 (20.0-26.0)	20.0 (15.0-28.0)	21.0 (15.0-26.0)
	21-40 years	32.0 (25.0-35.0)	30.0 (28.0-30.0)	17.0 (13.0-23.0)	25.0 (18.0-31.0)
	41-50 years	14.0 (13.0-17.0)	15.0 (15.0-18.0)	15.0 (13.0-20.0)	15.0 (13.0-18.0)
	51-60 years	12.0 (11.0-16.0)	12.0 (12.0-13.0)	18.0 (14.0-20.0)	15.0 (12.0-20.0)
	61-75 years	10.0 (7.0-15.0)	12.0 (9.0-12.0)	15.0 (12.0-20.0)	12.5 (10.0-15.0)
	>75 years	9.0 (5.0-11.0)	8.0 (5.0-9.0)	10.0 (5.0-15.0)	8.5 (5.0-12.0)
Number of FTE GPs	>0-1 GPs	0 (0.0)	2 (13.3)	3 (14.3)	5 (9.4)
	>1-3 GPs	5 (29.4)	7 (46.7)	13 (61.9)	25 (47.2)
	>3-5 GPs	7 (41.2)	1 (6.7)	2 (9.5)	10 (18.9)
	>5 GPs	4 (23.5)	5 (33.3)	2 (9.5)	11 (20.8)
	Missing	1 (5.9)	0 (0.0)	1 (4.8)	2 (3.8)
Other staff	>0-1 staff	0 (0.0)	0 (0.0)	1 (4.8)	1 (1.9)
	>1-3 staff	3 (17.6)	5 (33.3)	10 (47.6)	18 (34.0)
	>3-5 staff	8 (47.1)	3 (20.0)	3 (14.3)	14 (26.4)
	>5 staff	6 (35.3)	7 (46.7)	7 (33.3)	20 (37.7)

Practices located in urban and rural areas had a higher percentage of patients aged 21 to 40 years compared to practices in remote areas (Table 36 and Figure 6). In contrast remote practices had a higher proportion of patients aged 51 years and over (Table 36 and Figure 6). Practices in the remote areas were more likely to have between 1-3 FTE GPs working in the practices, in urban and rural areas, practices of >5 FTE GPs were more common. Rural and remote areas also had a larger percentage of solo practices, while the majority of urban practices consisted of 3-5 FTE GPs. The number of staff employed by the practice varied with geographic area. Nearly half of practices (47.6%) located in remote areas had between 1-3 other staff, while 47.1% of urban practices had between 3-5 staff in the practice and 46.7% of rural practices employed more than 5 staff.

**Figure 6: Estimated median percentage of practice patients by age group and geographic location**



#### 4.3.1.3. IT Characteristics

The most common software used by practices in the Trial was Medical Director (83.0%) and this was the same across treatment groups and geographic location (Table 36 and Table 37).

All practices reported using computers in their daily consulting. The most common functions for the computer were generation of scripts (100%), for clinical notes (94.3%), billing (96.2%), electronic receipt of pathology results (90.6%) and disease recall systems (81.1%) (Table 36). Practices in the intervention group were more likely to use their computers for disease registers (73.3%), disease recall systems (83.3%), emailing (60.0%) and printing of pathology results (96.7%) than control practices (Table 36).

Practices located in urban areas were more likely to use their computers for disease registers (82.4%) and disease recall systems (100%) than practices located in remote or rural areas (Table 37).

**Table 36: IT characteristics of practices by treatment group**

IT characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=23	N=30	N=53
Practice software	Genie	1 (4.3)	1 (3.3)	2 (3.8)
	MedTech 32	2 (8.7)	2 (6.7)	4 (7.5)
	Medical Director	19 (82.6)	25 (83.3)	44 (83.0)
	Medical Spectrum	0 (0.0)	2 (6.7)	2 (3.8)
	Plexus	1 (4.3)	0 (0.0)	1 (1.9)
Use of computer (yes response)	Generate scripts	23 (100)	30 (100)	53 (100)
	Clinical notes	22 (95.7)	28 (93.3)	50 (94.3)
	Disease registers	15 (65.2)	22 (73.3)	37 (69.8)
	Disease recall system	18 (78.3)	25 (83.3)	43 (81.1)
	Email pathology requests	11 (47.8)	18 (60.0)	29 (54.7)
	Print pathology requests	20 (87.0)	29 (96.7)	49 (92.5)
	Receive pathology results	20 (87.0)	28 (93.3)	48 (90.6)
	Billing	22 (95.7)	29 (96.7)	51 (96.2)

**Table 37: IT characteristics by geographic location**

IT characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=17	N=15	N=21	N=53
Practice software	Genie	0 (0.0)	1 (6.7)	1 (4.8)	2 (3.8)
	MedTech 32	2 (11.8)	2 (13.3)	0 (0.0)	4 (7.5)
	Medical Director	15 (88.2)	12 (80.0)	17 (81.0)	44 (83.0)
	Medical Spectrum	0 (0.0)	0 (0.0)	2 (9.5)	2 (3.8)
	Plexus	0 (0.0)	0 (0.0)	1 (4.8)	1 (1.9)
Use of computer (yes response)	Generate scripts	17 (100)	15 (100)	21 (100)	53 (100)
	Clinical notes	16 (94.1)	15 (100)	19 (90.5)	50 (94.3)
	Disease registers	14 (82.4)	10 (66.7)	13 (61.9)	37 (69.8)
	Disease recall system	17 (100)	11 (73.3)	15 (71.4)	43 (81.1)
	Email pathology requests	9 (52.9)	8 (53.3)	12 (57.1)	29 (54.7)
	Print pathology requests	16 (94.1)	15 (100)	18 (85.7)	49 (92.5)
	Receive pathology results	16 (94.1)	13 (86.7)	19 (90.5)	48 (90.6)
	Billing	17 (100)	15 (100)	19 (90.5)	51 (96.2)

#### 4.3.1.4. Practice recall and patient register systems

A total of 92.5% of practices used a patient register or recall system and this was similar for both control and intervention practices (Table 38). All urban practices used a patient register or recall system, but only 86.7% of rural practices and 90.5% of remote practices used these systems ().

Of practices that used patient register/recall systems, these were most often used for patients with diabetes (84.9%). Less than half the practices used register/recall systems for patients requiring anticoagulant therapy or for patients with cardiovascular disease (Table 38). Differences were found in the percentage of practices using patient register/recall systems for specific patient groups. A larger percentage of urban practices used their systems for patients with diabetes

(94.1%) compared to practices in rural (86.7%) or remote (76.2%) locations (). Remote practices were less likely than urban or rural practices to use register/recall systems for patients with cardiovascular disease.

Less than half the practices held clinics specifically for diabetes patients (45.3%), while only 7.5% of practices ran clinics for anticoagulant therapy and 5.7% for patients with hyperlipidaemia; however, practices in the intervention group were more likely to have clinics for these groups of patients (Table 38). A larger percentage of remote practices ran diabetes clinics (52.4%) compared to urban (41.2%) or remote (40%) practices.

**Table 38: Patient register/recall systems and clinics used in practices by treatment group**

Patient register and recall systems		Treatment group (%)		
		Control	Intervention	Total
		N=23	N=30	N=53
Use a patient register or recall system	Yes	21 (91.3)	28 (93.3)	49 (92.5)
	No	1 (4.3)	2 (6.7)	3 (5.7)
	Missing	1 (4.3)	0 (0.0)	1 (1.9)
Use of system for patient groups (yes response)	Patients with diabetes	21 (91.3)	24 (80.0)	45 (84.9)
	Patients requiring anticoagulant therapy	11 (47.8)	11 (36.7)	22 (41.5)
	Patients with hyperlipidaemia	11 (47.8)	12 (40.0)	23 (43.4)
Clinics in practice	Diabetes	7 (30.4)	17 (56.7)	24 (45.3)
	Anticoagulant therapy	1 (4.3)	3 (10.0)	4 (7.5)
	Hyperlipidaemia	0 (0.0)	3 (10.0)	3 (5.7)

**Table 39: Patient register/recall systems and clinics used in practices by geographic area**

Patient register and recall systems		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=17	N=15	N=231	N=53
Use a patient register or recall system	Yes	17 (100)	13 (86.7)	19 (90.5)	49 (92.5)
	No	0 (0.0)	1 (6.7)	2 (9.5)	3 (5.7)
	Missing	0 (0.0)	1 (6.7)	0 (0.0)	1 (1.9)
Use of system for patient groups (yes response)	Patients with diabetes	16 (94.1)	13 (86.7)	16 (76.2)	45 (84.9)
	Patients requiring anticoagulant therapy	8 (47.1)	6 (40.0)	8 (38.1)	22 (41.5)
	Patients with cardiovascular disease	9 (52.9)	8 (53.3)	9 (42.9)	26 (49.1)
Clinics in practice	Diabetes	7 (41.2)	6 (40.0)	11 (52.4)	24 (45.3)
	Anticoagulant therapy	0 (0.0)	2 (13.3)	2 (9.5)	4 (7.5)
	Hyperlipidaemia	1 (5.9)	0 (0.0)	2 (9.5)	3 (5.7)

#### 4.3.1.5. Practice pathology arrangements

Overall, 79.2% of practices in the Trial used more than one Pathology Provider (Table 40). A larger percentage of intervention practices had only one provider (33.3%). The use of multiple Pathology Providers was related to distance from metropolitan areas (Table 41). A larger percentage of urban practices used multiple providers, while remote practices were more likely to have only one Pathology Provider. Unsurprisingly, distance to the nearest Pathology Provider was greatest for

practices in remote areas (mean distance of 57.5 km) (Table 41). Practices based in rural areas had on average the shortest distance to a pathology laboratory (Table 41).

At the commencement of the Trial, 77.4% of practices performed venepuncture at their practice (Table 40), with control practices more likely to perform venepuncture (87.0%) than practices in the intervention group (70.0%). All the urban practices and 76.2% of remote practices undertook venepuncture (Table 41). Of the practices that performed their own venepuncture, the majority used a courier service to transport the blood to a pathology laboratory (69.8%) (Table 40). Practices in the control group also used a private vehicle to transport blood (Table 40).

A small percentage of practices had used a PoCT device in the past (15.1%), with a larger percentage of the intervention practices having used a PoCT device (Table 40), particularly those practices located in a remote area (28.6%). These devices were mainly used for patients with diabetes and for INR testing (Table 40).

**Table 40: Practice pathology arrangements prior to Trial commencement by treatment group**

Pathology arrangements		Treatment Group (%)		
		Control	Intervention	Total
		N=23	N=30	N=53
Venepuncture performed at the practice	Yes	20 (87.0)	21 (70.0)	41 (77.4)
	No	3 (13.0)	9 (30.0)	12 (22.6)
Method of transporting blood to pathology laboratory**	Private vehicle	0 (0.0)	3 (10.0)	3 (5.7)
	Courier service	20 (87.0)	17 (56.7)	37 (69.8)
	Aeroplane	0 (0.0)	1 (3.3)	1 (1.9)
Use multiple pathology laboratories	Yes	22 (95.7)	20 (66.7)	42 (79.2)
	No	1 (4.3)	10 (33.3)	11 (20.8)
Distance from practice to pathology laboratory - median (IQ range)		14.0 (5.0-31.0)	5.0 (1.0-65.0)	12.0 (1.0-50.0)
Used a PoCT device in the past	Yes	3 (13.0)	5 (16.7)	8 (15.1)
Area of use of PoCT device	Diabetes	2 (8.7)	5 (16.7)	7 (13.2)
	INR	2 (8.7)	4 (13.3)	6 (11.3)
	Cholesterol	0 (0.0)	3 (10.0)	3 (5.7)
	Other	1 (4.3)	1 (3.3)	2 (3.8)

\*Multiple responses

+ Only for practices which performed venepuncture

**Table 41: Practice pathology arrangements prior to Trial commencement by geographic location**

Pathology arrangements		Geographic location (%)*			
		Urban	Rural	Remote	Total
		N=17	N=15	N=21	N=53
Venepuncture performed at the practice	Yes	17 (100)	8 (53.3)	16 (76.2)	41 (77.4)
	No	0 (0.0)	7 (46.7)	5 (23.8)	12 (22.6)
Method of transporting blood to pathology laboratory**	Private vehicle	2 (11.8)	0 (0.0)	1 (4.8)	3 (5.7)
	Courier service	15 (88.2)	8 (53.3)	14 (66.7)	37 (69.8)
	Aeroplane	0 (0.0)	0 (0.0)	1 (4.8)	1 (1.9)
Use multiple pathology laboratories	Yes	17 (100)	13 (86.7)	12 (57.1)	42 (79.2)
	No	0 (0.0)	2 (13.3)	9 (42.9)	11 (20.8)
Distance from practice to pathology laboratory - median (IQ range)		12.0 (5.0-15.0)	3.3 (0.5-6.0)	57.5 (1.0-100.0)	12.0 (1.0-50.0)
Used a PoCT device in the past	Yes	1 (5.9)	1 (6.7)	6 (28.6)	8 (15.1)
Area of use of PoCT device	Diabetes	1 (5.9)	1 (6.7)	5 (23.8)	7 (13.2)
	INR	1 (5.9)	1 (6.7)	4 (19.0)	6 (11.3)
	Cholesterol	1 (5.9)	0 (0.0)	2 (9.5)	3 (5.7)
	Other	0 (0.0)	0 (0.0)	2 (9.5)	2 (3.8)

\*Multiple responses

+ Only for practices which performed venepuncture

#### 4.3.2. General Practitioners

The characteristics of the GPs recruited for the Trial are summarised in Table 42. A larger percentage of GPs in the Trial were male (62.9%) and this was consistent across both treatment groups and geographic regions, although the percentage of males increased in the rural areas. The median age of GPs at commencement of the Trial was 45.5 years, ranging from 37 to 53 years. This was similar across treatment groups and geographic location. Over a quarter of the GPs were trained overseas, with a larger percentage found in the intervention group (Table 42) and in rural and remote locations (Table 43). The majority of GPs were vocationally registered (VR) (89.1%), with the largest percentage of VR GPs being in urban practices (98.0%) and in the intervention group (94.2%) (see Table 42 and). The median number of years in practice was 16.0 which was similar for both treatment groups and across geographic locations. GPs located in remote

practices (median 6.5 years) or in intervention practices (median 5 years) had spent the least number of years in their current practice. A greater percentage of GPs in rural or remote areas saw a larger number of patients per week than GPs in urban areas (Table 43).

**Table 42: GP characteristics by treatment group**

GP characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=86	N=135	N=221
Gender	Male	48 (55.8)	91 (67.4)	139 (62.9)
	Female	38 (44.2)	44 (32.6)	82 (37.1)
Age years - median (IQ range)		47.0 (39.0-54.0)	44.0 (37.0-53.0)	45.5 (37.0-53.0)
Sessions per week	1-4	22 (25.6)	22 (16.3)	44 (19.9)
	5-9	50 (58.1)	72 (53.3)	122 (55.2)
	10 or more	12 (14.0)	30 (22.2)	42 (19.0)
	Missing	2 (2.3)	11 (8.1)	13 (5.9)
Work in other practice	Yes	18 (20.9)	35 (25.9)	53 (24.0)
	No	68 (79.1)	100 (74.1)	168 (76.0)
Qualifications	FRACGP	41 (47.7)	57 (42.2)	98 (44.3)
	FACRRM	7 (8.1)	25 (18.5)	32 (14.5)
Overseas trained doctor	Yes	17 (19.8)	42 (31.1)	59 (26.7)
	No	69 (80.2)	92 (68.1)	161 (72.9)
	Missing	0 (0.0)	1 (0.7)	1 (0.5)
Vocationally registered	Yes	81 (94.2)	116 (85.9)	197 (89.1)
	No	5 (5.8)	17 (12.6)	22 (10.0)
	Missing	0 (0.0)	2 (1.5)	2 (0.9)
Number of years working in general practice - median (IQ range)		17.5 (10.0-25.0)	15.0 (6.0-23.0)	16.0 (8.0-24.0)
Number of years in current practice - median (IQ range)		9.5 (6.0-17.0)	5.0 (2.0-15.5)	8.0 (3.0-17.0)
Number of patients seen per week	<80	30 (34.9)	35 (25.9)	65 (29.4)
	80-120	18 (20.9)	38 (28.1)	56 (25.3)
	121-150	16 (18.6)	31 (23.0)	47 (21.3)
	>150	18 (20.9)	24 (17.8)	42 (19.0)
	Missing	4 (4.7)	7 (5.2)	11 (5.0)

Note: Five GPs were employed in two study practices and have each been counted twice in this table

**Table 43: GP characteristics by geographic location**

GP characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=98	N=68	N=55	N=221
Gender	Male	51 (52.0)	47 (69.1)	41 (74.5)	139 (62.9)
	Female	47 (48.0)	21 (30.9)	14 (25.5)	82 (37.1)
Age years - median (IQ range)		47.0 (37.0-55.0)	44.0 (36.0-52.0)	46.0 (36.0-51.0)	45.5 (37.0-53.0)
Sessions per week	1-4	25 (25.5)	13 (19.1)	6 (10.9)	44 (19.9)
	5-9	57 (58.2)	32 (47.1)	33 (60.0)	122 (55.2)
	10 or more	14 (14.3)	18 (26.5)	10 (18.2)	42 (19.0)
	Missing	2 (2.0)	5 (7.4)	6 (10.9)	13 (5.9)
Work in other practice	Yes	17 (17.3)	23 (33.8)	13 (23.6)	53 (24.0)
	No	81 (82.7)	45 (66.2)	42 (76.4)	168 (76.0)
Qualifications	FRACGP	47 (48.0)	27 (39.7)	24 (43.6)	98 (44.3)
	FACRRM	2 (2.0)	18 (26.5)	12 (21.8)	32 (14.5)
Overseas trained doctor	Yes	12 (12.2)	26 (38.2)	21 (38.2)	59 (26.7)
	No	86 (87.8)	42 (61.8)	33 (60.0)	161 (72.9)
	Missing	0 (0.0)	0 (0.0)	1 (1.8)	1 (0.5)
Vocationally registered	Yes	96 (98.0)	57 (83.8)	44 (80.0)	197 (89.1)
	No	2 (2.0)	10 (14.7)	10 (18.2)	22 (10.0)
	Missing	0 (0.0)	1 (1.5)	1 (1.8)	2 (0.9)
Number of years working in general practice - median (IQ range)		18.0 (10.0-25.0)	15.0 (8.0-25.0)	15.0 (6.0-20.0)	16.0 (8.0-24.0)
Number of years in current practice - median (IQ range)		9.5 (4.5-18.5)	8.0 (2.0-17.0)	6.5 (2.0-12.0)	8.0 (3.0-17.0)
Number of patients seen per week	<80	39 (39.8)	15 (22.1)	11 (20.0)	65 (29.4)
	80-120	23 (23.5)	14 (20.6)	19 (34.5)	56 (25.3)
	121-150	19 (19.4)	18 (26.5)	10 (18.2)	47 (21.3)
	>150	13 (13.3)	15 (22.1)	14 (25.5)	42 (19.0)
	Missing	4 (4.1)	6 (8.8)	1 (1.8)	11 (5.0)

Note: Five GPs were employed in two study practices and have each been counted twice in this table

### 4.3.3. Device Operators

Each intervention practice was required to identify a Device Operator or operators, who would be trained in the use of the PoCT devices and undertake PoCT in the practice. These Device Operators could be a GP, practice nurse or administrative person.

A total of 80 Device Operators were trained and certified as being competent in the use of the three PoCT devices (79 were involved at the commencement of the Trial), although 18 Device Operators left during the course of the Trial, leaving 61 Device Operators.

A summary of the baseline characteristics of the Device Operator is shown in Table 44. The majority of Device Operators were female (92.1%) and were fairly equally distributed across the three geographic regions. More than half the practices had more than one Device Operator in their practice (93.4%) and their median age was 45.0 years (Table 44). Most of the Device Operators worked full time (five sessions or more each week), although a quarter of Device Operators in rural and remote practices worked only 1-2 sessions per week.

Most Device Operators were either registered nurses (57.9%) or enrolled nurses (17.1%). Whilst several GPs were trained as Device Operators, none took on this role in the practice. The Device Operators' median number of years working was 13.0, although the median number of years Device Operators worked in remote practices was much less (9.0 years) compared to those based in urban or rural practices (Table 44). On average, the Device Operators had only been in their current practice for a median of 3 years, although those in urban practices had been with their current practice longer (6.8 years) than those based in rural or remote practices.

At commencement of the Trial many Device Operators had been involved in clinics within the practice, with the most common being diabetes clinics (44.7%). A greater percentage of Device Operators in remote practices were involved in diabetes (56.3%) and anticoagulant therapy clinics (43.8%) than Device Operators in rural or urban practices (Table 44). This suggests that Device Operators in remote practices take on a number of tasks.

**Table 44: Summary of baseline characteristics of device operators (intervention practices only)**

Device operator characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=18	N=26	N=32	N=76
Gender	Male	1 (5.6)	1 (3.8)	3 (9.4)	5 (6.6)
	Female	17 (94.4)	25 (96.2)	29 (90.6)	71 (93.4)
Age years - median (IQ range)		47.5 (44.0-53.0)	43.0 (35.0-49.0)	43.0 (33.0-51.0)	45.0 (37.0-51.0)
Sessions per week	1-2	2 (11.1)	7 (26.9)	8 (25.0)	17 (22.4)
	3-4	1 (5.6)	5 (19.2)	2 (6.3)	8 (10.5)
	5 or more	9 (50.0)	10 (38.5)	12 (37.5)	31 (40.8)
	Missing	6 (33.3)	4 (15.4)	10 (31.3)	20 (26.3)
Qualification	Registered nurse	13 (72.2)	21 (80.8)	10 (31.3)	44 (57.9)
	Enrolled nurse	1 (5.6)	1 (3.8)	11 (34.4)	13 (17.1)
	Administrative staff	3 (16.7)	2 (7.7)	2 (6.3)	7 (9.2)
	Other	1 (5.6)	2 (7.7)	9 (28.1)	12 (15.8)
Number of years working - median (IQ range)		13.5 (6.0-20.0)	14.0 (9.0-23.0)	9.0 (3.0-21.0)	13.0 (5.8-21.5)
Number of years in current position – median (IQ range)		6.8 (1.5-10.0)	3.0 (1.5-7.0)	3.0 (0.8-5.5)	3.0 (1.0-8.0)
Involvement in clinics (yes response)	Diabetes clinic	6 (33.3)	10 (38.5)	18 (56.3)	34 (44.7)
	Anticoagulant therapy clinic	2 (11.1)	4 (15.4)	14 (43.8)	20 (26.3)
	Cholesterol lowering clinics	1 (5.6)	5 (19.2)	12 (37.5)	18 (23.7)

#### 4.3.4. Patients

The baseline information on participating patients is grouped into demographic characteristics and clinical characteristics. The baseline characteristics of patients by condition and geographic location are shown in Appendix 16.

##### 4.3.4.1. Demographic characteristics

A summary of key patient demographics by control and intervention group is provided in Table 45 and Table 46.

At baseline there were slightly more males (52.9%) than females (47.1%) participating in the Trial (Table 45) which was similar for both arms of the Trial. The mean age of patients at baseline was 67.0 years with 74.7% of patients aged 60 years or more. This was similar for both arms of the Trial and across geographic regions, although a slightly larger percentage of patients in urban locations were more likely to be aged over 60 years (Table 46).

The majority of patients were married or in a de facto relationship (72.3%) which was the same for patients in both the intervention and control groups (Table 45) and across geographic locations (Table 46). Less than a quarter of patients were the only adult living in the house which was the same across treatment groups (Table 45) and geographic location (Table 46). Three quarters of the patients were born in Australia (77.3%). A higher percentage of patients in rural (78.7%) and remote (89.4%) areas and in the intervention group (80.3%) were born in Australia. Only 1.0% of participants were of Aboriginal and Torres Strait Islander descent, with a slightly larger percentage in the intervention group (1.2%) and located in a remote area (1.8%).

In terms of qualifications, nearly two thirds of the patients had up to secondary education and this was similar across the treatment arms and geographic locations (Table 45 and Table 46). More than half the patients in the Trial were retired (54.4%), with a quarter being in some type of employment. A slightly larger percentage of remote patients were employed (31.2%) compared with patients in rural (22.8%) or urban (22.1%) areas.

The most common type of government support for patients in the Trial was pensions (60.6%) and Health Care Cards (31.1%). This pattern was similar across treatment groups and geographic locations (Table 45 and Table 46).

**Table 45: Summary of baseline patient demographic characteristics by treatment group**

Demographic characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=180	N=2827	N=4707
Gender	Male	978 (52.0)	1514 (53.6)	2492 (52.9)
	Female	902 (48.0)	1313 (46.4)	2215 (47.1)
Age group (years)	18-39	19 (1.0)	43 (1.5)	62 (1.3)
	40-49	103 (5.5)	175 (6.2)	278 (5.9)
	50-59	316 (16.8)	537 (19.0)	853 (18.1)
	60-69	586 (31.2)	975 (34.5)	1561 (33.2)
	70-79	657 (34.9)	814 (28.8)	1471 (31.3)
	80+	199 (10.6)	283 (10.0)	482 (10.2)
Age (years): median (IQ range)		68.0 (60.0-75.0)	66.0 (59.0-74.0)	67.0 (59.0-75.0)
Marital status	Married/de facto	1364 (72.6)	2040 (72.2)	3404 (72.3)
	Divorced/separated	188 (10.0)	247 (8.7)	435 (9.2)
	Widowed	258 (13.7)	394 (13.9)	652 (13.9)
	Never married	64 (3.4)	139 (4.9)	203 (4.3)
	Missing	6 (0.3)	7 (0.2)	13 (0.3)

Demographic characteristics		Treatment group (%)		
		Control	Intervention	Total
		N=180	N=2827	N=4707
Lives alone (adult) - yes		412 (21.9)	622 (22.0)	1034 (22.0)
Country of birth	Australia	1369 (72.8)	2270 (80.3)	3639 (77.3)
	United Kingdom	305 (16.2)	360 (12.7)	665 (14.1)
	Other	206 (11.0)	197 (7.0)	403 (8.6)
Aboriginal & Torres Strait Islander descent (yes)		14 (0.7)	34 (1.2)	48 (1.0)
Government assistance/support	Health Care Card	576 (30.6)	889 (31.4)	1465 (31.1)
	Pension	1168 (62.1)	1686 (59.6)	2854 (60.6)
	Department of Veteran Affairs card	138 (7.3)	141 (5.0)	279 (5.9)
Highest qualification	Bachelor degree or higher	167 (8.9)	245 (8.7)	412 (8.8)
	Certificate/advanced diploma	455 (24.2)	659 (23.3)	1114 (23.7)
	Up to Secondary education	1211 (64.4)	1848 (65.4)	3059 (65.0)
	Other	22 (1.2)	39 (1.4)	61 (1.3)
	Missing	25 (1.3)	36 (1.3)	61 (1.3)
Current employment status	Employed - full time	189 (10.1)	335 (11.9)	524 (11.1)
	Employed – part time	104 (5.5)	169 (6.0)	273 (5.8)
	Self employed	136 (7.2)	276 (9.8)	412 (8.8)
	Home duties	250 (13.3)	430 (15.2)	680 (14.4)
	Unemployed	36 (1.9)	48 (1.7)	84 (1.8)
	Student	13 (0.7)	10 (0.4)	23 (0.5)
	Retired	1090 (58.0)	1471 (52.0)	2561 (54.4)
	Other	57 (3.0)	73 (2.6)	130 (2.8)
Missing	5 (0.3)	15 (0.5)	20 (0.4)	

**Table 46: Summary of baseline patient demographic characteristics by geographic location**

Demographic characteristics		Geographic region (%)			
		Urban	Rural	Remote	Total
		N=1678	N=1290	N=1739	N=4707
Gender	Male	903 (53.8)	688 (53.3)	901 (51.8)	2492 (52.9)
	Female	775 (46.2)	602 (46.7)	838 (48.2)	2215 (47.1)
Age group (years)	18-39	21 (1.3)	13 (1.0)	28 (1.6)	62 (1.3)
	40-49	87 (5.2)	70 (5.4)	121 (7.0)	278 (5.9)
	50-59	270 (16.1)	266 (20.6)	317 (18.2)	853 (18.1)
	60-69	514 (30.6)	459 (35.6)	588 (33.8)	1561 (33.2)
	70-79	564 (33.6)	385 (29.8)	522 (30.0)	1471 (31.3)
	80+	222 (13.2)	97 (7.5)	163 (9.4)	482 (10.2)
Age (years): median (IQ range)		69.0 (60.0-76.0)	66.0 (59.0-74.0)	66.0 (59.0-74.0)	67.0 (59.0-75.0)
Marital status	Married/de facto	1210 (72.1)	922 (71.5)	1272 (73.1)	3404 (72.3)
	Divorced/separated	172 (10.3)	126 (9.8)	137 (7.9)	435 (9.2)
	Widowed	241 (14.4)	175 (13.6)	236 (13.6)	652 (13.9)

Demographic characteristics		Geographic region (%)			
		Urban	Rural	Remote	Total
		N=1678	N=1290	N=1739	N=4707
	Never married	51 (3.0)	61 (4.7)	91 (5.2)	203 (4.3)
	Missing	4 (0.2)	6 (0.5)	3 (0.2)	13 (0.3)
Lives alone (adult) - yes		384 (22.9)	302 (23.4)	348 (20.0)	1034 (22.0)
Country of birth	Australia	1069 (63.7)	1015 (78.7)	1555 (89.4)	3639 (77.3)
	United Kingdom	382 (22.8)	172 (13.3)	111 (6.4)	665 (14.1)
	Other	227 (13.5)	103 (8.0)	73 (4.2)	403 (8.6)
Aboriginal & Torres Strait Islander descent (yes)		6 (0.4)	10 (0.8)	32 (1.8)	48 (1.0)
Government assistance/support	Health Care Card	514 (30.6)	433 (33.6)	518 (29.8)	1465 (31.1)
	Pension	1040 (62.0)	842 (65.3)	972 (55.9)	2854 (60.6)
	Department of Veteran Affairs card	122 (7.3)	63 (4.9)	94 (5.4)	279 (5.9)
Highest qualification	Bachelor degree or higher	195 (11.6)	100 (7.8)	117 (6.7)	412 (8.8)
	Certificate/advanced diploma	420 (25.0)	293 (22.7)	401 (23.1)	1114 (23.7)
	Up to Secondary education	1022 (60.9)	854 (66.2)	1183 (68.0)	3059 (65.0)
	Other	24 (1.4)	20 (1.6)	17 (1.0)	61 (1.3)
	Missing	17 (1.0)	23 (1.8)	21 (1.2)	61 (1.3)
Employment status	Employed - full time	209 (12.5)	132 (10.2)	183 (10.5)	524 (11.1)
	Employed – part time	78 (4.6)	81 (6.3)	114 (6.6)	273 (5.8)
	Self employed	85 (5.0)	82 (6.3)	250 (14.2)	417 (8.8)
	Home duties	205 (12.2)	220 (17.1)	255 (14.7)	680 (14.4)
	Unemployed	19 (1.1)	25 (1.9)	40 (2.3)	84 (1.8)
	Student	10 (0.6)	11 (0.9)	2 (0.1)	23 (0.5)
	Retired	1029 (61.3)	684 (53.0)	848 (48.8)	2561 (54.4)
	Other	36 (2.1)	49 (3.8)	45 (2.6)	130 (2.8)
	Missing	7 (0.4)	6 (0.5)	7 (0.4)	20 (0.4)

#### 4.3.4.2. Clinical characteristics

A majority of patients in the Trial had either never smoked or were ex-smokers (90.8%) (Table 47), with the percentage increasing when moving from remote (88.3%) to urban areas (93.3%). A total of 39.7% of the patients at baseline did not consume alcohol and this was the same for both treatment arms (Table 47)), although a higher percentage of patients in rural areas did not consume alcohol (43.7%). Of those patients who reported drinking alcohol, 46.7% of patients consumed 1-2 standard drinks daily and with a slightly higher percentage of control patients (48.2%) and patients in urban areas (52.5%) consuming 1-2 standard drinks daily (Table 47 and Table 48).

The most common co-morbidities for patients (other than the conditions in the Trial) were coronary heart disease (15.3%) or previous heart attack (15.5 %) or depression or anxiety (14.1%). This pattern was similar across treatment arms and geographic location (Table 47 and Table 48).

For patients on anticoagulant therapy, atrial fibrillation was the most common reason (38.5%), followed by prosthetic valve replacement (15.8%) and deep vein thrombosis (8.6%)( Table 49) The least common reason for being on anticoagulant therapy was recurrent deep vein thrombosis (4.4%).

**Table 47: Summary of baseline patient clinical characteristics by treatment group**

Clinical characteristics		Treatment Group (%)		
		Control	Intervention	Total
		N=1880	N=2827	N=4707
Weight (kg): median (IQ range)		80.0 (69.9-91.0)	80.0 (70.0-92.0)	80.0 (70.0-92.0)
BMI	Underweight	21 (1.1)	23 (0.8)	44 (0.9)
	Normal	459 (24.4)	628 (22.2)	1087 (23.1)
	Overweight	684 (36.4)	1131 (40.0)	1815 (38.6)
	Obese	612 (32.6)	875 (31.0)	1487 (31.6)
	Missing	104 (5.5)	170 (6.0)	274 (5.8)
Smoking status	Never	855 (45.5)	1301 (46.0)	2156 (45.8)
	Ex-smoker	875 (46.5)	1245 (44.0)	2120 (45.0)
	Current smoker	141 (7.5)	254 (9.0)	395 (8.4)
	Missing	9 (0.5)	27 (1.0)	36 (0.8)
Alcohol consumption	None	741 (39.4)	1127 (39.9)	1868 (39.7)
	0-2 daily standard drinks	909 (48.4)	1289 (45.6)	2198 (46.7)
	3-4 daily standard drinks	146 (7.8)	274 (9.7)	420 (8.9)
	5 or more daily standard drinks	34 (1.8)	58 (2.1)	92 (2.0)
	Missing	27 (1.4)	35 (1.2)	62 (1.3)
Type of co-morbidity (yes) other than condition in Trial	Angina	263 (14.0)	353 (12.5)	616 (13.1)
	Heart failure	97 (5.2)	110 (3.9)	207 (4.4)
	Coronary heart disease	297 (15.8)	422 (14.9)	719 (15.3)
	Heart attack	302 (16.1)	428 (15.1)	730 (15.5)
	Stroke	164 (8.7)	219 (7.7)	383 (8.1)
	Renal failure	26 (1.4)	45 (1.6)	71 (1.5)
	Depression/anxiety	283 (15.1)	379 (13.4)	662 (14.1)
Cancer	157 (8.4)	233 (8.2)	390 (8.3)	

**Table 48: Summary of baseline patient clinical characteristics by geographic location**

Clinical characteristics		Geographic location (%)			
		Urban	Rural	Remote	Total
		N=1678	N=1290	N=1739	N=4707
Weight (kg): median (IQ range)		79.0 (69.9-91.0)	80.0 (70.0-92.0)	80.0 (70.0-92.0)	80.0 (69.9-92.0)
BMI	Underweight	12 (0.7)	11 (0.9)	21 (1.2)	44 (0.9)
	Normal	427 (25.4)	273 (21.2)	387 (22.3)	1087 (23.1)
	Overweight	655 (39.0)	496 (38.4)	664 (38.2)	1815 (38.6)
	Obese	500 (29.8)	426 (33.0)	561 (32.3)	1487 (31.6)
	Missing	84 (5.0)	84 (6.5)	106 (6.1)	274 (5.8)
Smoking status	Never	788 (47.0)	564 (43.7)	804 (46.2)	2156 (45.8)
	Ex-smoker	777 (46.3)	611 (47.4)	732 (42.1)	2120 (45.0)
	Current smoker	103 (6.1)	105 (8.1)	187 (10.8)	395 (8.4)
	Missing	10 (0.6)	10 (0.8)	16 (0.9)	36 (0.8)
Alcohol consumption	None	602 (35.9)	557 (43.2)	709 (40.8)	1868 (39.7)
	0-2 daily standard drinks	881 (52.5)	557 (43.2)	760 (43.7)	2198 (46.7)
	3-4 daily standard drinks	135 (8.0)	116 (9.0)	169 (9.7)	420 (8.9)
	5 or more daily standard drinks	21 (1.3)	30 (2.3)	41 (2.4)	92 (2.0)
	Missing	23 (1.4)	15 (1.2)	24 (1.4)	62 (1.3)
Type of co-morbidity (yes) other than condition in Trial	Angina	215 (12.8)	188 (14.6)	213 (12.2)	616 (13.1)
	Heart failure	79 (4.7)	53 (4.1)	75 (4.3)	207 (4.4)
	Coronary heart disease	289 (17.2)	195 (15.1)	235 (13.5)	719 (15.3)
	Heart attack	271 (16.2)	215 (16.7)	244 (14.0)	730 (15.5)
	Stroke	139 (8.3)	102 (7.9)	142 (8.2)	383 (8.1)
	Renal failure	16 (1.0)	31 (2.4)	24 (1.4)	71 (1.5)
	Depression/anxiety	232 (13.8)	176 (13.6)	254 (14.6)	662 (14.1)
	Cancer	147 (8.8)	103 (8.0)	140 (8.1)	390 (8.3)

**Table 49: Baseline condition characteristics by treatment group - anticoagulant therapy**

Condition		Treatment group (%)		
		Control	Intervention	Total
		N=355	N=536	N=891
Reason for anticoagulant therapy	Prosthetic valve replacement	52 (14.6)	89 (16.6)	141 (15.8)
	Deep vein thrombosis (DVT)	34 (9.6)	43 (8.0)	77 (8.6)
	Recurrent DVT	12 (3.4)	27 (5.0)	39 (4.4)
	Atrial fibrillation	137 (38.6)	206 (38.4)	343 (38.5)

#### 4.3.5. Pathology Providers

Baseline data was collected on 14 Pathology Providers involved in the Trial. A summary of these characteristics is provided in Table 50.

The majority of laboratories provided services to both private and public patients (71.4%). Nearly all of these laboratories provided both a laboratory and specimen collection service (92.9%). A total of 85.7% of laboratories associated with the Trial performed more than 500 tests per day (85.7%).

In terms of staffing, these laboratories had medians of 4.5 FTE pathologists, 16 FTE technicians and 12.5 FTE scientists (Table 50). Nearly two-thirds of these laboratories have visiting pathologists, with the frequency of their visits evenly split between daily, monthly and other.

The most common method used by these laboratories to dispatch test results to GPs was by telephone (92.9%) and fax (92.9%) (Table 50). Most of the laboratories dispatched results in less than one day (64.3%).

**Table 50: Characteristics of pathology laboratories**

Pathology characteristics		Total (%)
		N=14
Type of patients serviced	Private patients	4 (28.6)
	Private and public patients	10 (71.4)
Type of service performed	Collection centre	1 (7.1)
	Laboratory and collection centre	13 (92.9)
Number of tests performed per day	Less than 500	2 (14.3)
	500-1000	4 (28.6)
	More than 1000	8 (57.1)
Number of FTE Pathologists: median (IQ range)		4.5 (0.5-16.0)
Number of FTE Medical Practitioners: median (IQ range)		0.0 (0.0-3.0)
Number of FTE Technicians: median (IQ range)		16.0 (1.5-78.0)
Number of FTE Scientists: median (IQ range)		12.5 (3.5-46.0)
Laboratory has visiting pathologist	Yes	9 (64.3)
	No	5 (35.7)
Frequency of pathologist visits (only those who responded yes to having a visiting pathologist)	Daily	3 (21.4)
	Monthly	3 (21.4)
	Other	3 (21.4)
Method of dispatching results to GPs	Telephone	13 (92.9)
	Email	8 (57.1)
	Fax	13 (92.9)
	Other	9 (64.3)
Average time for results to reach GP	Less than 1 day	9 (64.3)
	1 day	5 (35.7)

#### 4.4. DISCUSSION

The Trial obtained a very high response rate for the baseline questionnaires for all participant groups except Pathology Providers. It is clear that the strategy selected for ensuring a high response was successful and also reflected the interest of participants in the Trial. The participant group with the lowest response rate for the baseline questionnaires was the Pathology Providers. This was not surprising in that they had less direct involvement in the Trial and also benefited least from PoCT in general practice.

##### 4.4.1. Practices

For a number of characteristics there were few differences by treatment group or geographic location. However, where differences occurred, geographic location accounted for a number of these. Practices in remote areas tended to be solo, bulk-bill all patients, have a smaller patient list size and their patients were older. In contrast, practices in urban areas tended to be partnerships, bulk-bill only particular groups of patients, were larger in terms of number of patients and their patients tended to be younger.

Urban practices were more likely to use computer systems for disease register and recall systems than rural and remote practices. They were also more likely to use these systems for specific patient groups (such as diabetes), although a larger percentage of remote practices ran diabetes clinics compared to urban practices. This is likely to reflect difficulties in accessing specialist medical services in rural and remote regions, requiring that practices provide such services and therefore have the systems to support this.<sup>88</sup>

Not surprisingly, the use of more than one Pathology Provider decreased with distance, with remote practices being a much greater distance from their Pathology Provider. This may reflect the greater use of PoCT devices in the past for these remote practices.

#### 4.4.2. General Practitioners

Many of the patterns found in the baseline characteristics of the GPs in the Trial reflect patterns found across the GP workforce in Australia.<sup>89, 90</sup> A number of differences in characteristics were found across geographic location. A larger percentage of GPs in rural or remote practices were overseas trained, were male, were not VR and had spent the least number of years in their current location. The data on number of patients per week seen by the GPs suggests that the GPs located in rural and remote areas work longer hours than the GPs in urban locations. This type of pattern is not found when viewed by treatment group.

The relationship between Overseas Trained Doctor (OTD) status and rural and remote practice reflects the increasing reliance on OTDs to fill areas of workforce shortage in rural and remote Australia. A number of government strategies have targeted OTDs for this particular purpose<sup>90</sup> and in 2003 OTDs accounted for 29.4% of the workforce in rural and remote Australia.<sup>91</sup> In remote areas the shorter length of time in current practice and the higher percentage of GPs without vocational registration is likely to reflect the OTD group of doctors; a similar picture is found across Australia.<sup>90</sup>

The relationship between geographic location and vocational registration status, type of practitioner, fewer females in remote areas and hours worked were similar to those found for the GP population as a whole.<sup>89, 90</sup>

#### 4.4.3. Device Operators

For the Trial, the Device Operators tended to be female and this is likely to relate to their profession, as most Device Operators were nurses – enrolled and registered. As with GPs, the differences in some of the characteristics related to geographic location. A larger percentage of Device Operators in remote practices worked part-time, had worked for a shorter number of years, had been at the current practice for a shorter period of time and took on a number of different tasks in the practice.

The characteristics of Device Operators participating in the Trial were similar to the profile of nurses in general practice nationally. In Australia, general practice nurses are predominantly female, registered nurses, working part-time and are older.<sup>88, 92</sup>

#### 4.4.4. Patients

The patients recruited to the Trial tended to be older (reflecting the conditions being evaluated in this Trial), male, married and born in Australia. Most participants were retired and had reached a secondary level of education. Few differences were found across treatment groups; however when the variables were viewed by geographic location some differences were seen. Patients located in remote areas were less likely to be retired and more likely to be self-employed and born in Australia. This is likely to reflect the type of work available in remote communities and that migrants are less likely to be located in a remote area.

The clinical characteristics of the patients in the Trial relate to the conditions being evaluated – conditions related to cardiovascular disease and diabetes. For example, the risk factors identified for Type 2 diabetes included overweight or obesity, age (older population), physical inactivity, poor

nutrition, tobacco smoking and high cholesterol and triglycerides.<sup>93</sup> Some of these risk factors are also related to cardiovascular disease.<sup>31, 85, 94</sup> The clinical characteristics show that the majority of patients were overweight or obese, ex-smokers, drank 1-2 standard alcoholic drinks daily and had either coronary heart disease, recent heart attack, and/or depression and anxiety. This pattern was similar across treatment groups and geographic location, although some differences were found in urban patients. A larger percentage of urban patients than patients in rural or remote locations consumed 1-2 alcoholic drinks daily, as well as having coronary heart disease. A higher percentage of patients in remote locations smoked.

#### 4.4.5. Pathology Providers

The Pathology Providers linked in the Trial through practices were fairly uniform across the characteristics collected. They serviced a mixture of private and public patients and provided both laboratory and collection services, with technicians and scientists forming the majority of staff.

### 4.5. CONCLUSION

The results of the baseline questionnaires indicated that, on the whole, the participants in each of the treatment groups had similar characteristics. A wider divergence in their characteristics was evident when the data was analysed by geographic location. Rural/urban differences found in the participant characteristics based on geographic location reflected the difference:

- in the populations between urban and rural regions
- in health care provision between urban and rural regions and
- in access to services including GP and other services.

The data obtained from the baseline questionnaires verified that the characteristics and patterns found in the data on the whole reflected the patterns found for the GP workforce in Australia, the structure of practices, GP nursing workforce and the characteristics of patients with the conditions being evaluated.

## 5. SAFETY OF PoCT IN GENERAL PRACTICE PART 1 - PERFORMANCE IN QUALITY MANAGEMENT

### SUMMARY OF THE CHAPTER

This chapter describes the methods used to establish a quality management system for the PoCT in General Practice Trial and the results of quality testing undertaken to assess the analytical performance of the devices used in the Trial.

The quality management system incorporated (i) an ongoing training and competency assessment program to ensure for PoCT Device Operators had the skill set required to conduct PoCT safely and effectively, (ii) the provision of internal quality control (IQC) and external quality assurance (EQA) programs to continually monitor both operator competency and the analytical quality of the PoCT devices used in the Trial and (iii) a comparison between the observed performance for IQC and EQA testing with the profession-derived analytical goals that were established for each PoC test for the Trial.

The PoCT Device Group was primarily responsible for training of practice staff and the implementation of an IQC program, while the RCPA Quality Assurance Program Pty Ltd was responsible for the delivery of an EQA program. IQC and EQA are established quality practices undertaken by all Australian pathology laboratories.

The key findings of this chapter are:

- all 80 Device Operators passed their initial competency assessment prior to the commencement of the live phase of the Trial
- the overall participation rate for IQC and EQA testing across the live phase of the Trial averaged greater than 90% for all POC tests
- Device Operator competency skills were maintained throughout the live phase of the Trial with only one operator having their competency revoked
- Device Operators conducted IQC testing to an analytical standard that met the goals set for the Trial for each PoC test (except HDL-cholesterol Level 1 QC where less than 60% of practices met the goal)
- Device operators conducted EQA to an acceptable level of accuracy when compared to pathology laboratories (84% to 98% acceptable results)

Device operators conducted EQA to an acceptable level of precision that met the goals set for the Trial for HbA1c and urine ACR. The other tests, particularly total cholesterol and HDL cholesterol were not able to meet all assessments of precision.

The key conclusion:

- the methods established for the implementation and delivery of training, competency assessment, IQC and EQA programs were appropriate for the General Practice Trial and PoCT Device Operators conducted PoCT to a generally acceptable analytical standard.

### 5.1. INTRODUCTION

Integral components of pathology testing in a laboratory setting include on-going training and competency assessment for staff conducting pathology testing and the continued surveillance of analytical quality of laboratory devices.<sup>95</sup> All laboratories assess analytical quality using two processes, namely internal quality control testing (IQC) and external quality assurance testing (EQA).<sup>96</sup>

In simplest terms, these processes involve the testing of 'artificial' samples (generally either liquid or lyophilised samples requiring reconstitution with water) that have known (or 'target') values of the analyte being tested. The results of IQC and EQA testing are compared with the known values of

the analyte. For IQC testing, the target values are known at the time of testing, whereas with EQA, testing is conducted in a 'blind' sense; that is, values are not known at the time of testing. Two key performance indicators termed precision and accuracy can be calculated from the results of IQC and EQA results and compared to profession-derived benchmarks, known as analytical goals.<sup>97</sup> These goals define the standard of analytical performance that devices for pathology tests should be able to achieve to provide good patient care.

For PoCT conducted in a non-laboratory clinical setting, similar standards of practice to those expected in a laboratory should be maintained; thus ongoing training for staff conducting PoCT and the continuing assessment of analytical quality must be critical components of a sound and sustainable PoCT system.<sup>98</sup> For the general practice setting, there is only very limited information in the literature on training and quality management models for PoCT.<sup>3, 47</sup>

Thus a key aspect of this Trial was to develop and implement a quality management system for general practice that (i) ensured PoCT operators had the skill set required to conduct PoCT safely and effectively, (ii) continually assessed the analytical quality of the PoCT devices used in the Trial and (iii) determined whether the observed performance met the analytical goals that were established for this Trial.<sup>99</sup> The PoCT Device Group was primarily responsible for training of practice staff and the implementation of an IQC program, while the RCPA Quality Assurance Program Pty Ltd (known hereon as QAP Group) was responsible for the delivery of an EQA program.

## **5.2. AIMS AND OBJECTIVES**

To assess the overall effectiveness of the PoCT quality management system implemented for the Trial, the following set of hypotheses was tested:

Hypothesis 1: All designated staff in the PoCT practices met the required competency level to perform PoCT.

Hypothesis 2: All PoCT practices obtained IQC results within the acceptable performance range.

Hypothesis 3: In terms of accuracy, all PoCT practice results meet the required quality assurance performance levels for the pathology laboratories.

Hypothesis 4: In terms of precision, PoCT practice results meet the required quality assurance levels for the pathology laboratories.

## **5.3. COMPETENCY OF DEVICE OPERATORS**

### **5.3.1. Aim/hypothesis**

To assess the effectiveness of the training and competency assessment programs implemented as part of the PoCT quality management system for the Trial, the following hypothesis was tested:

"All designated staff in the PoCT practices met the required competency level to perform PoCT."

### **5.3.2. Methods**

#### **5.3.2.1. Training Resources**

An education and training resource package was developed for the Trial comprising:

- a Training Manual
- A3 laminated posters and
- a CD ROM.

The resource set was developed and written by the PoCT Device Manager, with input from scientists from the PoCT Device Group and the QAP Group. The full colour training manual covered the theory of PoCT, including the conduct of quality management processes, and the practical side of performing each of the four PoC tests measured in the Trial. The set of 12 laminated posters provided a step-by-step guide on how to conduct patient, IQC and EQA testing for each PoC test. The CD ROM contained an electronic copy of the above resources.

#### 5.3.2.2. *Training workshops*

Five Initial Training Workshops were held for intervention practices between August and October 2005 at three centres – Adelaide SA, Dubbo NSW and Bendigo Victoria to cater for the urban, remote and rural practices respectively.

The workshops, each of two-days duration, combined theoretical training in the principles and practice of PoCT, the tests and devices used and quality management procedures (IQC and EQA) with 'hands on' practical training in small groups in how to perform patient, IQC and EQA tests. The training workshops also included sessions on PoCT Accreditation and Trial Protocol implementation.

Practice staff trained as Device Operators were required to perform PoCT in the presence of a scientific staff member from the Device and/or QAP groups and to correctly answer a set of written competency questions related to each test. Upon successful completion of this written and practical assessment Competency Certificates were presented to practice staff.

A satisfaction survey designed by the PoCT Device Group was completed by Device Operators at the conclusion of each initial Training Workshop. Full details of the initial training process are reported separately in the Final Report of the PoCT Device Group.

From January to August 2006, further training sessions were held to cater for intervention practices that required new nursing staff to be trained either because (i) their previous Device Operator had left the practice or (ii) the practice deemed that additional Device Operators were required to support PoCT services.

Five Refresher Training Workshops covering all geographic regions were delivered during late August 2006, coinciding with the 12-month point of the live phase of the Trial, as a commitment to continuing education and training for Device Operators.

During the live phase of the Trial, Device Operator competency continued to be assessed by the routine conduct of IQC and EQA testing (see next sections). Monthly IQC/EQA meetings were held between the PoCT Device Group and the QAP Group to monitor and assess competency and analytical performance.

A Competency Register was maintained by the PoCT Device Group throughout the live phase of the Trial.

#### 5.3.3. Results

##### 5.3.3.1. *Initial training*

Sixty two Device Operators from 31 practices completed initial training and received Competency Certificates.

Results from the satisfaction survey completed by Device Operators at the conclusion of each initial Training Workshop indicated that there was widespread acceptance of training methods and their effectiveness.

From January to August 2006, a further 18 practice staff and one GP from 10 intervention practices were trained as new Device Operators and received Competency Certificates.

Thus, in total, 80 Device Operators comprising 74 practice staff and six GPs from 31 practices were trained and received Competency Certificates as part of the Trial. A summary of these practices and Device Operators, split by geographic region, is provided in Table 51.

Across the life of the Trial, 19 Device Operators left the Trial either through personal resignation from an existing practice or because their practice withdrew from the Trial.

**Table 51: Practices' and device operators' training during the Trial by geographic region**

Geographic location	Initial training workshop August – October 2005			Additional training January – August 2006			Total device operators trained over Trial		
	Practices	Device operators		Existing practices	Device operators		Practices	Device operators	
		Practice Staff	GP		Practice staff	GP		Practice staff	GP
Urban	8	18	0	1	1	0	8	19	0
Rural	9	20	2	4	6	0	9	26	2
Remote	14	17	3	7	12	1	14	29	4
Total	31	55	5	12	19	1	31	74	6

#### 5.3.3.2. Refresher training

A total of 42 Device Operators from 25 practices attended refresher training in the second half of 2006 (Table 52). Only Device Operators who were still actively conducting PoCT at their practice were required to attend refresher training.

**Table 52: Practices and device operators undertaking refresher training by geographic region**

Geographic location	Refresher Training August – November 2006		
	Practices	Device operators	
		Practice staff	GPs
Urban	8	12	0
Rural	7	15	1
Remote	10	14	0
Total	25	41	1

The PoCT Device Group, QAP Group and the Trial Management Group contributed to the refresher training sessions, presenting overviews and updates of training, results, and Trial protocols and processes.

The refresher training also provided the opportunity for Device Operators to raise any issues and provide feedback on their involvement in the Trial. Device Operators were in general agreement that:

- the poster set provided for practices remained useful, its size and clarity was good, while the ability to fold the posters back was an advantage
- deliveries from the Bayer Central Warehouse were being received in a timely manner
- PoCT devices had generally proven robust during the Trial thus far
- the Help Desk Support hotline had been useful in providing an immediate support service for participants and
- patients were generally satisfied with the PoC testing process and they felt a greater sense of ownership of their pathology results.

The following test-specific issues were raised:

*INR Testing:* Several nurses reported that the CoaguChek S did not operate when the temperature in the practice was very cold. INR sample collection, in particular applying the sample to the device's application area, remained an issue for PoCT operators although operators generally felt more comfortable with this aspect as they conducted more testing.

*Lipid Testing:* In contrast to INR, several nurses reported that the Cholestech LDX would not operate in excessive heat.

*Urine ACR:* Two nurses at different workshops reported that they had received broken sample holders in their urine ACR reagent kit. These were replaced by the Bayer Central Warehouse.

*HbA1c:* No specific issues of concern were raised with this test.

#### 5.3.3.3. *On-going competency assessment*

Competency continued to be assessed throughout the live phase of the Trial through the routine conduct of IQC and EQA testing. Twenty one QC/QA Review meetings were held during this period to review and monitor competency and analytical performance. Across the life of the Trial, only one Device Operator had their competency revoked due to poor participation and poor analytical performance in IQC (and EQA) testing.

The copy of the Competency Register is provided in the PoCT Device Group's Final Report to the Department of Health and Ageing June 2007.

## **5.4. ASSESSMENT OF INTERNAL QUALITY CONTROL PROGRAM**

### 5.4.1. Aims and Objectives

To assess the effectiveness of the internal quality control program implemented as part of the PoCT quality management system for the Trial, the following hypothesis was tested:

"All PoCT practices obtained IQC results within the acceptable performance range (that is, the performance standards for IQC testing by practices met the analytical goals for imprecision set for the Trial)".

## 5.4.2. Methods

A comprehensive description of the methods employed for the development and implementation of the internal quality control program is provided in PoCT Device Group's Final Report to the Department of Health and Ageing June 2007.

### 5.4.2.1. Quality control materials and testing regimen

Once the live phase of the Trial commenced, Device Operators were required to test one set of internal quality control materials (comprising two levels of analyte for HbA1c, urine ACR and lipids and one level for INR) for each test every fortnight for the first three months of the Trial (September to November 2005) and monthly thereafter (from December 2005 to February 2007).

The analyte concentration(s) for each lot number of QC used in the Trial is shown in Table 53. Three different lot numbers of QC material were used for lipid testing, two for HbA1c and INR testing, and a single lot number for urine ACR testing.

**Table 53: Analyte concentrations in QC material used in the Trial**

Test	Manufacturer	Lot Number	QC Level 1		QC Level 2	
			Name	Concentration	Name	Concentration
HbA1c	Bayer	27	Normal	5.5%	Abnormal	10.7%
	Bayer	28	Normal	5.6%	Abnormal	11.6%
UAlbumin	Bayer	28	Low	34 mg/L	High	219 mg/L
UCreatinine	Bayer	28	Low	8.8 mmol/L	High	34.2 mmol/L
Urine ACR	Bayer	28	Low	3.9 mg/mmol	High	6.4 mg/mmol
Total cholesterol	POCD	5082	Level 1	4.2 mmol/L	Level 2	6.0 mmol/L
	POCD	5230	Level 1	4.4 mmol/L	Level 2	6.4 mmol/L
	POCD	6165	Level 1	4.2 mmol/L	Level 2	6.3 mmol/L
Triglycerides	POCD	5082	Level 1	1.6 mmol/L	Level 2	2.9 mmol/L
	POCD	5230	Level 1	1.5 mmol/L	Level 2	3.1 mmol/L
	POCD	6165	Level 1	1.8 mmol/L	Level 2	3.3 mmol/L
HDL-C	POCD	5082	Level 1	0.88 mmol/L	Level 2	1.8 mmol/L
	POCD	5230	Level 1	0.90 mmol/L	Level 2	1.8 mmol/L
	POCD	6165	Level 1	0.86 mmol/L	Level 2	1.6 mmol/L
INR	Roche	800042	PT	4.7	n/a	n/a
	Roche	800049	PT	2.8	n/a	n/a

The participation rate for QC testing (defined as the total number of QC results returned by practices for each test divided by the total number of QC results expected to be returned according to the required protocol, expressed as a percentage) was monitored monthly throughout the Trial.

#### 5.4.2.2. Recording quality control results

Device Operators were provided with a colour-coded Quality Control Result Sheet on which to record their results. The Result Sheet documented:

- the target value for each sample (as assigned by the manufacturer)
- limits for acceptable performance (as determined by the PoCT Device Group – see below) [coloured green]
- limits where analytical performance required close monitoring (warning limits [orange]) and
- limits where analytical performance was considered unacceptable and required the cessation of patient testing until the reason for unacceptable performance had been investigated and rectified (action limits [red]).

QC limits for acceptable performance used for the Trial are shown in Table 54 below. The following points should be noted:

- QC limits are designed to provide a general or 'crude' guide to overall analytical performance. (As will be described, the key performance indicator to assess the quality of IQC testing for this Trial and for all Australian laboratories is the measurement of precision).
- QC limits are generally equated with total allowable error; that is, they encompass allowable error due to both the inaccuracy and imprecision of test results. They also represent overall error between sites (in this case, general practices). (Thus QC limits are allowable limits for between-practice total error and should not be confused with the imprecision goals set for this Trial [see later] which are within-practice goals for imprecision only).
- QC limits selected for this Trial acknowledge the fact that, in practice, the manufacturer-assigned target value for QC material often does not correspond accurately to the mean value obtained by users of the QC material.

**Table 54: Limits for acceptable performance for QC testing used in the Trial**

Test	QC Limits for acceptable performance used in this Trial
HbA1c	10%
UAlbumin	12.5%
UCreatinine	7.5%
UACR	15%
Total cholesterol	10%
Triglycerides	15%
HDL-C	15%
INR	15%

*Note: Warning limits were between 1.0 and 1.5 times the acceptable limits, while action limits were outside 1.5-times the acceptable limits.*

The full rationale used by the PoCT Device Working Group in setting acceptable limits for QC testing is described in detail in the PoCT Device Group's Final Report to the Department of Health and Ageing June 2007.

Device operators were also required to record the date of testing, their initials and their decision as to whether to accept or reject their QC results on their QC Result Sheet (using their QC Action Sheet described below).

#### 5.4.2.3. *On-site interpreting and actioning of quality control results by practices*

A laminated QC Action Sheet was provided for each practice to enable the PoCT Device Operator to interpret the QC results on-site and to make an immediate informed decision as to whether to:

- accept the results of QC testing and proceed with patient testing [where QC results were green/green or green/orange] or
- reject the results of QC testing, stop testing patients and telephone the PoCT Device Group (through the telephone help desk support service) to determine the next course of action [where QC results were orange/orange or any QC result was red].

The colour codes used for deciding whether to accept or reject the results of QC testing were designed to mimic a 'traffic light' system; that is, green means 'go', orange means 'proceed with caution' and red means 'stop'.

#### 5.4.2.4. *Management and analysis of IQC testing results by PoCT Device Group*

Upon completion of testing a set of QC samples, the Device Operator was required to immediately fax the QC Result Sheet to the PoCT Device Working Group, which then entered the results into an Excel spreadsheet.

This spreadsheet was used to calculate three measures of precision:

- the monthly between-practice imprecision [coefficient of variation (CV%)] to enable trends in this performance indicator to be tracked over the study period
- the within-practice imprecision [coefficient of variation (CV%)] for each individual practice, following receipt of a minimum of five quality control results for each level tested and
- the within-practice imprecision [coefficient of variation (CV%)] for each individual practice, following receipt of a minimum of five quality control results for each level tested, split by geographic region.

Precision is defined as the ability of a PoCT (or laboratory) device to obtain close to the same result upon repeated analysis of that sample (in this case quality control material). Imprecision is the statistical measure of that repeatability, expressed as a coefficient of variation according to the formula  $CV\% = (SD/\text{mean of replicate measurements} * 100)$ . As a general guide, the lower the imprecision (CV%), the better the analytical performance of the device.

Regular monthly meetings between representatives of the PoCT Device Working Group and the QAP Group were held to discuss and review all IQC and EQA results returned by practices for that month. Minutes from these meetings were taken and sent to the Chair of the Safety Subcommittee (under the direction of the Trial Management Committee). These QC/QA Review Meetings enabled on-going Device Operator competency to be monitored and poor analytical performance and/or non-compliance with IQC/EQA testing schedules to be actioned and addressed in a timely fashion during the Trial.

A Quality Control Feedback Report was sent to each practice at six-monthly intervals during the live phase of the Trial. The Feedback Report documented the practice's IQC results in both graphic and tabular form, recorded the practice's imprecision for IQC testing and the median imprecision achieved by all practices (to provide a peer reviewed comparative assessment of their performance).

Overall assessment of the analytical quality of IQC results for the Trial

The within-practice imprecision for each test was able to be compared with the analytical goals for imprecision set for the Trial, which were within-practice goals reflecting the analytical standard that individual practices would be expected to achieve for the Trial (Table 55).

**Table 55: Analytical goals for imprecision set for the PoCT Trial**

Analyte	Goal for imprecision		
	Minimum	Desirable	Optimal
HbA1c	4%	3%	
Urine Albumin			10%
Urine Creatinine			6%
Urine ACR			12%
Total cholesterol	5%	3%	
Triglycerides		7.5%	5%
HDL-C	6%	4%	
INR	10%*		

Notes: Although an imprecision goal for INR was not specifically set for this Trial, CV% of 10% would generally be considered to represent acceptable performance for patient care

Minimum, desirable and optimal profession-based goals can be set for different analytes, depending on how well (or otherwise) the test can be measured in practice by current laboratory methods. Thus, an optimal analytical goal provides a measure of the standard of analytical performance that the very best methods for a particular test can achieve. A desirable analytical goal provides a measure of the standard of analytical performance that should be generally achievable by most methods for a particular test. A minimum analytical goal provides a measure of the widest allowable standard of analytical performance that methods for a particular test should be able to achieve. The rationale for setting the analytical goals for the Trial is described in the (Interim) Standards developed for the Trial.<sup>27</sup>

5.4.2.5. Other quality management practices

Whilst IQC testing represented the principal quality management procedure under the charter of the PoCT Device Working Group, other quality management data were also recorded and collected during the Trial.

Each practice was required to complete and return the following sheets to the PoCT Device Working Group:

- Test Error Log Sheet (to record specific error codes displayed on PoCT devices when such an event occurred)
- Optical Test Result Sheet (as part of general maintenance, an optical test was required to be performed monthly on the Bayer DCA 2000 and weekly on the Cholestech LDX device)
- Device Maintenance Schedule (detailing a set timeframe for basic maintenance procedures performed on all devices).

### 5.4.3. Results

#### 5.4.3.1. Participation rate

The total number of QC tests expected to be performed over the period 1 September 2005 to 28 February 2006 was 1102 for HbA1c, 3303 for urine ACR (1101 each for urine albumin, urine creatinine and urine ACR), 3303 for lipids (1101 each for total cholesterol, triglyceride and HDL-C) and 610 for INR. The overall participation rate for QC testing across the live phase of the Trial averaged 93% for HbA1c, urine ACR and lipids, and 91% for INR.

#### 5.4.3.2. Percentage acceptable results

The number and percentage of QC results that fell within the acceptable (green), warning (orange) and action (red) zones across the Trial period is shown in Appendix 17. Over 95% of results for all PoCT tests were considered acceptable, less than 3% were in the warning zone and less than 1% were in the action zones.

As mentioned previously, the QC limits for this Trial were set conservatively and the very high percentage of acceptable results was due in part to this strategy. The PoCT Device Working Group adopted this strategy due to concerns particularly regarding the potential for discrepancy between the manufacturer-specified target and the mean of results obtained by Device Operators in the Trial.

The observed differences between the target and mean values obtained by Device Operators were tracked during the Trial and the results are shown in Table 56.

**Table 56: Percentage differences observed between the manufacturer-derived target values and mean values obtained from practices for QC testing during the Trial**

Test	Lot number	Target value (manufacturer)		Mean value (obtained by device operators)		% difference	
		QC 1	QC 2	QC 1	QC 2	QC 1	QC 2
HbA1c	27	5.5	10.7	5.5	11.3	0	5.6
HbA1c	28	5.6	11.6	5.7	11.9	1.8	2.6
UAlbumin	28	34	219	35.4	228	4.1	4.1
UCreatinine	28	8.8	34.2	8.8	34.3	0	0.3
ACR	28	3.85	6.4	4.0	6.7	3.9	4.7
Total cholesterol	5082	4.20	6.04	4.06	5.93	3.3	1.8
Total cholesterol	5230	4.39	6.40	4.12	6.16	6.2	3.8
Total cholesterol	6165	4.20	6.32	4.13	6.21	1.7	1.8
Triglycerides	5082	1.55	2.94	1.65	2.90	6.5	2.0
Triglycerides	5230	1.54	3.13	1.59	3.22	3.2	2.9
Triglycerides	6165	1.84	3.26	1.82	3.23	1.1	0.9
HDL-C	5082	0.88	1.83	0.98	1.82	11.4	0.6
HDL-C	5230	0.90	1.77	0.90	1.84	0	4.0
HDL-C	6165	0.86	1.56	0.83	1.56	1.6	0
INR	800042	4.7	na	4.5	na	4.3	na
INR	800049	2.8	na	2.8	na	0	na

The data in this table indicates that the perceived concerns of the PoCT Device Group were justified. A difference between target and mean values of greater than 10% was observed for HDL-C (Level 1 LN 5082). This finding was reported to the Cholestech Corporation (Hayward, CA) in the

USA, which acknowledged that their target value for this QC may have been incorrect. As a result, the interim mean value obtained by Device Operators for this QC was used as the target until the lot number of material ran out and a new QC Result Sheet with amended targets and ranges was issued to each practice.

Differences of greater than 5% were found for HbA1c (Level 2 LN 27), total cholesterol (Level 1 LN 5230) and triglyceride (Level 1 LN 5082), and differences between 4%-5% were seen for urine albumin (Levels 1 and 2 LN 28), urine ACR (Level 2 LN 28), HDL-C (Level 2 LN 5230) and INR (LN 800042). Thus none of the four tests was immune from a discrepancy of 4% or more across one or more lot numbers of QC material used.

#### 5.4.3.3. Assessment of imprecision for quality control testing

As previously indicated, the key analytical performance indicator to assess the quality of QC testing is imprecision, expressed as a coefficient of variation (CV%).

Monthly between-practice imprecision

The between-practice imprecision was calculated monthly for each level of QC. (For the first three months of the Trial, where the QC testing was performed fortnightly, the data from both fortnights were pooled to calculate the monthly CV%). The average monthly between-practice imprecision is summarised in Table 57.

**Table 57: Average monthly between-practice imprecision observed across the Trial**

Test	QC lot number	Average monthly between-practice CV%	
		QC Level 1	QC level 2
HbA1c	27	3.0%	4.2%
HbA1c	28	3.1%	4.2%
UAlbumin	28	6.0%	4.9%
UCreatinine	28	4.0%	3.9%
ACR	28	5.8%	4.9%
Total cholesterol	5082	3.7%	3.8%
Total cholesterol	5230	3.1%	4.0%
Total cholesterol	6165	3.1%	3.4%
Triglycerides	5082	4.6%	5.2%
Triglycerides	5230	3.9%	4.5%
Triglycerides	6165	4.0%	3.7%
HDL-C	5082	5.7%	4.9%
HDL-C	5230	5.9%	5.5%
HDL-C	6165	5.8%	5.2%
INR	800042	7.9%	n/a
INR	800049	8.0%	n/a

This strategy of calculating monthly between-practice imprecision was adopted to enable shifts or trends in overall performance for QC testing to be identified (notably continuing deterioration in performance across time indicating a diminution in operator competency). However, the between-practice imprecision remained relatively constant across different lot numbers of QC throughout the live phase of the Trial for all tests (with the exception of HDL-C LN 5230). This finding indicated that the competency skills of Device Operators were maintained throughout the Trial. The late deterioration of between-practice imprecision observed with HDL-C LN 5230 could partly be explained by the fact that the quality control materials were at the end of their specified expiry date in October 2006.

### Within-practice imprecision

The within-practice imprecision was calculated for each practice that returned a minimum of five QC results for each level and lot number of QC tested. The within-practice imprecision for each level and lot number was then ranked from lowest to highest and the median (50<sup>th</sup> percentile) CV%, as well as the 25<sup>th</sup> and 75<sup>th</sup> percentile CV%, calculated. This approach was adopted because:

- the distribution of within-practice CV% was non-Gaussian and therefore it was more appropriate to analyse this data by non-parametric statistics and
- the RCPA QAP Pty Ltd (as the External Proficiency Testing Provider for the Trial) routinely reports the median within-practice imprecision for all its pathology tests (including those for the Trial) and therefore the imprecision for QC and QA testing in this Trial could be compared using the same performance indicator.

Table 58 summarises the median within-practice imprecision for each QC level and PoC test and also compares the observed performance with the within-practice analytical goals for imprecision set for this Trial (refer Table 55).

**Table 58: Comparison of median within-practice imprecision and the analytical goals for imprecision set for the Trial**

Test	QC lot number	Imprecision goal (CV%) set for Trial	Within-practice median CV%		Number of practices used in calculation of median CV%	
			QC level 1	QC level 2	QC level 1	QC level 2
HbA1c	27	4%	2.5%	2.8%	26	26
	28	4%	2.9%	3.3%	27	27
UAlbumin	28	10%	5.0%	4.1%	27	27
UCreatinine	28	6%	3.5%	3.5%	27	27
ACR	28	12%	5.0%	4.0%	27	27
Total cholesterol	5082	5%	3.1%	3.0%	26	26
	5230	5%	2.3%	2.9%	26	26
Triglycerides	5082	7.5%	3.9%	3.7%	26	26
	5230	7.5%	5.0%	5.4%	26	26
HDL-C	5082	6%	5.5%	3.9%	26	26
	5230	6%	6.7%	4.8%	26	26
INR	800042	10%*	7.0%	n/a	27	27
	800049	10%*	6.4%	n/a	26	26

Note: There was insufficient data available to calculate within-practice CV for lipid lot number 6165.

Looking at each test specifically:

HbA1c: The median within-practice imprecision for HbA1c met the minimum analytical goal of 4% for all levels and both lot numbers of QC tested. For LN 27 and LN 28 (Level 1), the median within-practice imprecision for HbA1c also met the desirable analytical goal of 3%.

Urine ACR: The median within-practice imprecision for urine albumin, urine creatinine and urine ACR readily met the optimal analytical goals of 10%, 6% and 12% respectively.

Total cholesterol: The median within-practice imprecision for total cholesterol met the minimum analytical goal of 5% for all levels and both lot numbers of QC tested. For LN 5230 and LN 5082 (Level 2), the median within-practice imprecision for total cholesterol also met the desirable analytical goal of 3%.

Triglyceride: The median within-practice imprecision for triglyceride met the desirable analytical goal of 7.5% for all levels and both lot numbers of QC tested. For LN 5082 and LN 5230 (Level 1), the median within-practice imprecision for triglyceride also met the optimal analytical goal of 5%.

HDL-C: The median within-practice imprecision for HDL-C met the minimum analytical goal of 6% for LN 5082 and LN 5230 (Level 2); but did not meet the minimum goal for LN 5082 (Level 1). For LN 5082 (Level 2), the median within-practice imprecision for HDL-C also met the desirable analytical goal of 4%.

INR: As mentioned previously, an imprecision goal for INR was not set for this Trial, but the PoCT Device Working Group considered that the observed within-practice imprecision for INR of less than 10% was acceptable.

Overall, greater than 80% of practices achieved the imprecision goals for the Trial for all analytes and lot numbers of QC material used, except for HbA1c Level 2 for both lot numbers (73% and 67%) and HDL-C (LN 5082 Level 1 58% and LN 5230 Level 1 33% and Level 2 63%). Although an analytical goal for INR was not set for the Trial, 89% of all practices achieved an imprecision of less than 10% (Table 59).

**Table 59: Percentage of practices which met the imprecision goals set for the PoCT Trial**

Test	QC lot number	Imprecision goal (CV%) set for Trial	Percentage of practices which met the imprecision goals	
			QC level 1	QC level 2
HbA1c	27	4%	96%	73%
HbA1c	28	4%	89%	67%
UAlbumin	28	10%	100%	100%
UCreatinine	28	6%	96%	100%
ACR	28	12%	100%	100%
Total cholesterol	5082	5%	96%	96%
Total cholesterol	5230	5%	100%	96%
Triglycerides	5082	7.5%	100%	100%
Triglycerides	5230	7.5%	100%	79%
HDL-C	5082	6%	58%	96%
HDL-C	5230	6%	33%	63%
INR	800042	10%*	89%	n/a
INR	800049	10%*	88%	n/a

## 5.5. ASSESSMENT OF EXTERNAL QUALITY ASSURANCE PERFORMANCE

### 5.5.1. Aims and objectives

To assess the effectiveness of the EQA Program implemented as part of the PoCT quality management system for the Trial, the following hypotheses were tested:

Hypothesis 1: In terms of accuracy, all PoCT practice results meet the required quality assurance performance levels for the pathology laboratories (that is, practices obtained accurate results from EQA testing)

Hypothesis 2: In terms of precision, PoCT practice results meet the required quality assurance levels for the pathology laboratories (that is, the performance standards for EQA testing by practices met the analytical goals for imprecision set for the Trial).

### 5.5.2. Methods

An EQA program was developed that comprehensively and efficiently assessed participating general practices, provided peer-review appraisal, allowed critical comparison of analytical systems and evaluated performance relative to that required for satisfactory patient care. This EQA was designed to be suitable for a general practice PoCT environment, cover the pathology tests under consideration and be suitable to assess the objectives of the Trial. Details of the EQA program developed can be found in the Final Report – External Proficiency Testing to the Australian Government Department of Health and Ageing.

The key aspects of the external quality assurance program were:

#### *Material*

Material was developed that would cover the six tests and be suitable for the three different instruments being used in the Trial.

The material was designed to be:

- human based – as similar as possible to patient material
- suitable matrices for the tests:
  - HbA1c – whole blood haemolysate
  - microalbumin – urine
  - lipids (total cholesterol, triglycerides, HDL-C) – serum
  - INR – serum with activator
- a range of concentration levels from normal to disease
- six different concentrations of material which were run on more than one occasion throughout the program increasing the value of the data analysis
- linearly related specimens. Specimens were manufactured to produce a range of linearly related values. This tested whether the analysers could produce the designed linear response, over the complete range of values and enabled the calculation of linear regression statistics for the summary performance
- paired specimens – two specimens were analysed by the practice each time

- suitable for use in the general practice environment where access to laboratory equipment to reconstitute or pipette the samples was not available
- long-term stability – the material was stable for the 18 month period of the Trial. Lyophilisation (freeze drying) was used to stabilise the HbA1c, lipid and INR testing and the ACR material was sealed in plastic pipettes.

The practices were supplied with the four types of material and paperwork prior to the beginning of each cycle.

### Reports

Reports were designed to provide a comprehensive graphical summary of the data of each individual practice and all participants. These reports were designed as modifications to the existing QAP reports with the aim of making them more user-friendly to non-laboratory personnel whilst still showing the practice's performance and comparison with other practices.

The features developed specifically for the PoCT Trial were recording of the operator, lot number of reagent and colour coding of results.

Colour coding was used to give participants an assessment of whether their result was within the clinically acceptable range:

- **Green** – within the allowable limits of performance
- **Orange** – +/-1 to 2 allowable limits of performance
- **Red** – greater than +/- 2 allowable limits of performance

An Action Sheet was developed to assist participants to review their EQA results and take appropriate action based on the colour coding.

- **Green** – excellent
- **Orange** – review QA and QC results
- **Red** – action; contact QA organisers via telephone hotline

The practices received Interim and End-of-Cycle Reports.

The Interim Reports were received by the practices after each pair of samples had been run, that is two weekly in phase I of the Trial and monthly for the remainder of the Trial. These reports summarise the practice's performance for each pair of specimens in the analytical period or cycle.

Reports were designed to graphically show the practice their results compared to all other practices in the PoCT Trial. The End-of-Cycle Report was received by the practices at the end of each six month cycle. These reports summarised the practice's performance over the cycle. There were three cycles in the Trial and therefore three End-of-Cycle reports generated.

The End-of-Cycle Report was a comprehensive and detailed statistical review and assessment of the results of each practice based on the full range of linearly-related specimens in the cycle compared to the results of all practices in the PoCT Trial.

A Supervisor's Report which summarised the results of all the practices in the Trial was sent to the Department of Health and Ageing Project Manager at the same time as the Interim report was printed for the practices.

### Website development

The RCPA Chemical Pathology QAP Pty Ltd website was modified to allow data entry for the PoCT Trial participants. Participants were also able to view a modified version of their Interim and End-of-Cycle Report on the website.

### Frequency of challenges

The QAP was organised into three analytical periods called cycles. Each cycle covered a period of six months. The frequency of challenges for the first cycle was two samples per two weeks. At the end of the first cycle this frequency was reviewed by the PoCT Steering Group and the frequency for cycles 2 and 3 became two samples per month. This is consistent with pathology laboratory quality assurance frequency.

Cycle 1 (5 September 2005 – 13 February 2006) 24 samples

Cycle 2 (6 March 2006 – 24 July 2006) 12 samples

Cycle 3 (21 August 2006 – 15 January 2007) 12 samples

### 5.5.3. Results

#### 5.5.3.1. Participation rate

All practices were required to perform the EQA program and submit the results to the QAP Office monthly. The percentage participation rate was from 95% to 99% as can be seen in Table 60.

**Table 60: Percentage participation rate**

	Cycle 1	Cycle 2	Cycle 3
Number of Results	580	307	314
% Participation	94.8	94.8	99.4

#### 5.5.3.2. Accuracy

The hypothesis to be tested was: In terms of accuracy, all PoCT practice results meet the required QA performance levels for the pathology laboratories. The acceptable values, outliers and central values of the QAP results were investigated.

##### a. Acceptable values

An acceptable result was one that was within the allowable limit of performance for that test that is a result that would be within a clinically acceptable range. In the PoCT Trial the allowable limits were the same as used by the RCPA Quality Assurance Programs Pty Ltd for pathology laboratories (Table 61).

**Table 61 Allowable limits of performance**

Test		
HbA1c	±0.5 up to 10.0%	±5% > 10.0%
Urine Albumin	±4.0 up to 30.0mg/L	±12% > 30.0mg/L
Urine Creatinine	±0.8 up to 10.0mg/L	±12% > 10.0mg/L
Urine ACR	±0.5 up to 3.5mg/mmol	±15% > 3.5mg/mmol
Total Cholesterol	±0.50 up to 10.00mmol/L	±5% > 10.00mmol/L
HDL-C	±0.20 up to 2.00mmol/L	±10% > 2.00mmol/L
Triglycerides	±0.20 up to 2.00mmol/L	±10% > 2.00mmol/L
INR	±0.3 up to 2.0 Ratio	±15% > 2.0 Ratio

Colour coding as described in the Method Section was used to give practices an assessment of whether their result was within the clinically acceptable range. The following table (Table 62) shows the percentage of practices for each analyte for each colour.

**Table 62: Percentage of acceptable results by cycle**

Test	Cycle 1			Cycle 2			Cycle 3		
	Green	Orange	Red	Green	Orange	Red	Green	Orange	Red
HbA1c	93.4	6.0	0.6	95.7	3.2	1.2	93.9	4.8	1.3
ACR	97.9	2.0	0.5	98.3	0.3	1.4	98.1	0.9	0.9
Total cholesterol	83.0	13.6	3.4	80.8	13.9	5.3	87.0	10.5	2.5
HDL-C	90.6	7.4	2.3	87.4	7.6	5.0	92.7	5.1	2.2
Triglycerides	90.3	6.0	3.7	91.5	5.3	3.2	95.5	2.5	1.9
INR	94.4	4.1	1.5	94.8	2.6	2.6	93.9	2.6	3.5

For green results (clinically acceptable) urine ACR was the best performer and total cholesterol the poorest. For orange results HbA1c was the best performer and total cholesterol the poorest. For red results (clinically unacceptable) urine ACR was the best performer and total cholesterol the poorest.

Overall all tests have acceptable performance (green) with urine ACR being the best performer and total cholesterol being the weakest performer.

b. Acceptable results for other QA programs

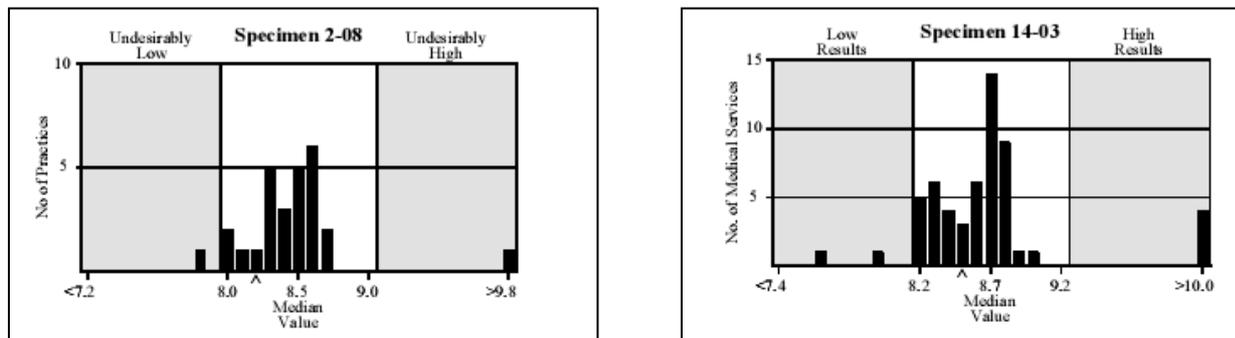
A comparison was made with other external quality assurance programs offered by the RCPA Quality Assurance Programs to put the number of acceptable results for the Trial into perspective.

For HbA1c (Figure 7) the comparison was made using an Aboriginal PoCT program (QAAMS) and the main laboratory program. QAAMS (Quality Assurance for Aboriginal Medical Services) offers a PoCT QA program in HbA1c and urine ACR for Aboriginal Medical Services in urban, rural and remote communities. All participants in QAAMS use the DCA 2000 instrument but in the main laboratory program 29 different instruments are used.

It can be seen that the spread of results for HbA1c in the PoCT QA Program was similar to that seen in the QAAMS PoCT QA Program which was similar to the laboratory spread of results. There was inter-laboratory variability which was due to variation both within and between instrument groups.

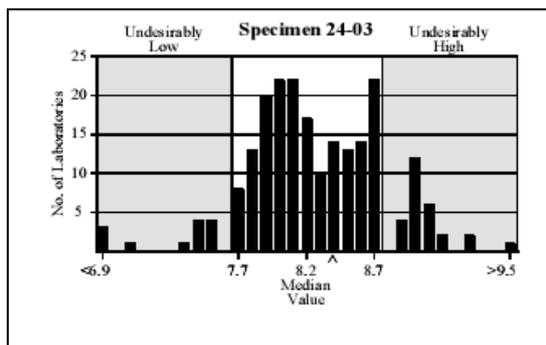
Figure 8 shows the outliers (outside ALP = orange or >3SD = red) for the PoCT Trial cycles, the QAAMS, all instruments in the laboratory program and the DCA 2000 instruments in the laboratory program for HbA1c. The >3SD group was the red group in the Trial.

**Figure 7: Comparison of PoCT QA results with other QA Program results**



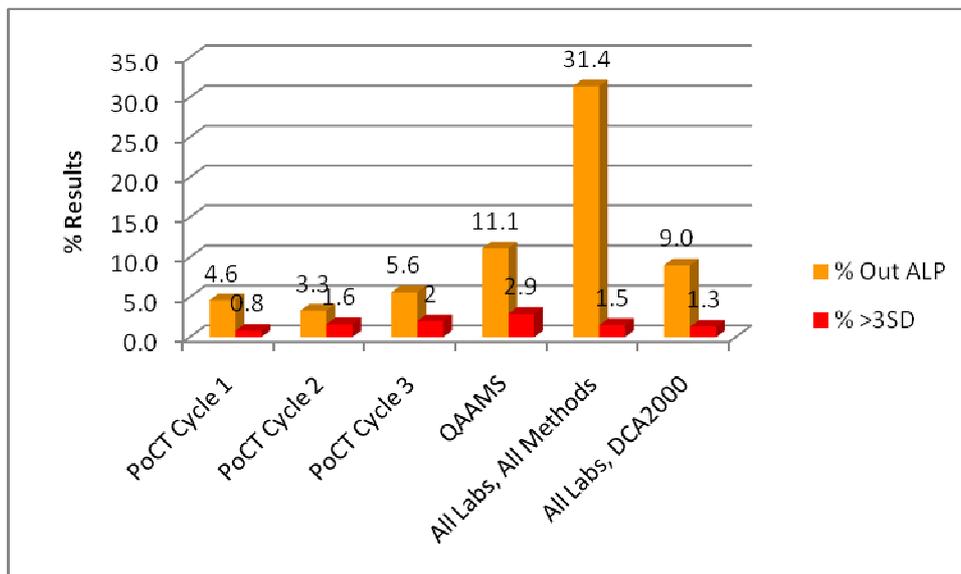
PoCT Trial QA Results (using DCA 2000)

Aboriginal PoCT QA Results (using DCA 2000)



Laboratory QA Results (29 different methods)

**Figure 8: Percentage outliers in HbA1c QA Programs**



This demonstrates that for HbA1c the Trial participants had less outliers than other quality assurance programs.

c. Central values

The central value used for the quality assurance program was the overall median value that is the central value of all results returned. To assess accuracy it is desirable to compare the results to target values which have been set using internationally recognised methods. Target values were set on the material for HbA1c, and the lipids (total cholesterol, HDL-C and triglycerides) (Table 63). No reference methods are available for urine ACR or INR.

**Table 63: Target value methods**

Test	Target value
HbA1c	DCCT method <sup>1</sup>
ACR	None
Lipids	CDC Referenced Methods <sup>2</sup>
INR	None

<sup>1</sup> Diabetes Control and Complications Trial. The method used for this trial is currently the internationally recognised method for standardisation of HbA1c.

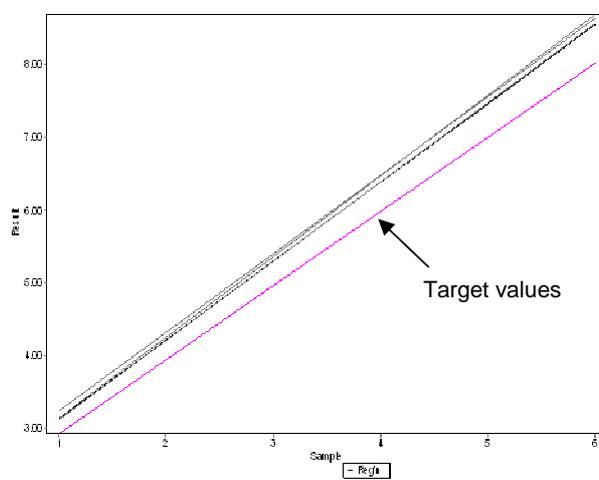
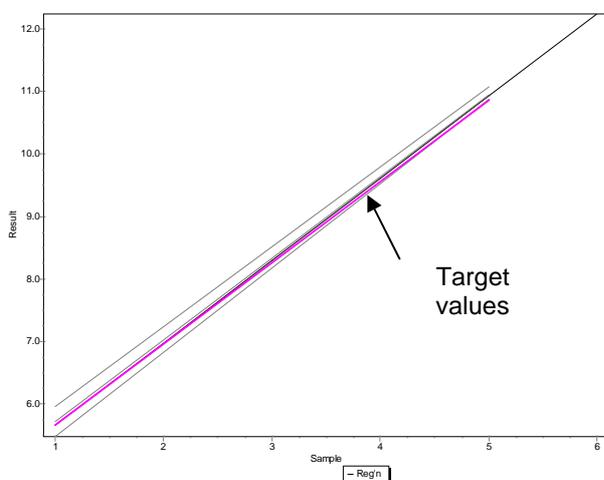
<sup>2</sup> Centre For Disease Control; Atlanta Georgia USA offers standardisation for lipid laboratories in a world wide network

The following figure (Figure 9) shows the linear regression lines for the three Trial cycles compared with the target values.

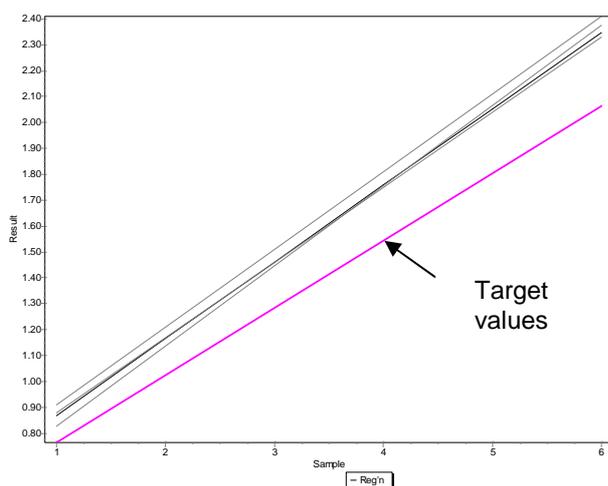
**Figure 9: Comparison of target and median value linear regression lines**

**HbA1c Target and Cycle Linear Regressions**

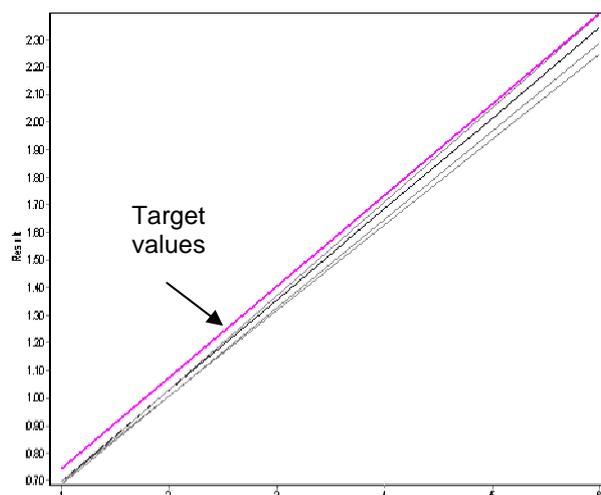
**Cholesterol Target and Cycle Linear Regressions**



### HDL Cholesterol Target and Cycle Linear Regressions



### Triglycerides Target and Cycle Linear Regressions



#### Comments:

- HbA1c: the Trial results compared to the target values are within acceptable limits for the first five concentration levels. There is a discrepancy with the highest concentration level which appears to be an error in the assigned target value
- Total cholesterol: the Trial results show a significant positive bias over all concentration ranges
- HDL-C: the Trial results show a proportional positive bias over the concentration ranges. This has been observed in other quality assurance programs
- Triglycerides: the Trial results compared to the target values are within acceptable limits

#### 5.5.3.3. Imprecision

The hypothesis to be tested was: In terms of precision, all PoCT practice results meet the required QA performance levels for the pathology laboratories.

##### a. Definitions

The standard deviation (SD) used in the RCPA QAP statistics is the standard error of the estimate  $S_{y,x}$  and can be regarded as the average standard deviation across the range of concentrations analysed. The coefficient of variation (CV%) is the standard deviation divided by the midpoint of the concentrations, expressed as a percentage. The CV% values reported for all participants is the median (central value) of the within practice CV % of individual practices.

b. Comparison with quality goals

The quality specification goals for imprecision were set by the Trial Steering Committee (see Table 64). Goals were not set for INR but an imprecision goal of 10% is considered as one which will not affect patient care.

**Table 64: Comparison of median within-practice imprecision and quality goals**

Test	Imprecision goal	Cycle 1	Cycle 2	Cycle 3	Average
HbA1c	4%	2.9%	2.4%	2.4%	2.6
Urine Albumin	10%	3.6%	4.8%	5.6%	4.7
Urine Creatinine	6%	3.8%	3.7%	3.7%	3.7
Urine ACR	12%	3.1%	2.4%	2.9%	2.8
Total cholesterol	5%	6.0%	6.1%	5.1%	5.7
HDL-C	6%	6.3%	7.6%	6.0%	6.6
Triglycerides	7.5%	7.5%	6.5%	6.1%	6.7
INR	10%	7.2%	7.1%	7.2%	7.2

Comments:

- HbA1c met the minimum and desirable analytical goal for all three cycles
- urine albumin, urine creatinine and urine ACR were well within the optimal analytical goals for all three cycles
- total cholesterol was just acceptable for the minimum analytical goal of 5% for one of the three cycles but exceeded the minimum goal for two cycles
- HDL-C was acceptable for the minimum analytical goal for one of the three cycles but exceeded the minimum goal for two cycles
- triglyceride met the desirable analytical goal for the three cycles but did not attain the optimal goal of 5%
- INR – it is considered that this level of imprecision would not affect the treatment of a patient.

Further information can be gained by looking at the percentage of practices that were able to attain the imprecision goals for each analyte (Table 65).

**Table 65: Percentage of practices able to attain the imprecision goals**

Test	Cycle 1	Cycle 2	Cycle 3	Overall
HbA1c	92.6	88.9	96.3	92.6
Urine Albumin	77.8	92.6	96.3	88.9
Urine Creatinine	85.2	81.5	85.2	84.0
Urine ACR	100.0	96.3	96.3	97.5
Total cholesterol	40.7	25.9	48.1	38.3
HDL-C	48.1	33.3	48.1	43.2
Triglycerides	51.9	48.1	59.3	53.1
INR	70.4	66.7	70.4	69.1

Urine ACR had the highest percentage of practices attaining the imprecision goals followed by HbA1c and INR. Total cholesterol, HDL cholesterol and triglycerides showed the poorest percentage.

c. Comparison with other QA programs

A comparison was performed using the relevant laboratory RCPA Quality Assurance Program Pty Ltd, the RCPA Near Patient Testing Program and the QAAMS Program (Table 66). The average of the CV% for the three PoCT cycles was used.

**Table 66: Median coefficient of variation (%) of PoCT Trial results and other QA programs**

Test	PoCT Trial	RCPA QAP (labs <sup>1</sup> )	RCPA QAP (Near Patient Testing <sup>2</sup> )	QAAMS
HbA1c	2.6	2.6	-	3.2
ACR	2.8	-	-	2.5
Total cholesterol	5.7	2.4	3.0	-
HDL-C	6.6	3.7	5.0	-
Triglycerides	6.7	3.1	8.2	-
INR	7.2	4.8	6.0	-

<sup>1</sup> All instruments

<sup>2</sup> Equivalent instruments to those being used in the PoCT Trial

The Trial CVs were comparable with laboratory or other applicable quality assurance programs for HbA1c and urine ACR. Triglycerides were higher than the laboratory program but less than the

Near Patient Testing program whilst total cholesterol, HDL cholesterol, and INR were higher than both comparator programs.

## 5.6. DISCUSSION

Interest in the medical science discipline of PoCT in Australia has blossomed over the past decade. Large-scale national models such as the QAAMS PoCT program for diabetes management in Aboriginal and Torres Strait Islander medical services has provided a sound evidence base for the analytical, clinical and cultural effectiveness of PoCT in this most challenging of primary health care environments.<sup>48, 68, 71</sup> While local PoCT models have been developed for use in the Australian rural general practice environment<sup>47</sup>, the evidence base for the usefulness of PoCT in general practice both within Australia and globally has thus far been limited.<sup>3, 13</sup>

The objectives of this component of the PoCT Trial in General Practice were to develop, deliver and manage both:

- a structured training program for Device Operators from participating general practices, with concomitant ongoing assessment of operator competency, and
- internal quality control and external quality assurance programs (both aided by additional quality management support services)

to allow PoCT to be conducted safely for patient care and with an acceptable standard of analytical quality.

With this systematic approach and quality framework in place, it was possible to address and answer the hypotheses posed in this component of the Trial.

Hypothesis 1: All designated staff in the PoCT practices met the required competency level to perform PoCT.

The results of this Trial confirmed that practice staff met the required competency levels to perform PoCT across the life of the Trial, as evidenced by the observations that:

- all operators passed their initial competency assessment prior to commencement of routine PoCT
- only one Device Operator had their competency revoked during the live phase of the Trial due to poor participation and poor analytical performance, as judged by the results of IQC and EQA testing
- the monthly between-practice imprecision recorded for all PoC tests remained relatively stable across the entire Trial period.

Hypothesis 2: All PoCT practices obtained IQC results within the acceptable performance range (that is, the performance standards for IQC testing by practices met the analytical goals for imprecision set for the Trial).

Device Operators conducted internal quality control testing to an acceptable analytical standard, as evidenced by the median within-practice imprecision meeting the analytical goals for imprecision set for the Trial for all PoC tests (except for HDL-C, where observed performance was outside the minimum required goal for one level and one lot number of QC).

Overall, greater than 80% of practices achieved the imprecision goals for the Trial for all analytes and lot numbers of QC material used, except for HbA1c Level 2 for both lot numbers (73% and 67%) and HDL-C (LN 5082 Level 1 58% and LN 5230 Level 1 33% and Level 2 63%).

Hypothesis 3: In terms of accuracy, all PoCT practice results meet the required quality assurance performance levels for the pathology laboratories (that is, practices obtained accurate results from EQA testing).

The accuracy of the EQA results was assessed by three methods:

- calculating the percentage of EQA results that were considered to be clinically acceptable. For all tests the acceptable results (green) ranged from 84% (total cholesterol) to 98% (urine ACR). This is considered to be acceptable external quality assurance performance
- comparison with other relevant EQA programs for HbA1c demonstrated that the spread of results and number of outliers was equivalent or less for the Trial practices when compared with another equivalent PoCT program and the pathology laboratory program
- comparison of the results with target values set using internationally recognised reference methods for HbA1c, total cholesterol, HDL cholesterol and triglycerides. HbA1c and triglycerides were within acceptable limits. Total cholesterol and HDL cholesterol practice results were higher than the target values. This was most likely due to the QAP material (See the Limitations discussion below).

Overall, the PoCT practice results were considered to have an acceptable level of accuracy when compared to pathology laboratories.

Hypothesis 4: In terms of precision, PoCT practice results meet the required quality assurance levels for the pathology laboratories (that is, the performance standards for EQA testing by practices met the analytical goals for imprecision set for the Trial).

The precision of the external quality assurance results was assessed by:

- comparison with quality goals. Using the median (50<sup>th</sup> percentile) CV% of all practice results, HbA1c, urine ACR, triglycerides and INR met the quality goals. Total cholesterol and HDL cholesterol did not meet the quality goals
- a further analysis of the percentage of practices that were able to meet these quality goals shows an acceptable performance for HbA1c and urine ACR. INR (69.1%), would be borderline and triglyceride (53.1%), HDL-cholesterol (43.2%) and total cholesterol (38.3%) unacceptable
- comparison with other relevant EQA programs demonstrated that HbA1c and urine ACR had the same performance level. However total cholesterol, HDL-cholesterol and INR performed poorer than equivalent programs. Triglyceride performance was better than an equivalent Near Patient Testing Program but poorer than the laboratory program.

Overall, the PoCT practices results were able to meet the analytical goals for HbA1c and urine ACR. The other tests, particularly total cholesterol and HDL cholesterol, were not able to meet all assessments of quality.

Comparisons with other studies

The methods for training, competency and quality assessment developed by the PoCT Device Group for use in this Trial were consistent with those:

- used successfully in PoCT programs for chronic disease management in the Aboriginal community setting in Australia, notably the QAAMS and Point-of-Care Testing in Aboriginal Hands Programs<sup>68, 70</sup>

- recommended for PoCT by The International Organisation for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI) [formerly the National Committee for Clinical Laboratory Standards (NCCLS)].<sup>98, 100</sup>

The overall workshop program, the use of interactive small group sessions for practical training managed by medical scientists and supported by industry, and the laminated poster series for day-to-day conduct of PoCT were all rated highly by Device Operators. The importance of having regular refresher training for existing Device Operators was emphasised by the positive feedback from the operators who attended this activity. The use of primary trainers with strong medical science backgrounds, experience in delivering PoCT training programs and having expertise in tailoring training methods to targeted audiences of different health professional groups contributed significantly to the success of the training program, as it done with other PoCT programs notably QAAMS.<sup>68, 69</sup> Of particular importance in this regard was the ability to translate complex laboratory terms such as accuracy, precision, quality control and quality assurance into readily understandable concepts for non-laboratory Device Operators, while at the same time adhering to the requirements of international (NCCLS/ISO) guidelines for the conduct of PoCT.

The CSLI recently published an approved guideline for the quality management of single-use PoCT devices (such as those used in this Trial), where only one sample can be performed at a time on each cartridge or strip which is then discarded.<sup>100</sup> This guideline recommends that a combination of different methods of control be used to maintain analytical surveillance of PoCT device operation and result quality. The quality management framework established for this Trial was consistent with this guideline in that internal quality control, optical testing, preventative maintenance, and EQA (the latter provided by the QAP Group) were all suitable methods to monitor analytical quality.

In terms of analytical quality, comparisons were made with other EQA programs provided by the RCPA Quality Assurance Programs. These were both pathology laboratory and equivalent PoCT programs and were used to demonstrate comparability with the number of outliers and imprecision.

### *Limitations*

#### A. Devices and IQC

The PoCT devices selected for the Trial proved user-friendly and were generally robust. Nonetheless, the 'mag read error' problem on the Cholestech LDX became a minor issue in the latter stages of the Trial while sample application was an area of concern for several operators with the CoaguChek S device. The temperature limits under which PoCT devices operated were well defined prior to the Trial (15-30°C) but, in everyday practice under Australian conditions, practice staff were confronted by the very real issue of what to do when their device would not operate under temperature extremes of heat (for the Cholestech LDX) and cold (for the CoaguChek S). This is an issue for device manufacturers in general to be conscious of when introducing PoCT technology into this country.

For HDL-C, issues arose during the Trial regarding:

- the accuracy of assigning target values for IQC material, where an 11% difference was observed between the manufacturer-set target and the mean value obtained by Device Operators for Level 1 QC LN 5082 and
- the median within-practice imprecision for HDL-C did not meet the minimum analytical goal set for the Trial for QC Level 1 LN 5230 overall, for QC Level 1 LN 5082 in urban practices and for QC Level 1 LN 5230 in rural and remote practices.

For lipid PoCT in general, two further observations warrant comment. The short expiry of IQC material necessitated three changes of lot number across the life of the Trial. A different method was used for loading IQC and patient samples into the sample well of the reagent cassette. With

IQC, a 50µL transfer pipette was used to transfer the IQC sample onto the sample well, whereas for a patient sample, a 35µL glass capillary was used.

For INR too, the steps and processes required to artificially mimic the coagulation cascade through an IQC test bore limited resemblance to patient testing procedures. Nonetheless all alternative options for INR QC remain imperfect.

#### B. Setting IQC limits

An important area for discussion is: were the IQC limits for the Trial appropriate, how should they be set in the future and what should the IQC limits be if PoCT were to be rolled out into general practice in the future?

As mentioned previously the IQC limits for the Trial were set conservatively due to concerns regarding the potential for discrepancy between the manufacturer-specified target and the mean of results obtained by PoCT operators in the Trial. As shown in Table 55 these perceived concerns were justified with discrepancies of 4% or greater between target and mean values observed for all tests across one or more lot numbers of IQC material used.

Given the real discrepancy observed between the target and mean QC values, the PoCT Device Group had three options during the Trial:

- to regularly reissue new IQC Result Sheets to general practices across the life of the Trial (with these sheets using the mean of all IQC results returned as the 'corrected or modified' target) each time a major discrepancy was observed
- to maintain the status quo and continue to use IQC Result Sheets with the target assigned by the manufacturer, acknowledging that imprecision was the key performance indicator for IQC testing and IQC limits were meant to be a guide to overall performance for Device Operators, and,
- to re-define the IQC limits mid-Trial, based on the evidence gained and the data collected.

The PoCT Device Group considered the second approach had greatest scientific and practical merit, particularly as this was less confusing and disruptive for Device Operators at participating practices. The one exception to this strategy was for HDL-C QC Level 1 LN 5082, where the difference between the target set by the manufacturer and the mean value from practices exceeded 10%. In this case a new QC Result Sheet was issued to practices (and reported to the Government in the monthly email report for November 2005). During the period when the manufacturer target value was used for this IQC, many practices were correctly (but needlessly) telephoning the PoCT Device Group help desk to report 'unacceptably high' results for this IQC when in fact their PoCT device was performing well. This created additional workload and stress for Device Operators when, in fact, they did not have an analytical problem.

The PoCT Device Group considered the third option also had some merit but decided to investigate the effect of redefining the limits internally. Using HbA1c as a test case, the effect of changing IQC limits on the percentage acceptable results was examined when both the manufacturer-assigned value and the mean of all PoCT operator results was used as a target (Table 67).

**Table 67: Effect of changing IQC limits on the percentage of acceptable QC results**

Test	QC lot number	QC warning limit	% acceptable results		Target used
			QC level 1	QC level 2	
HbA1c	27	10%	100%	91%	Manufacturer target
		7.5%	99%	74%	
		5%	94%	50%	
HbA1c	27	10%	100%	100%	Mean of all results
		7.5%	99%	92%	
		5%	94%	87%	

As reported previously in, for the HbA1c Level 2 QC for LN 27, there was a 5.6% discrepancy between the manufacturer-set value and the mean of all PoCT results. Using the manufacturer value as the target, the percentage acceptable results shifted significantly from 91% with a 10% limit to just 50% with a 5% limit. In addition, using 5% as the limit, one quarter of results (26%) would have required a 'stop' action. However, when using the mean result as target, the percentage acceptable results were 87% with a 5% limit and 100% with a 10% limit.

How should IQC limits be set post Trial? Ideally, a user-assigned target value could be set with a selected sample of practices testing a particular lot number of IQC material, returning results to a central site, a mean value established for the material and limits set around the mean. This practice is performed for target setting of EQA material where a single pool of EQA material is made to set specifications. However, this process would be too cumbersome for use in general practice where different devices and multiple lot numbers of QC material could be in field use at any one time. Therefore, the manufacturer-set target remains the most practical value to assign to IQC material but, as for this Trial, IQC limits would need to be set conservatively.

Were the IQC limits used for the Trial appropriate? The PoCT Device Group believes that, in general, the limits set for the Trial were appropriate, with the possible exception of HbA1c. For this analyte, a case for tightening the acceptable limits from 10% to 7.5% (and the warning limit from 15% to 10%) could be argued. These tighter limits have been trialled in the QAAMS Program over the past year (with the overall % acceptable, warning and action results being 85%, 12% and 3% respectively).

#### C. Analytical goals for the Trial

Were the analytical goals used for the Trial appropriate? As a general principle, analytical goals for PoC (and laboratory) tests should be flexible and continually reviewed and refined as more clinical outcome and state-of-the-art analytical data becomes available.<sup>101</sup> The PoCT Device Group believes that, in general, the analytical goals set for this Trial were appropriate, with the possible exception of urine ACR. While there have been no calls in the international literature to tighten the goals for this test, it is clear from the results of this Trial that the goals set were readily achieved, with greater than 75% of practices recording an imprecision well within the optimal goals set. In the national QAAMS Program, the median imprecision achieved by Aboriginal Medical Services for urine ACR testing has averaged 4.4% over the past three years.<sup>69</sup> It is therefore the view of the PoCT Device Group that the analytical goal for urine ACR should be tightened to 8% for imprecision and 10% for total allowable error.

#### D. EQA Assessment of Accuracy

In assessing accuracy it is ideal to compare the values obtained from the instrument under consideration with target values which have been set using international reference methods or

reference standards. The assumption is made when doing this that the EQA material will perform in the same manner as patient samples. This is not always the case as the processing and lyophilisation of the EQA material can result in structural changes to the lipoproteins.<sup>102</sup> When this occurs the results obtained from the EQA material do not show the same accuracy as those obtained from a patient comparison. This is referred to as a matrix effect.

In the comparison of the EQA results with target values total cholesterol and HDL-cholesterol EQA results were higher than the target values. This is inconsistent with phase I comparison of PoCT and pathology laboratory test results in which the PoCT results were less than the pathology laboratory results. It is considered that this was due to a matrix effect of the EQA material and the accuracy comparison using the EQA material and target values should not be used.

#### *E. EQA Assessment of Imprecision*

The percentage of practices able to attain the imprecision goals for total cholesterol, HDL cholesterol and triglycerides was very low. This was not related to the matrix effect described above but may be due to factors with the Cholestech instrument that was used to measure these tests.

Possibilities that should be considered are an inherent imprecision in the Cholestech method or the different manner in which the QA samples were introduced. A pipette is required to introduce IQC or EQA samples into the Cholestech instrument in contrast to the whole blood in a capillary for patient samples. Different skills were required for pipetting than for patient collection. This was not investigated further.

It is possible that a newer generation of lipid testing instruments would be able to achieve the imprecision goals.

## **5.7. CONCLUSION**

The methods established for the implementation and delivery of training, competency assessment, IQC and EQA programs were deemed appropriate for the General Practice Trial. Results from both IQC and EQA testing indicate that, in general, PoCT Device Operators conducted PoCT to an analytically acceptable standard, with the exception of HDL cholesterol (for IQC testing) and lipids (for EQA). For these tests, issues relating to technical handling of quality samples and possible matrix effects (for EQA) may have contributed to the relatively poorer performance observed.

## 6. SAFETY OF PoCT IN GENERAL PRACTICE PART 2 - STANDARDS AND ACCREDITATION FOR PoCT IN GENERAL PRACTICE

### SUMMARY OF THE CHAPTER

This chapter describes the evaluation of the (Interim) Standards for PoCT in General Practice and the accreditation program developed for the Trial. As part of the analysis of the safety of PoCT in general practice, the results of practice compliance with the (Interim) Standards were also reviewed.

The key findings of the chapter are:

- a Working Group developed the PoCT accreditation program based on the (Interim) Standards for PoCT in general practice
- the accreditation program included: development of resources for practices participating in accreditation; development of an assessment process; and assessment through a site visit by a survey team and report on the outcome of the site visit
- for the first round of accreditation, 90% of practices passed, 1 of the 3 practices which did not comply with the requirements subsequently met the criteria and was accredited. The remaining 2 practices voluntarily withdrew from the Trial
- for the second round of accreditation, 100% of the practices complied fully with accreditation requirements
- evaluation of the accreditation process indicated that practices and members of the survey team found the process appropriate
- in terms of the (Interim) Standards, these were seen as realistic and achievable for general practice
- accreditation surveyors reported that the (Interim) Standards provided an achievable minimum standard for general practice
- GPs and Device Operators found the (Interim) Standards applicable and relatively easy to use.

The key conclusions are:

- the accreditation program developed by the Trial, based on the (Interim) Standards for PoCT, provided an acceptable framework for evaluating quality management for PoCT
- practices were able to meet the (Interim) Standards and obtain accreditation
- the (Interim) Standards for PoCT in general practice were acceptable to GPs and Device Operators and members of the survey teams.

### 6.1. INTRODUCTION

The National Pathology Accreditation Advisory Council (NPAAC) is responsible for developing the standards against which the process of inspection and accreditation of pathology laboratories is assessed. Point of Care Testing in general practice is generally undertaken as an adjunct to existing

pathology services and should also be conducted within a framework of quality standards and accreditation.<sup>27, 103</sup> Anecdotal evidence suggests that this may not be the case, and that PoCT in general practice is often undertaken outside of any formal quality management process unless the practice voluntarily opts to participate. Where such a framework is tailored to recognise the resources of non-laboratory environments such as general practice, there should be confidence that the quality of test outputs is the same as for PoCT performed by the traditional pathology laboratory. This is important given that any pathology testing done or ordered by the practitioner clearly underpins the clinical decision-making process and that quality of patient care should always be the highest priority.<sup>103</sup>

A key aspect of the Trial was to ensure that an effective quality management program was developed and implemented to assure quality and safety of PoCT undertaken by participating practices. Requirements of the quality management program were included in the Trial Design.<sup>25</sup>

## **6.2. AIM AND OBJECTIVES**

The aim of this chapter is to address the research question: Is it safe to perform PoCT in a general practice setting focusing on the Accreditation and Standards for PoCT?

The hypothesis addressed in this chapter is:

All intervention practices meet the standards for PoCT in general practice and obtain accreditation.

An additional aim of the Trial was to explore how PoCT in general practice would work in the Australian regulatory environment for pathology testing. This includes effectiveness and applicability of the (Interim) Standards for PoCT in General Practice and evaluation of the accreditation process developed.

## **6.3. METHODS**

Methods for assuring quality and safety in the context of the Trial included the (Interim) Standards for PoCT in General Practice and the development and implementation of an accreditation program based on these Standards. Both the Standards and accreditation program were evaluated.

### **6.3.1. (Interim) Standards for PoCT in General Practice**

The (Interim) Standards for PoCT in General Practice (the Standards) were developed by the PoCT Implementation Subcommittee of the Quality Use of Pathology Committee of the Pathology Section of DoHA, following a process of consultation involving key representatives from relevant scientific and general practice groups. The Standards effectively incorporate the following:

- RACGP Standards for General Practice – against which agencies such as Australian General Practice Accreditation Ltd (AGPAL) and General Practice Accreditation (GPA) assess and accredit general practices; and
- National Pathology Accreditation Advisory Council (NPAAC) – standards against which the National Association of Testing Authorities (NATA) inspect and assess pathology laboratories.

The goal of the Standards was to ensure that PoCT did not compromise the standard of patient care and clinical decision making. The Standards:

- were tailored to recognise the resources of the non-laboratory environment
- aimed to ensure that quality of test outputs was equivalent to the traditional pathology laboratory, and

- defined the minimum standard required for accreditation of PoCT in general practice.

The Standards underpin all quality related activities in the Trial.

The Standards are grouped into 5 main areas:

1. CLINICAL GOVERNANCE: An essential first step for a practice proposing to undertake PoCT was for a designated doctor to be given primary responsibility for implementation and management.
2. ANALYTICAL REQUIREMENTS: Consideration of analytical requirements such as selection of testing devices, available space, cost of testing and Information Management. These requirements were pre-determined for the Trial but practices were assessed on these as in a real life situation.
3. STAFF TRAINING: Requirements for training and competency assessment of Device Operators including consideration of the volume of testing required in order to maintain competency and skill levels.
4. PERFORMANCE OF TESTING: The use of internal quality control (QC) and enrolment in an external proficiency testing program (QA) provided a real-time assessment of the PoCT instrument and consumables (QC) and allowed the practice to compare its performance with other practices (QA).
5. QUALITY of HEALTHCARE OUTCOMES: including clinical accountability, evidence-based best practice, clinical and cost-effectiveness and audit to safeguard the continuous improvement of patient care.

### 6.3.2. Evaluation of the Standards

It was considered important to evaluate the effectiveness and applicability of the Standards to assist in determining how PoCT in general practice might fit in the broader regulatory environment. To achieve this, PoCT accreditation surveyors participated in a telephone interview as part of the evaluation of Round 2 of the Accreditation Program and GPs, Device Operators and Practice Managers were asked about the Standards as part of a satisfaction survey conducted following completion of the Trial.

#### 6.3.2.1. Surveyor feedback

As part of the evaluation of Round 2 of the Accreditation Program, a section was included specifically on the (Interim) Standards for PoCT in General Practice. Given the specific training in the Standards provided for accreditation surveyors and their practical involvement in assessing practices for accreditation against the Standards, it was considered that this group would provide useful insight. Areas covered in this evaluation included Individual Standards 1 – 5 and general comments.

Data was collected on these areas through semi-structured telephone interviews with members of the teams undertaking the PoCT practice accreditation survey visits, e.g. the GP and medical scientist. A total of five surveyors were interviewed, two scientists, two GPs and one practice representative recruited as a GP surveyor. One scientist did not respond and 1 GP did not respond. The interviews with surveyors lasted between 15-30 minutes.

A descriptive analysis was undertaken with the key themes identified from the qualitative questions. The results are summarised in Table 68.

**Table 68: Summary of surveyor responses, evaluation of the Standards**

Area	Specific topic	Results
Overall		All respondents thought the Standards provided a realistic and achievable minimum standard for PoCT in general practice.
Standard 1: Clinical Governance	Adequate for clinical safety, responsibility and accountability	4/5 respondents thought the requirements for clinical governance were an acceptable minimum standard. There were two negative responses. One respondent commented that some results were dealt with inappropriately and that <i>Pharmaco-clinical review by GP was necessary, leaving up to nurse was inappropriate</i> , whilst the negative respondent commented that <i>frequently in practice the PN was really the responsible party</i> .
Standard 2: Analytical Requirements	Suitable for GP environment	All scientists (N=2) responded no and all GPs (N=3) responded yes.  Comments from scientists indicated that they felt GP staff do not have technical knowledge to adequately select instruments and determine reference intervals, and that these processes should be streamlined for practice staff.
Standard 3: Staff Training	Requirements for training and competency assessment reasonable	All respondents agreed. One comment indicated that the Trial handled it well.
	Requirements for retraining and education updates reasonable	All respondents agreed.  One scientist suggested that the requirements were reasonable if adhered to the way the Trial ran and one commented that a lot needed a bit of <i>'over the phone' assistance/follow-up</i> .  One respondent noted that this area will be a new concept for staff, needs to be marketed properly, staff will think why needed? (GP)
Standard 4: Test Implementation	Expectations and requirements of	All respondents agreed.

Area	Specific topic	Results
and Performance	physical capacity for testing reasonable	
	Routine testing requirements adequately detailed	3/5 respondents agreed. The remaining respondents (GPs) felt they could not, or were not qualified, to comment.
	Data management expectations adequate	All respondents agreed.  One scientist noted the issue of transcription of results and the need to be well aware of this area, need to have validation of data entered into patient records.
	Overall requirements for implementation and performance of testing appropriate and applicable	4/5 respondents agreed. Comments:  Apart from selection of instrumentation and reference ranges (S)  But, need to look at standards more closely to adapt appropriately for general practices. Explain standards more, they are fine but room for improvement, streamlining, knowing deficiencies that arose in general practice (S)  Negative respondent commented that QA is the biggest hassle, making sure your test results correspond with lab standard results is difficult. QC OK (GP).
Standard 5: Quality Outcomes	Requirement for compliance with Quality Control reasonable	All respondents agreed.  One scientist thought the requirements were reasonable and not difficult, whilst one GP thought a change of culture was required for general practice staff in terms of QC, to be achievable, and felt this was a difficult aspect for practice staff.
	Requirement for compliance with External Proficiency Testing or QA program reasonable	4/5 respondents agreed.  It would be nice to think they would continue with this outside the Trial. Trial set an appropriate model, frequency satisfactory, quality targets within limits expected for general practice (S)  format might need simplification for general practice

Area	Specific topic	Results
		<p>setting. QA reports are quite complex (feedback from practices) (GP)</p> <p>The negative respondent commented that it would be very difficult to get operational (GP)</p>
	Overall requirement for quality audit of policy & procedures	<p>4/5 respondents agreed.</p> <p>One scientist agreed so long as it's monitored – audit and accreditation process associated with it.</p> <p>The negative respondent (GP) was not confident to answer, scientists area.</p>
Other comments about Standards		<p>Standards fine, they do reflect the requirements for analytical testing to manage a patient. The only issue is the selection of instrumentation and determining reference ranges (S)</p> <p>Deleted part of standard between 1st and 2nd round (about correlations &amp; before instrument in use). Appropriate audits needed for compliance if PoCT implemented in general practice (S)</p> <p>No GP comments.</p>
General comments		<p>While the Standards should not be compromised it is an onerous task for general practice. Another PoCT model involving path labs undertaking QA for practices might work for this setting (GP)</p> <p>INRs valued most by practices (GP)</p> <p>No scientist comments.</p>

Overall, all surveyors thought the Standards provided a realistic and achievable minimum standard for PoCT in general practice. There was some difference in response by type of surveyor, particularly in relation to analytical requirements (selection of instruments and reference intervals) and test implementation and performance, where GPs felt unqualified to answer.

With reference to Standard 2, all scientists thought that the analytical requirements were not suitable for the GP environment; however, all GPs thought they were. Comments from scientists indicated that the selection of instruments and determination of reference intervals required more technical knowledge than practice staff had, and that these requirements should be streamlined.

For the purposes of the Trial, instruments were selected and reference intervals determined for practices.

Specific comments from scientists indicated that, overall, it was felt that practice staff had the required support and assistance to meet the Standards and that since some components of the Standards were predetermined for the Trial they might require review with a view to simplification. Overall, it was felt that PoCT in general practice should be monitored.

Specific comments from GP surveyors indicated that some components of the Standards were quite complex and onerous for general practice, particularly QC and QA, and might be difficult to implement in practice. One GP thought QA was *the biggest hassle*, whilst one thought QC was a *difficult aspect for practice staff*. It was also noted that PoCT would be a new concept as would the specific training and ongoing requirement for education updates.

### 6.3.2.2. GP and Device Operator feedback

At the end of the Trial, GP and Device Operators were asked to complete a satisfaction survey. As part of this survey, GPs and Device Operators in the intervention practices were asked to rate their ease of use of the Standards using a visual analogue scale (VAS) and to assess the applicability of the various sections of the Standards.

Descriptive analysis of these questions and for the rating of the ease of use of the Standards, a median score was calculated. A total of 55 questionnaires from the Device Operators was analysed and 100 from the GPs.

From a score out of 10, Device Operators gave a median score of 7.8 for ease of use of the (Interim) Standards for PoCT, while GPs rated the ease of use of the Standards as 6.9 (Table 69).

**Table 69: Median VAS score for ease of use of interim standards by intervention GPs and device operators**

Statement	GPs	Device Operators
Ease of use of (Interim) Standards: Median (IQ range)	6.9 (6.0-8.4)	7.8 (6.5-8.7)

GPs and Device Operators were asked to determine if the following parts of the Standards were applicable to GP. The results are shown in Table 70. Across the board, the majority of Device Operators reported that the PoCT Standards were applicable to general practice. The areas they rated as most applicable were staff training (90.0%) and implementation and performance (87.3%) (Table 70).

Over half of the GPs thought that the areas related to clinical governance (59%) and analytical requirements (61%) were applicable to general practice. For GPs, the majority reported that the Standards relating to staff training (79%) and implementation and performance (78%) were the areas most applicable to general practice (Table 70).

**Table 70: Applicability of the PoCT standards to general practice by GPs and device operators**

Area of the PoCT standards		GPs		Device Operators	
		N=100		N=55	
		Freq	%	Freq	%
Clinical governance	No	3	3.0	0	0
	Yes	59	59.0	39	70.9
	Unsure	32	32.0	12	21.8
	Missing	6	6.0	4	7.3
Analytical requirements	No	2	2.0	0	0
	Yes	61	61.0	40	72.7
	Unsure	31	31.0	11	20.0
	Missing	6	6.0	4	7.3
Staff training	No	2	2.0	1	1.8
	Yes	79	79.0	50	90.0
	Unsure	13	13.0	1	1.8
	Missing	6	6.0	3	5.5
Implementation and performance	No	1	1.0	0	0
	Yes	78	78.0	48	87.3
	Unsure	15	15.0	2	3.6
	Missing	6	6.0	5	9.1
Quality outcomes	No	1	1.0	0	0
	Yes	71	71.0	43	78.2
	Unsure	22	22.0	8	14.5
	Missing	6	6.0	4	7.3

A number of comments were also made by the Device Operators regarding the accreditation process:

*although a bit daunting at the start was great to reinforce our procedures and processes. Also a great time to ask questions which were readily and competently answered*

*no, accreditation process was fine*

*I think the accreditation process and including Standards, quality assurance and quality control was all monitored very efficiently and effectively.*

### 6.3.3. Accreditation program

#### 6.3.3.1. *Development*

The PoCT Trial accreditation program was the culmination of a broad quality management system based on different sets of standards developed by and for different professional disciplines, effectively encompassed in the (Interim) Standards for PoCT in general practice.

PoCT should be conducted within a framework of quality standards and accreditation, and the program developed for the Trial needed to bring together the two different standards frameworks of general practice and pathology to develop a method that would be relevant and applicable to the general practice environment. It was therefore important to involve both disciplines in development of the accreditation process, so a Working Group was established to achieve this. The Working Group included a GP with experience as an accreditation surveyor, scientists with both Point of Care Testing experience and laboratory backgrounds, and a Trial representative with practice management experience.

The Working Group developed the PoCT accreditation program including establishing a timeline for implementation, review of the existing Standards, development of all related documentation to support the process, identification of roles and responsibilities for surveyors, selection criteria for recruitment and surveyor training.

#### 6.3.3.2. *Timeline and Process*

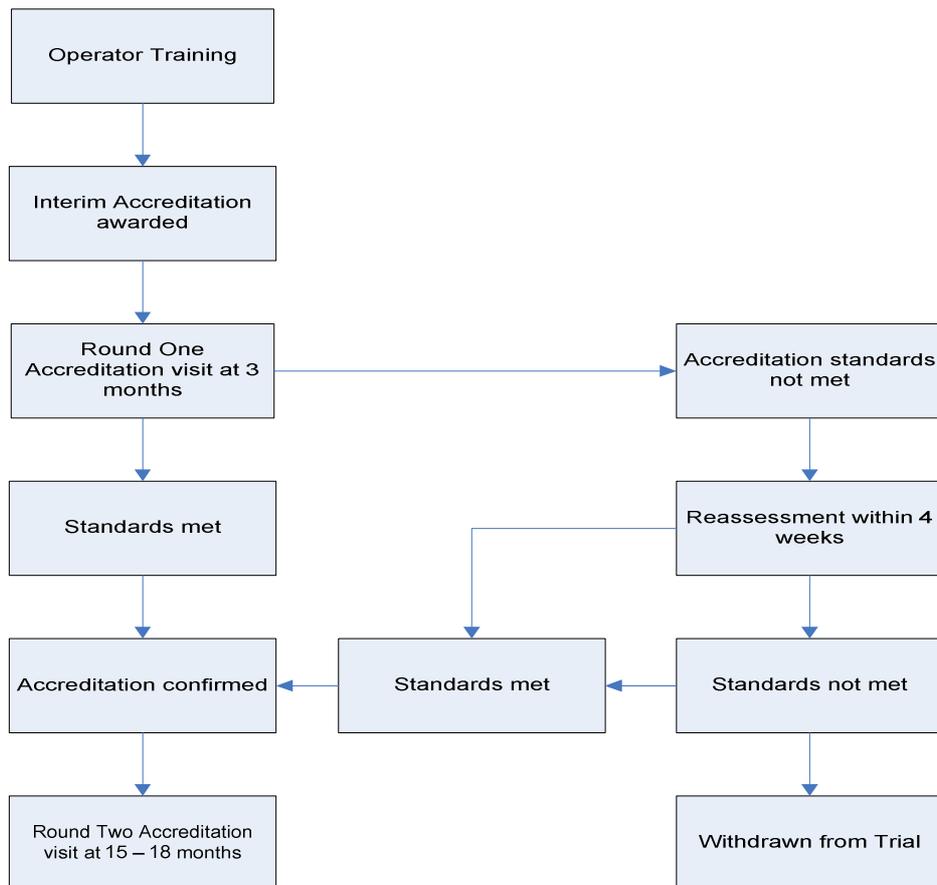
A timeline (see Figure 10) was defined early in the Trial for establishing and implementing the PoCT accreditation program. Practices needed to be aware of the requirements of PoCT accreditation and willing to commit to them as part of their agreement to participate in the Trial. The process involved training for Device Operators after which interim accreditation was awarded. The first accreditation visit was undertaken after three months of testing to allow practices time to set up their testing sites and implement the process of testing. Accreditation was confirmed (or not) following this visit and a second accreditation visit followed at between 15 and 18 months, but prior to completion of Phase II of the Trial.

Practices that did not achieve accreditation at the first visit were given an opportunity to resolve any issues and undertake a reassessment within a four week period. If accreditation was still not obtained following the reassessment and the Standards remained unmet, the practice was to be withdrawn from the Trial. No practices were withdrawn from the Trial.

#### 6.3.3.3. *Review of the Standards*

The Standards firstly required reformatting into a more visually appealing document for reference as part of the PoCT Trial protocol, and secondly review and transcription into a user-friendly resource for use by practices and surveyors. Significant consideration was given to the practical implementation of the Standards as opposed to the provision of a theoretical background. Each area of the Standards and each individual criterion was therefore reviewed and incorporated into a range of supporting documentation to be used by practices to prepare for the Trial and surveyors in undertaking the on-site accreditation visits.

**Figure 10: PoCT Trial accreditation process flowchart**



#### 6.3.3.4. Supporting documentation

A comprehensive series of easy-to-use resources, based on the Standards, was developed to support the various aspects of the accreditation process, including how to prepare for the accreditation visit and what to look for as a surveyor.

To enable practices to prepare for the accreditation visit, a checklist was developed which provided detail about how the visit would be conducted and how long it might take, expectations for achievement of each criterion and how each criterion would be assessed.

A Guide for Surveyors was designed to provide background and an overview of each of the areas of the Standards, together with a description of realistic expectations of PoCT in the context of the Trial. The Guide also supported a surveyors' checklist, which was designed to be used when conducting the accreditation visit at the practice.

#### 6.3.3.5. Surveyors

The Working Group identified the need to have a multidisciplinary team of accreditation surveyors, incorporating a scientist and a GP to undertake the survey visit itself, together with a Trial Management Team representative to co-ordinate the visit and ensure that the outcomes were appropriately relayed to the practice and documented for reporting purposes. Roles and responsibilities of these surveyors were determined according to the assessment requirements of the Standards. Selection criteria were then developed for each role.

Requirements for surveyor training were developed and included a summary of the Trial and its purpose, provision of a full copy of the (Interim) Standards for Point of Care Testing in General Practice, a copy of the Guide for Surveyors and Surveyors' Checklist and Practice Checklist. It was not possible to undertake face-to-face training with surveyors before the first round of visits because of the diversity of location of surveyors and time constraints arising from difficulty with surveyor recruitment. This was addressed prior to Round Two visits. Training for Round One comprised a teleconference between individual surveyors, the Trial Manager and the Chair of the Accreditation Working Group. The teleconference followed circulation of the relevant documentation which was required pre-reading.

Expressions of interest (EOI) were called for Surveyors interested in participating in the PoCT accreditation program. GP EOI were called through Divisions of General Practice which were asked to include a promotion item in their regular practice information fax. Scientist EOI were called via an Australian Association of Clinical Biochemists (AACB) newsletter. A total of 26 expressions of interest were received from Scientists (Table 71) but only three from GPs together with one enquiry from a Practice Manager. Of the three GP EOI, 2 were from urban Adelaide and one from remote NSW, creating a significant problem in development of surveyor teams for Victoria. It had been agreed that if there was not enough GP interest, Practice Managers interested in participating and who could take on the GP role in the surveying team, would be considered as an alternative. As a result, a Practice Manager was recruited from remote Victoria and joined the other three surveyors. Of the 26 EOI received from scientists, five were from rural/remote areas and of these, one was recruited from SA and one from Victoria. Urban scientist surveyors were recruited from NSW, SA and Victoria.

**Table 71: Surveyor expressions of interest by location**

Type	State	Urban	Rural/Remote	Total EOI	Number recruited
Scientist	NSW	2	1	3	1 urban
	ACT	1	0	1	nil
	QLD	3	0	3	nil
	SA	3	1	4	1 urban/1 rural
	VIC	4	3	7	1 urban/1 rural
	WA	8	0	8	nil
	Subtotal		21	5	26
GP	SA	2	0	2	2 urban
	NSW	0	1	1	1 remote
	Subtotal	2	1	3	
Other	VIC	0	1	1	1 remote
Total		23	6	29	

Surveyor teams were prepared dependent upon surveyor availability and location and seven teams were required to cover all the regions (Table 72). Nine surveyors participated in Round One and seven surveyors participated in Round Two, two withdrawing citing work pressure.

**Table 72: Surveyor teams and regions covered**

State	Location	Teams
NSW	Dubbo region	1
	Broken Hill region	1
Victoria	Bendigo region	1
	Colac region	1
SA	Adelaide	2
	Iron Triangle	1

#### 6.3.4. Implementation of the Accreditation Program

##### 6.3.4.1. Round One

Round One accreditation survey visits were conducted through November and December 2005 following around three months of testing in the practice. Following early practice withdrawals, 30 intervention practices commenced PoCT and needed to meet the requirements of the Standards. These 30 practices were surveyed over a 3 week period, with each visit taking 1½ - 2 hours plus travel. Significant travel was required for the regional areas, particularly remote outback NSW, which took almost a full week to complete.

Following the visit a comprehensive summary report and detail of achievement of individual criteria was provided. Verbal feedback was also given at the time of the visit. A Certificate of Accreditation was awarded to those practices that met the Standards.

##### 6.3.4.2. Round Two

Round Two accreditation survey visits were conducted in October and November 2006. Following withdrawals after Round One, 27 intervention practices remained in the Trial. Of these 27 practices, one decided to withdraw at the time of the second accreditation visit and although a visit was undertaken this practice has not been included in the results. Additional time was allowed for survey visits given that there were more patient records and test results to review than at Round One visits; each visit took between 2 – 2½ hours to complete plus travel.

As with the first round of visits, a comprehensive summary report was provided for the practice following the visit, with immediate verbal feedback also being given.

##### 6.3.4.3. Outcomes of accreditation visits

The outcomes of both accreditation visits are shown in Table 73. A total of 27 (90%) of 30 practices passed the first visit and all 26 (100%) passed the second visit. At the first visit a total of three practices did not comply with the requirements of the Standards; however, one of the three subsequently met the criteria and was accredited. The remaining two practices withdrew from the Trial voluntarily after recognising that they were unable to meet the requirements. Of the 27 practices that complied fully at the first visit, two had required follow-up for a number of issues including low patient throughput, incomplete or tardy documentation, set up of testing area and clinical governance issues.

All urban practices complied fully at the first accreditation visit (Table 73) while nearly 90% of rural practices but just less than 70% of remote practices complied. All practices in all regions complied fully at the second visit (Table 73).

**Table 73: Outcomes of first and second accreditation visits by region**

Accreditation visit	Outcome	Geographic location							
		Urban		Rural		Remote		Total	
		N	%	N	%	N	%	N	%
First visit	Complies fully	8	100	8	88.9	9	69.2	25	83.3
	Complies but requires review	0	0	0	0	2	15.4	2	6.7
	Not comply	0	0	1	11.1	2	15.4	3	10
	Total	8	100	9	100	13	100	30	100
Second visit	Complies fully	8	100	7	100	11	100	26	100
	Not comply	0	0	0	0	0	0	0	0
	Total	8	100	7	100	11	300	26	300

Overall, the surveyors agreed that most practices had adopted the new technologies effectively and were working within the Trial protocol and Standards. Common issues identified at Round One visits across many practices but not affecting the accreditation outcome were as follows:

- action taken for any QC/QA results out of range (outliers) was not being documented at the practice level as confirmation that action had been taken on outliers
- QA reports were not being initialled and dated following review by the primary PoCT operator as confirmation that they had been read, and
- consumables inventory not being maintained.

Some practices found clinical governance a major challenge and this was of greater concern to the Trial Team. Issues included recruitment of patients who did not meet the selection criteria, incorrect frequency of testing and lack of time available to the key GP for monitoring and review of PoCT procedures, patient results and QC/QA reports.

#### 6.3.5. Evaluation of Round One of accreditation process

An evaluation of Round One of the accreditation process was undertaken upon completion of the first accreditation visit. The evaluation was divided into two parts focusing on different aspects of the accreditation process. The first part evaluated the process from the survey team's perspective and the second part from the practice perspective.

Areas covered in the evaluation included:

- documentation and preparation for accreditation
- the accreditation visit, and
- feedback provided.

Data was collected on these areas through semi-structured telephone interviews with practice staff involved in the accreditation survey (GPs, Device Operators and Practice Managers) and the members of the survey teams (GP, Trial Management representative and Medical Scientist).

The interviews with surveyors lasted between 15-30 minutes and with practices 5-10 minutes, and were conducted after the visit and after the practice received the written report.

A descriptive analysis was undertaken with the key themes identified from the qualitative questions.

#### 6.3.5.1. Surveyors

A total of 15 surveyors were interviewed, 3 GPs, 5 scientists, 6 Trial Management representatives and 1 practice representative. Overall there was no difference in the responses to the questions by type of surveyor.

Overall, the evaluation from the surveyors' perspective indicated that:

- the survey team was provided with appropriate documentation for the visits
- the team composition was appropriate and for most visits the time allowed was sufficient, and
- the entire process was well organised.

Areas identified for improvement by the surveyors included:

- opportunity for survey team to meet prior to the practice visit to review documents and responsibilities
- that all necessary practice staff be available for the visit so the need for follow-up contact would not be necessary
- device training sessions should cover all the requirements of the Standards for PoCT in General Practice, and
- all staff involved in PoCT are included in the visits and verbal feedback sessions at the end of the accreditation visit so that all staff are aware of the Standards and requirements and to also allow for queries to be addressed face-to-face.
- Practices

A total of 63 practice staff were interviewed, 24 GPs (38.1%), 20 Device Operators (31.7%) and 19 Practice Managers (30.2%). Three were non-responders. The results are summarised below in Table 74.

**Table 74: Summary of practice responses, first round of PoCT accreditation process, March 2006**

Area	Specific Topic	Results
Documentation and preparation	Usefulness of initial training as introduction to accreditation	<p>The majority of respondents found the training a very useful introduction to the accreditation process.</p> <p>Several respondents felt that the initial training session contained too much information and so was very intense. However, once they commenced PoCT in the</p>

Area	Specific Topic	Results
		practice, the information was more useful.
	Accreditation checklist	The majority of respondents found the checklist very useful, clear and straightforward. One respondent reported that they required clarification from Trial management as they were not used to language used in the Standards.
	Overall adequacy of training and documentation provided	54/63 (85.7%) of respondents rated the training and documentation as good to very good.
	Suggestions for improvement	<p>Whilst most practice staff did not make any suggestions for improvement, some suggestions provided included:</p> <p>broad overview only in training;</p> <p>earlier dissemination of information; and</p> <p>contradiction between training information and surveyor's information regarding QA needed to be resolved.</p>
Accreditation visit	Appropriateness of surveyor team e.g. skills, size etc.	54/63 practice staff (85.7%) reported that the survey team contained an appropriate mix of skills and size. Several respondents felt the size of the survey team was too large and therefore imposing and intrusive. It was also reported that some members lacked some knowledge.
	Sufficient time for visit	55/63 (87.3%) of respondents reported that sufficient time had been provided for the visit.
	Questions appropriate	56/63 (88.9%) of respondents reported that the questions posed by the survey team were appropriate. One respondent commented that some members of the team lacked an understanding of the GP environment.
	Problems during visit	62/63 respondents reported no problems during the practice visit. The one problem identified was the absence of the Device Operator during the visit.
	Suggestions to improve	Suggestions for improvement included:

Area	Specific Topic	Results
	feedback	<p>timing - organise visit around suitable time for practice e.g. lunchtime and when relevant staff are present</p> <p>more time allocated for the visit to allow for a longer discussion</p> <p>smaller accreditation team and</p> <p>more appreciation of role of practice in the Trial.</p>
Feedback	Verbal feedback at end of visit	Most respondents found the verbal feedback very useful as it clarified issues and provided reassurance that practices were carrying out the correct procedures.
	Usefulness of written feedback	Of those who responded to this question (95%), all of them rated the written feedback as somewhat useful to very useful. Most of those who did not respond did so because they had not seen the written feedback.
	Gaps in feedback provided to practices	<p>The majority of respondents reported no gaps in the feedback provided - <i>'very professional'</i>.</p> <p>However, some suggested that the written feedback did not incorporate individual issues discussed during the accreditation visit.</p>
	Suggestions to improve feedback	<p>Some suggestions to improve the feedback process included:</p> <p>all relevant staff should be present for the verbal feedback</p> <p>more comprehensive written summary and</p> <p>provision of reports sooner after the visit and by email.</p>
General comments		<p>Most practice staff commented positively on the process, including the organisation of the process.</p> <p>One practice member felt the process was good compared to other accreditation processes.</p>

Overall, the evaluation from the practice perspective indicated that:

- the process was very streamlined and
- survey visit and verbal feedback provided were important in reassuring the practices that they were doing things correctly and allowed clarification of processes.

Areas identified for improvement by the practice included:

- smaller survey team
- more notice of visit and dissemination of information and
- better timing of visit.

The evaluation of the first accreditation visit indicated that all participants (surveyors and practices) found the process fairly straightforward and clear. Most areas identified as requiring improvement related to the organisation of the visits, particularly the short notice given for the visit. The practices found the visits important in terms of reassuring them of their processes as well as providing an opportunity to clarify issues. The survey team seemed to be the right mix and size, although a minority found it too large.

#### 6.3.6. Evaluation of Round Two of accreditation process

An evaluation of Round Two of the accreditation process from the surveyor's perspective was undertaken upon completion of the Trial.

Areas covered in the evaluation included:

- documentation and preparation for accreditation
- the accreditation visit and
- feedback provided.

In addition, a section was included specifically on the (Interim) Standards for PoCT in General Practice. Areas covered in this evaluation included:

- individual Standards 1 – 5 and
- general comments.

Data was collected on these areas through semi-structured telephone interviews with the members of the teams undertaking the survey visit e.g. the GP and medical scientist. The Trial Management representative was not interviewed as part of this process since they no longer had an active role in the assessment of criteria as part of the visit, and surveyors who did not participate in Round Two were not interviewed. A total of 5 surveyors were interviewed, 2 scientists, 2 GPs and 1 practice representative recruited as a GP surveyor. One scientist did not respond and 1 GP did not respond.

The interviews with surveyors lasted between 15-30 minutes.

A descriptive analysis was undertaken with the key themes identified from the qualitative questions. The results are summarised in Table 75 below.

**Table 75: Summary of surveyor responses, PoCT accreditation process, July 2007**

Area	Specific topic	Results
Documentation and preparation	Sufficient training provided prior to the second survey visit	All respondents thought there was sufficient training prior to the second survey visit. One thought that the second training was much better than the first and another thought that it was organised well and answered a lot of questions.
	Revised Accreditation Surveyor Guidelines provide sufficient additional information	4/5 respondents thought there was sufficient information in the revised Surveyor Guidelines. One was unsure as they could not remember there being any difference. Two commented that they had not thought the previous guidelines were insufficient or lacking.
	Overall usefulness of revised Surveyor Guidelines in preparing for the survey visit	4/5 respondents thought the Guidelines were either useful or very useful. One respondent was unsure.
	Suggestions for improvement	<p>There were no specific suggestions</p> <p>One respondent noted that All suggestions after first visit were addressed (especially time allocation)</p> <p>Another respondent had no further suggestions because [it] was well organised, I felt capable and informed, I understood my role well, all training and information sufficient to do a good job</p>
Accreditation visit	Appropriateness of surveyor team e.g. skills, size etc.	<p>4/5 respondents thought the team was appropriate. One thought that since there was no GP in the NSW team there was no GP perspective on patient results</p> <p>NOTE: there was one remote NSW region with two practices for which a GP was not available.</p>
	Sufficient time for visit	All respondents thought sufficient time was provided
	Criteria appropriate	All respondents thought the criteria were appropriate
	Problems during visit	None of the respondents thought there were any problems with or during the visit. Two felt that the second visits were better and that staff were more relaxed and intuitive. One respondent felt that too much time was allowed at both visits, but at the same time acknowledged that the timing had to be conservative as they could not hold practices up if running late.
	Suggestions to improve	Provide a GP on surveyor team

Area	Specific topic	Results
	visit	<p>Down the track may be possible to train 1 surveyor to assess all indicators</p> <p>Scientist had too much work (1st visit), reallocated work load and worked better (2nd visit).</p>
General comments		<p>Professionally (well) organised</p> <p>Some GPs wanted to know what would happen post-trial. QC considered to be overkill (consensus amongst practice staff/GPs). Overall process handled well, better 2nd time around</p> <p>Robust, fair, great experience for general practices that undertook PoCT - a non general practice accreditation experience. The way assessments were done was very applicable should PoCT be rolled out generally</p> <p>Well organised, ran smoothly.</p>

Overall, from the surveyor's perspective, the evaluation of Round 2 indicated that:

- sufficient information was provided in the revised Surveyor Guidelines and that they were either useful or very useful and
- sufficient time was provided and there were no problems with the second visit.

There were no specific areas identified for improvement; however, it was suggested that in the future one surveyor could be trained to assess all indicators.

## 6.4. DISCUSSION

### *Evaluation of Standards*

On the whole both GPs and scientists reported that the Standards provided an achievable minimum standard for PoCT in general practice. Scientist and GP views diverged for Standard 2 relating to selection of instrumentation for the practice. Scientists believed that GP staff lacked technical knowledge to perform this task while GP surveyors believed they were capable.

Concern was also expressed for Standard 5 relating to quality control and quality assurance. Scientists' issues relating to this Standard were if the QA model used for the Trial was sustainable post Trial. GPs' concern revolved around culture change required for practice staff performing PoCT and complexity of the QA reports.

The Trial's quality framework was generally accepted by both scientists and GPs. The most challenging aspect of the Standards was to adapt what could be described as laboratory quality standards to a general practice environment. Check-lists prepared to itemise accreditation points were found to be extremely useful for both practice staff preparing for accreditation and surveyors accrediting practice sites. What may be perceived as straightforward and acceptable to laboratory scientists may appear a little more complicated and challenging to GP staff. Conversely what scientists believe would be challenging to GP staff, was regarded as

straightforward by GP staff. This particularly related to selection of PoCT equipment. As this was predetermined by the Trial there was no evidence to support either view.

Comments from both scientists and GPs implied that although the Standards were appropriate to achieve a minimum PoCT quality standard, there was room for improvement to make them more suitable for the GP environment. Although GPs thought that QA was challenging they did agree that the Standards should not be compromised and believed that alternative QA models should be investigated.

#### *Applicability of Standards to general practice*

Surveys to assess ease of use of the Standards suggested that in general Device Operators found the Standards more user-friendly than GPs.

Surveys to assess the suitability of the Standards to the general practice environment showed that for every Standard, Device Operators thought the Standards were more applicable than GPs. The difference was smaller for Implementation and Performance and Quality Outcomes. It is interesting to note that both these parts of the Standards had the largest proportion of missing data. This is easily explained as elements for this part of the Standards were predetermined for the Trial and not tested. The largest difference was observed for the Clinical Governance part of the Standards where only 57% of GPs and 68% of Device Operators thought that this part applied to general practice. Clearly if the Trial were to be introduced more widely some work would be required around these parts of the Standards to ensure all users had a sound understanding of what was required. Support systems need to be developed to assist GPs in making sensible decisions when choosing equipment/methods to implement in surgeries. Round One of accreditation highlighted that practices had some difficulty in understanding QC and QA which is potentially supported by the fact that 25% of both GPs and Device Operators responded in the satisfaction survey as unsure, or not at all, to whether the Quality Outcomes section of the Standards applied to general practice. Additional training and support in QC and QA procedures achieved the desired effect with practices having a better understanding and 100% of practices achieving accreditation.

Approximately 80% of GPs believed that the Staff Training and Implementation and Performance parts of the Standards applied to general practice. Device Operators concurred strongly with this.

#### *Evaluation of Accreditation*

Comparison of the evaluations of surveyors following Round One and Round Two indicated that there was improvement following the changes implemented after the first round of accreditation visits. All surveyors were brought together to discuss the Standards and the outcomes of the evaluation of the first visits, following which some minor alterations were made to the Surveyors' Checklist. Other strategies were implemented as a result of this session, including provision to surveyors of the first survey visit report and checklist to enable comparison at the second practice visit. This also enabled surveyors to provide feedback on any improvement achieved. From the organisational perspective, practices were advised to ensure that relevant personnel were in attendance at the survey visit, as a previous concern had been time spent by surveyors following up either the responsible GP or Device Operator to finalise the visit. This was not a problem in the second round. Overall it was difficult to schedule visits given the travel and distance issues in rural and remote regions which impacted on the timeliness of visits to some degree. The time allowed for the actual visits, however, was accurate in the second round.

The size of the survey team had been an issue for practices at the first visit and this was subsequently reviewed. As a result roles and responsibilities were streamlined and a maximum of three attended the second round visits: the scientist and GP surveyors and the Trial representative. Round 1 had attracted much interest and at some of the visits several observers had attended. However, it is acknowledged that this may have been too onerous for practices. The suggestion that surveyors could in future be trained to assess all indicators was interesting and may be worthy of discussion. The model developed for this accreditation process involved engaging people with specific skills and training to assess defined criteria within their areas of expertise.

## 6.5. CONCLUSION

Overall the Standards provided a good framework for the Trial. Point of Care Testing can be a controversial topic amongst some scientists who have reservations that it can be performed successfully outside of the laboratory environment. The Trial has provided an opportunity for scientists to see that with appropriate education and support, PoCT can be run in general practice within a quality framework.

If PoCT were to be introduced more widely, Standard 2 relating to selection of instrumentation may need to be modified. Ideally instrument evaluations should be performed under the guidance of either the local laboratory or a suitably qualified scientist. If it were deemed that general practice was capable of performing this function independently, checklists detailing steps to follow should be developed to assist them. Checklists appear to be a successful way of achieving success with new tasks and certainly made the accreditation procedure run smoothly.

Quality control and quality assurance were considered onerous for general practice but performed relatively well particularly in the second accreditation round. If a general practice was to enrol in a QAP program such as the RCPA Quality Assurance Program Pty Ltd they could, if necessary, receive assistance with the interpretation of QA results. Interpretation of QA results is a function of the scientists employed by the RCPA QAP Program Pty Ltd and is an activity they currently perform for laboratory staff requiring help. The local laboratory or an affiliated scientist could assist with interpretation of QC results if required. The number of QCs performed should reflect recommendations of professional organisations such as AACB. Practices should at least perform the minimum number of QCs within their practice as is outlined in the AACB PoCT position statement updated in 2007.<sup>104</sup>

Having appropriately qualified people in the survey team is important if a meaningful accreditation is to be undertaken. If PoCT accreditation were to be part of the practice accreditation a scientist with a good understanding of quality procedures should be included. This need may only be a temporary requirement until GPs participating in accreditation visits gained necessary skills to review QC and QA data.

Finally the accreditation process highlighted that education is the secret to success. Second round accreditation was achieved by 100% of the practices after implementing further education on how to handle QC/QA results was undertaken. First round accreditation highlighted this as an issue which disappeared after some re-education in this area. If PoCT were to be deployed into general practice, specific education should be provided, either through existing CPD structures or as a stand-alone program. Educational modules on PoCT covering the (Interim) Standards for PoCT for both GPs and nurses would need to be developed to ensure good understanding of the framework within which all PoCT should be undertaken.



## 7. SAFETY OF PoCT IN GENERAL PRACTICE PART 3 – COMPARISON OF PoCT AND PATHOLOGY LABORATORY TEST RESULTS

### SUMMARY OF THE CHAPTER

This chapter describes the methodology and results of the analysis of the comparison of PoCT and pathology laboratory test results undertaken as part of Phase I of the Trial. This analysis formed part of the assessment of whether PoCT was safe to perform in general practice.

Pathology laboratory test results were matched with PoCT test results for patients in the intervention group for the first six months of the Trial. Agreement was assessed using three methods: the Bland and Altman approach which includes mean differences and 95% limits of agreement followed by clinician review to determine the clinical acceptability of the results; analysis of the concordance between PoCT and laboratory results; and for INR assessment using published clinically relevant agreements.

The key findings of the chapter are:

the estimated bias for INR was 0.0034, that is, on average PoCT results were 0.0034 above the corresponding pathology laboratory test results. The 95% limits of agreement were -0.7851 and 0.7919

- the estimated bias for HbA1c was -0.0504%. This means that on average, PoCT results were 0.0504% below the corresponding pathology laboratory test result. The 95% limits of agreement were -1.0658 and 0.9650%
- the estimated bias for urine albumin was -0.7632mg/L. This indicates that, on average, PoCT results were 0.7632mg/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -11.4719 and 9.9455mg/L
- the estimated bias for ACR was -0.1513mg/mmol. This means that on average, PoCT results were 0.1513mg/mmol below the corresponding pathology laboratory test result. The 95% limits of agreement were -2.0488 and 1.7461mg/mmol
- the estimated bias for total cholesterol was -0.2645mmol/L. This indicates that, on average, PoCT results were 0.2645mmol/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -1.0931 and 0.5641mmol/L
- the estimated bias for HDL-C was -0.0694mmol/L. This means that on average, PoCT results were 0.0694mmol/L below the corresponding pathology laboratory test result. The 95% limits of agreement were -0.4899 and 0.3510mmol/L
- the estimated bias for triglycerides was 0.2014mmol/L. This means that PoCT results were 0.2014mmol/L above the corresponding pathology laboratory test result on average. The overall 95% limits of agreement were -0.9540 and 1.3569mmol/L
- concordance analysis found that 23.3% of INR results, 15.1% of total cholesterol results, 14.2% of HDL-C results, 10.6% of HbA1c results, 10.5% of ACR and triglyceride results and 2.5% of urine albumin results theoretically could have led to a different decision depending on whether the test was from the laboratory or PoCT
- evaluation of INR results showed that overall, 86% of dual INR measurements were within 0.5 INR units of each other. For laboratory INR <2.00, 2.0-3.0, 3.1-4.0 and >4.0, 94%, 90%, 69% and 67% of readings were within 0.5 INR units, respectively
- for INR, clinical agreement occurred 91% and 89% of the time against published expanded and narrow criteria, respectively.

The key conclusion:

- review of the results from the various methods determined that the mean difference in results and the 95% limits of agreement were clinically acceptable.

## **7.1. INTRODUCTION**

For PoCT to be introduced into a general practice setting, it is important that it has been proven to be accurate and reliable. The benefits of PoCT in general practice will only be effective if the results obtained from the devices are comparable with laboratory results.<sup>1, 13</sup> A number of studies have shown that PoCT using a variety of portable monitoring machines can produce similar results to laboratory tests for a number of specific tests including HbA1c,<sup>14, 45</sup> anticoagulation monitoring,<sup>15-19</sup> microalbuminuria and cholesterol.<sup>20</sup> However, variability between laboratories and primary care sites demonstrates the need for participation in quality assurance programs.<sup>1</sup>

This chapter reports the analyses that focus on determining if the PoCT devices closely agree with the results from a pathology laboratory when undertaken on the same patient.

## **7.2. AIMS AND OBJECTIVE**

The purpose of this section of the report is to address the following hypothesis relating to safety.

Hypothesis: Results obtained from PoCT devices for each patient closely agree with results obtained for the same patient from pathology laboratory testing.

## **7.3. METHODS**

To investigate whether results obtained from PoCT devices closely agree with results obtained from pathology laboratory testing, PoCT and pathology laboratory results collected during Phase I relating to intervention patients were considered. PoCT and pathology laboratory results were matched and several methods of analysis were considered: calculation of bias and 95% limits of agreement followed by clinician review to determine clinical acceptability of the results; concordance between PoCT results and pathology laboratory results; and assessment using published clinically relevant agreements for INR. The matching process and methods of analysis will now be described in further detail.

### **7.3.1. Matching PoCT and pathology laboratory test results**

Before performing the statistical analysis, PoCT results first needed to be matched to pathology laboratory test results. The need for matching was a consequence of the way in which the data were obtained. The two types of results were received separately, with PoCT results received from practices in paper form requiring data entry and pathology laboratory test results received from pathology laboratories in electronic form or in paper form requiring data entry.

In order for a PoCT result and a pathology laboratory test result to be matched, each of the following criteria must have been met:

- the test results related to the same type of test (e.g. INR)
- the tests were performed on the same patient, and
- the tests were performed on the same date.

Following matching, in the case of a large (potentially outlying) difference between the PoCT result and the corresponding pathology laboratory result, the PoCT result was checked for data entry error. The pathology laboratory result was also checked for data entry error if the result was received in paper form rather than electronic form. However, there is no way of knowing whether the PoCT result was recorded correctly by the Device Operator or whether the pathology laboratory result was recorded correctly at the laboratory.

### 7.3.2. Bias and limits of agreement

In order to assess the level of agreement between PoCT and pathology laboratory testing, the approach suggested by Bland and Altman<sup>77</sup> was adopted. This approach involved applying the following steps to the matched PoCT and pathology laboratory results for each type of test:

- *calculate the mean difference in results.* This is used to estimate the bias. The bias is positive if the PoCT result tends to be greater than the pathology laboratory result. Similarly, the bias is negative if the PoCT result tends to be less than the pathology laboratory result. A 95% confidence interval for the true bias can also be calculated. *The bias must be judged against clinically acceptable average differences in PoCT and pathology laboratory test results.*
- *calculate the 95% limits of agreement.* These limits can be interpreted as follows. If multiple PoCT and pathology laboratory tests were performed and the difference in results calculated, it would be expected that the difference would fall between the limits of agreement approximately 95% of the time, provided these differences were normally distributed. If the limits of agreement are too wide, it means that a GP cannot be confident that the PoCT result obtained for their patient is similar to the result they would have obtained if the patient was sent to the pathology laboratory for testing. *The limits of agreement must be judged against clinically acceptable individual differences in PoCT and pathology laboratory results.*
- *plot the difference in results against the average of the results.* This plot can be used to visually assess the level of agreement between the two testing methods. Each plot contains three horizontal lines. The middle (solid) line is the mean difference in the results obtained using the two methods. The upper and lower (dashed) lines are the 95% limits of agreement.

When calculating the difference in results, both the absolute difference and the relative difference (e.g. the difference relative to the pathology laboratory test result) were considered. The method of calculation for each type of difference was as follows:

$$\text{Absolute Difference} = \text{PoCT result} - \text{Pathology laboratory test result}$$

$$\text{Relative Difference} = \frac{\text{PoCT result} - \text{Pathology laboratory test result}}{\text{Pathology laboratory test result}} \times 100\%$$

Note that the plots shown in the following sections are of the absolute difference against the average and not the relative difference. The results showing the relative difference by geographic location are reported in Appendix 18.

Regression analysis was also performed to determine whether the mean absolute difference (or bias) was linearly related to the average of the results. Adjustment was made for the fact that some patients may have multiple pairs of results for a given type of test and hence, these pairs of results are not independent. Where a significant linear trend was observed, the between subjects correlation coefficient was calculated using the method suggested by Bland and Altman.<sup>105</sup> The change in bias resulting from a one unit increase in the average of the results is also reported. The change in bias must be judged against clinically acceptable changes in the average difference between PoCT and pathology laboratory test results.

Not all matched PoCT and pathology laboratory test results could be used in the analysis. This was due to the fact that either the PoCT result or the pathology laboratory test result (or both) fell outside the measurable range of results. Where this was the case, the matched pair of results was not used to calculate the bias or the limits of agreement but was reported on descriptively.

Results are reported for each type of test, both overall and broken down by geographic location (urban, rural and remote). For INR, results are broken down further by practice and pathology laboratory.

When interpreting the results, it is important to note that the 95% confidence interval for the bias and the 95% limits of agreement relate to two separate ideas. The 95% confidence interval indicates how accurately true bias has been estimated using the available data. The 95% limits of agreement describe the range of differences within which 95% of all differences are expected to fall if the differences are normally distributed. It is the 95% limits of agreement which indicate how closely results obtained by the two different testing methods tend to agree with each other.

### 7.3.3. Clinical acceptability of bias and limits of agreement

While the bias and 95% limits of agreement provide a description of the level of agreement between PoCT and pathology results, they cannot determine the clinical significance of these measures of agreement as this requires clinical input. Thus, a group of clinicians reviewed the bias and 95% limits of agreement to determine whether these values were clinically acceptable in terms of their impact on changing clinical management. To assist this, concordance analysis was undertaken.

### 7.3.4. Concordance

Test results were classified as being within or outside target range (see Table 92). The number and percentage of tests where the PoCT and pathology laboratory results agree (e.g. both test results within or outside target range) or disagree (e.g. one test within and one test outside target range) were calculated. This provides an indication of the percentage of test results where the clinical decision would have been altered depending on whether the test was from the laboratory or PoCT (assuming clinical decisions are based solely on whether the test result lies within or outside the target range).

### 7.3.5. Clinically relevant agreement

The expanded and narrow criteria for clinical agreement according to Douketis et al<sup>19</sup> and based on work by Anderson et al<sup>106</sup> were applied to the INR results only, since criteria have been developed for INR but not for other tests considered in the Trial. This method gives an indication of whether a clinical decision would have changed if the pathology result was provided by a laboratory or PoCT device. The additional analysis for the INR results was undertaken because of the importance of the INR results to determine dosage levels and because of the potential for serious adverse outcomes if the decision is incorrect, for example, thromboembolic event or haemorrhagic events.

Expanded clinical agreement was achieved if both the CoaguChek S and the laboratory INR were within, above or below the therapeutic range or the difference between the CoaguChek S and laboratory INR when one of the pair was within the therapeutic range was no more than 0.5 INR units. Narrow agreement was achieved if both the CoaguChek S and the laboratory INR were within the therapeutic range, both the CoaguChek S and the laboratory INR were above the therapeutic range and the values were within 0.8 INR units, both CoaguChek S and laboratory INR were below the therapeutic range within 0.4 INR units, or when one was within therapeutic range and this pair was within 0.5 INR units. The proportions of dual INR measurements that satisfied the expanded and narrow criteria were determined and corresponding 95% confidence intervals calculated. The mean difference in results and the percentage of dual INR measurements within 0.5 INR units for laboratory INR ranges of <2.0, 2.0-3.0, 3.1-4.0 and >4.0 were also calculated.

## 7.4. RESULTS

Table 76 summarises the PoCT and pathology laboratory test results (for intervention patients only) that had been received for Phase I at the time of the analysis and the number that were matched. The numbers indicate that more PoCT results had been received than pathology laboratory test results. They also indicate that most of the PoCT results had been matched to a pathology laboratory test result and vice versa.

**Table 76: PoCT and pathology laboratory test results received and matched by type of test**

Test	Matched tests	Lab tests	% Lab tests matched	PoCT	% PoCT matched
INR	1677	1770	94.75	2126	78.88
Total cholesterol	864	940	91.91	1171	73.78
HDL-C	778	823	94.53	1160	67.07
Triglycerides	861	907	94.93	1171	73.53
HbA1c	498	535	93.08	663	75.11
Urine albumin	320	347	92.22	512	62.50
ACR	304	331	91.84	511	59.49
Total	5302	5653	93.79	7314	72.49

#### 7.4.1. Comparison of PoCT and pathology laboratory test results for INR

As an indication of the order of magnitude of the INR results, the average result across both PoCT and pathology laboratory tests is 2.54. Table 77 gives results for INR relating to absolute differences between PoCT and pathology laboratory test results overall. These results are reported in the same units as INR test results were reported. The estimated bias is 0.0034. This means that, on average, PoCT results are 0.0034 above the corresponding pathology laboratory test result. For INR the true bias lies between -0.0159 and 0.0227 (95% CI).

The 95% limits of agreement over all geographic regions are -0.7851, 0.7919. Approximately 95% of the time, INR results obtained using a PoCT device will be between 0.7851 below and 0.7919 above the corresponding pathology laboratory test result. Figure 11 shows the absolute difference in results for INR plotted against the average of the results for all geographic regions combined. The plot shows substantial scatter, with differences of up to 1.5 units in either direction commonly observed.

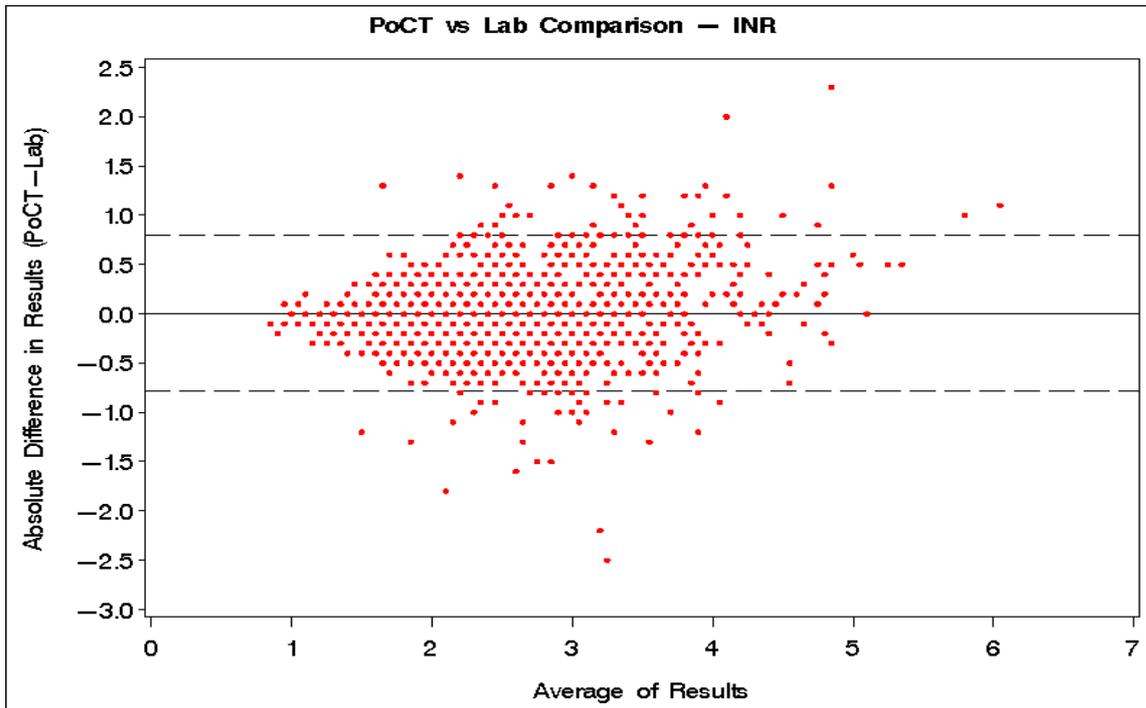
**Table 77: Mean absolute difference in INR test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
Overall	0.0034	-0.0159	0.0227	-0.7851	0.7919	1676

Results for INR relating to relative differences between PoCT and pathology laboratory test results can be seen in Appendix 18.

Regression analysis shows that there is a significant linear trend in the bias. When all regions are considered, the correlation coefficient is 0.1892, indicating a weak positive linear trend. As the average of the PoCT and pathology laboratory test results increases by one, the bias increases by an estimated 0.1058 ( $p < 0.0001$ ). The 95% confidence interval for the true increase in bias is 0.0646, 0.1471. This means that when the average of the results increases by one, the bias increases by between 0.0646 and 0.1471 (95% CI).

Figure 11: Absolute difference in results vs average of results for INR over all geographic regions



Only one of the 1677 matched PoCT and pathology laboratory test results for INR, reported in Table 76, could not be used in the above analysis. This was due to the PoCT result falling above 8, which is the maximum the PoCT device is able to detect. The corresponding pathology laboratory test result was 6.2.

In order to investigate whether differences observed in PoCT and pathology laboratory test results could be attributed to a particular practice or pathology laboratory, results were broken down by pathology laboratory and practice.

The results for INR relating to absolute differences between PoCT and pathology laboratory test results, broken down by pathology laboratory, are provided in Table 78. The estimated bias ranges from  $-0.2000$  to  $0.1881$ , with most values being negative. The widths of the 95% limits of agreement appear to be similar for the different pathology laboratories, excluding the two laboratories with minimal sample size (pathology laboratories 10166 and 10176).

**Table 78: Mean absolute difference in INR test results and 95% limits of agreement by pathology laboratory**

Laboratory ID	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
10166	-0.1000	-0.3235	0.1235	-0.5997	0.3997	5
10167	-0.1726	-0.2255	-0.1197	-0.9744	0.6291	230
10168	-0.1570	-0.2004	-0.1136	-0.7808	0.4668	207
10170	0.0014	-0.0525	0.0553	-0.6479	0.6506	145
10174	-0.1287	-0.1889	-0.0685	-0.8121	0.5548	129
10175	0.1881	0.1560	0.2202	-0.5739	0.9501	564
10176	-0.2000	-0.3960	-0.0040	-0.4772	0.0772	2
10177	-0.0277	-0.0665	0.0112	-0.7981	0.7428	394

Results for INR relating to absolute differences between PoCT and pathology laboratory test results, broken down by practice, can be seen in Table 79. The estimated bias ranges from -0.3952 to 0.4246, with most values being negative. The widths of the 95% limits of agreement vary considerably between practices. For example, the 95% limits of agreement are very narrow for practice 6020 in comparison to practice 6022. However, the sample size for many practices is small and the 95% limits of agreement are not robust to outliers. Hence, these results should be interpreted with caution.

**Table 79: Mean absolute difference in INR test results and 95% limits of agreement by practice**

Practice ID	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
6003	-0.2806	-0.4458	-0.1153	-1.2720	0.7109	36
6004	-0.3524	-0.4881	-0.2167	-0.9741	0.2693	21
6005	-0.0850	-0.2473	0.0773	-0.8108	0.6408	20
6009	0.2000	0.0790	0.3210	-0.6295	1.0295	47
6010	0.1562	0.0947	0.2177	-0.5869	0.8992	146
6013	0.2276	0.1875	0.2676	-0.3431	0.7983	203
6014	0.0014	-0.0519	0.0548	-0.6273	0.6302	139
6017	-0.1009	-0.1622	-0.0395	-0.7616	0.5599	116
6019	-0.0468	-0.1071	0.0136	-0.7961	0.7026	154
6020	-0.1480	-0.2206	-0.0754	-0.5108	0.2148	25

Practice ID	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
6022	-0.0474	-0.2678	0.1731	-1.0084	0.9137	19
7000	-0.0218	-0.1399	0.0962	-0.8973	0.8537	55
7004	-0.2625	-0.4786	-0.0464	-1.1269	0.6019	16
7006	-0.2864	-0.4471	-0.1257	-1.0401	0.4674	22
7007	-0.0821	-0.1445	-0.0196	-0.6335	0.4694	78
7011	0.4246	0.3707	0.4786	-0.2181	1.0674	142
7016	-0.1479	-0.2126	-0.0833	-0.9297	0.6338	146
7018	-0.3952	-0.4861	-0.3044	-0.9840	0.1935	42
8002	-0.0324	-0.1248	0.0600	-0.5946	0.5297	37
8005	-0.3000	-0.6920	0.0920	-0.8544	0.2544	2
8006	-0.1000	-0.3235	0.1235	-0.5997	0.3997	5
8007	-0.1962	-0.2776	-0.1148	-0.9197	0.5273	79
8009	-0.2000	-0.4671	0.0671	-0.9067	0.5067	7
8010	-0.1700	-0.2988	-0.0412	-0.7462	0.4062	20
8012	-0.1277	-0.1837	-0.0716	-0.6710	0.4157	94
8017	0.0800	-0.0160	0.1760	-0.1347	0.2947	5

Of the 26 practices included in Table 79, seven (26.9%) had pathology laboratory test results for their patients from multiple pathology laboratories; however, in most cases there was one pathology provider being used. Thus, results were not broken down further into combination of practice and pathology laboratory.

#### 7.4.2. Comparison of PoCT and pathology laboratory test results for HbA1c

As an indication of the order of magnitude of HbA1c results, the average result across both PoCT and pathology laboratory tests is 6.96%. Table 80 gives results for HbA1c relating to absolute differences between PoCT and pathology laboratory test results, overall. These results are reported as percentages (e.g. the same units in which the PoCT device reports HbA1c test results).

When all regions are considered, the estimated bias is -0.0504%. This means that, on average, PoCT results are 0.0504% below the corresponding pathology laboratory test result. For HbA1c results the true bias lies between -0.0960 and -0.0048% (95% CI).

The 95% limits of agreement over all geographic regions are -1.0658, 0.9650%. Approximately 95% of the time, HbA1c results obtained using a PoCT device will be between 1.0658% below and 0.9650% above the corresponding pathology laboratory test result.

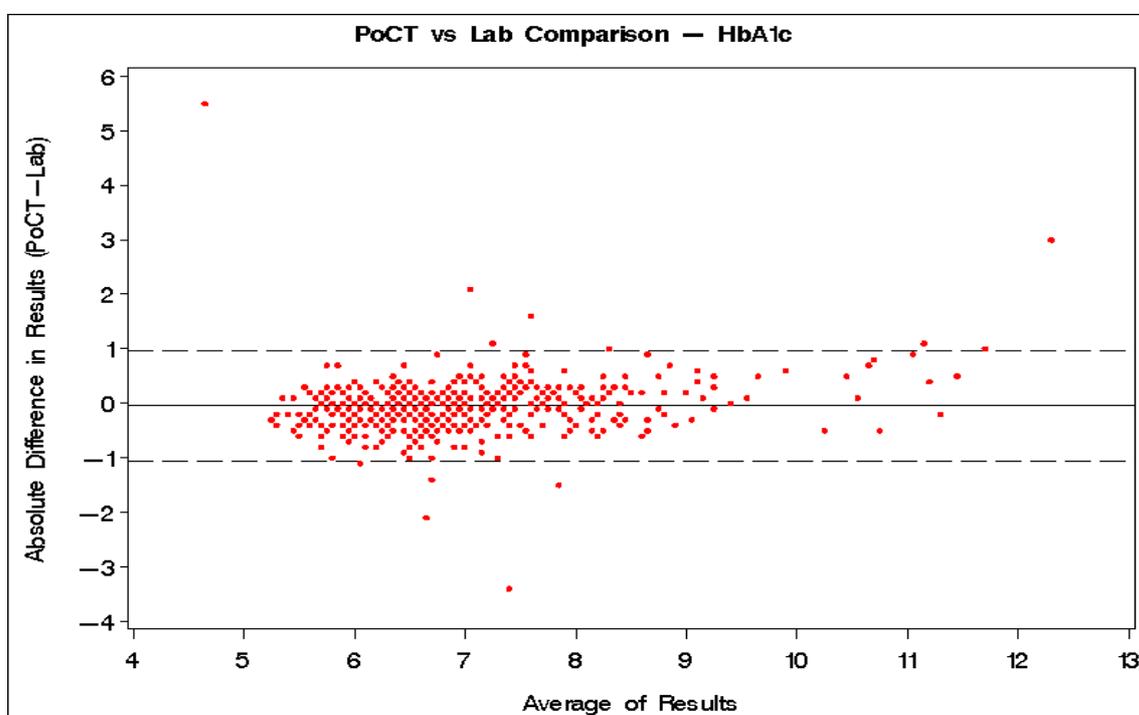
The plot in Figure 12 is the absolute difference in HbA1c results against the average of the results, indicating that differences of up to one unit in either direction are common, with larger differences also possible.

**Table 80: Mean absolute difference in HbA1c test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
Overall	-0.0504	-0.0960	-0.0048	-1.0658	0.9650	496

Results for HbA1c relating to relative differences between PoCT and pathology laboratory test results are in Appendix 18. These results are reported as percentage differences relative to the pathology laboratory test result.

**Figure 12: Absolute difference in results vs average of results for HbA1c over all geographic regions**



Based on the results of the regression analysis, there is a significant positive linear trend in the bias. The correlation between the bias and the average of the results for all regions combined was extremely weak, however, with a correlation coefficient of 0.0187. As the average of the PoCT and pathology laboratory test results increases by one unit, the bias increases by an estimated 0.1005 units ( $p=0.0043$ ). The 95% confidence interval for the true increase in bias is (0.0315, 0.1695) units. This means that when the average of the results increases by one unit, the bias increases by between 0.0315 and 0.1695 units (95% CI).

There were 498 PoCT and pathology laboratory test results reported as being matched in Table 76. Of these, 496 (99.6%) were used in the above analysis. The remaining two matched results could not be included due to the PoCT result falling above 14% which is the maximum result the device is able to detect. Table 81 shows the corresponding pathology laboratory test results.

**Table 81: Pathology laboratory results for PoCT HbA1c results >14%**

Lab result	Frequency	%
11.9	1	50.00
13.1	1	50.00
Total	2	100.00

#### 7.4.3. Comparison of PoCT and pathology laboratory test results for urine albumin

The average urine albumin result across both PoCT and pathology laboratory tests is 21.20mg/L, which may be used to indicate the order of magnitude of the results. Table 82 gives results for urine albumin relating to absolute differences between PoCT and pathology laboratory test results, overall. These results are reported in mg/L.

When all geographic regions are combined, the estimated bias is  $-0.7632\text{mg/L}$ . This indicates that, on average, PoCT results are  $0.7632\text{mg/L}$  below the corresponding pathology laboratory test result. For urine albumin the true bias falls between  $-1.4405$  and  $-0.0859\text{mg/L}$  (95% CI).

The 95% limits of agreement over all regions are  $(-11.4719, 9.9455)$  mg/L. Urine albumin results obtained using a PoCT device will fall between  $11.4719\text{mg/L}$  below and  $9.9455\text{mg/L}$  above the corresponding pathology laboratory test result approximately 95% of the time.

Figure 13 shows that there is a considerable range of differences possible between the PoCT and pathology laboratory test results.

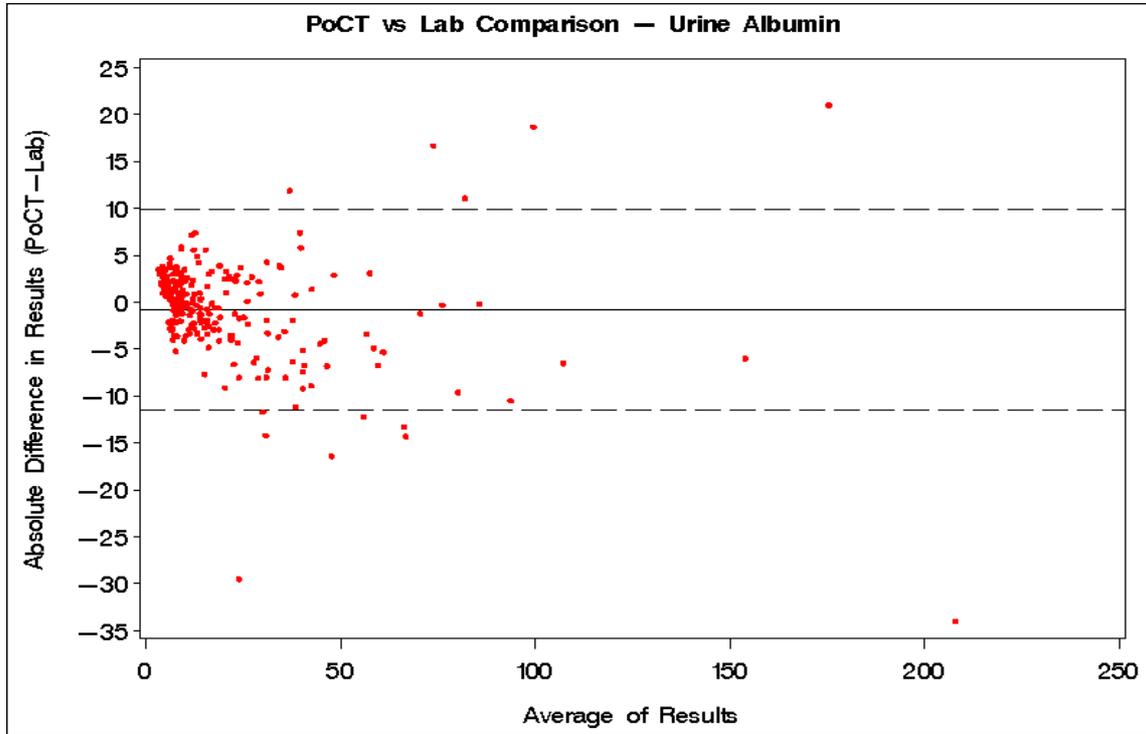
**Table 82: Mean absolute difference in urine albumin test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
Overall	-0.7632	-1.4405	-0.0859	-11.4719	9.9455	250

The results for urine albumin relating to relative differences between PoCT and pathology laboratory test results are provided in Appendix 18. These results are reported as percentage differences relative to the pathology laboratory test result.

When all regions were considered, regression analysis revealed no significant linear trend in the bias ( $p=0.2219$ ). These results should be interpreted with caution, due to the limited range of the average of the results for the majority of the data and the small number of influential observations with relatively large values for the average of the results.

**Figure 13: Absolute difference in results vs average of results for urine albumin over all geographic regions**



In Table 76, it was reported that 320 PoCT results could be matched to a pathology laboratory test result for urine albumin. However, the above analysis only used 250 (78.1%) of these results and the remaining 70 could not be used, due to either the PoCT result or the pathology laboratory test result falling outside the measurable range. The pathology laboratory test results corresponding to the PoCT results which were below 5mg/L or above 300mg/L are summarised in Table 83. Where the pathology laboratory test fell outside the measurable range, it was at the lower end of the spectrum, either being recorded as <1.0, <2.0 or <8.0mg/L, depending on the laboratory. In the one case where the result was <1.0 and the two cases where it was <2.0mg/L, the corresponding PoCT result was <5mg/L (as can be seen in Table 83). The PoCT results corresponding to the pathology laboratory test results which fell below 8.0mg/L are summarised in Table 83.

**Table 83: Pathology laboratory test results for PoCT urine albumin results at various levels**

Results	Lab result	Frequency	%
Test results <5mg/L	< 1.0	1	2.04
	1.4	2	4.08
	1.7	1	2.04
	1.8	2	4.08
	<2.0	2	4.08
	2.0	5	10.20
	2.1	1	2.04
	2.2	1	2.04
	2.4	2	4.08

Results	Lab result	Frequency	%
	2.5	1	2.04
	2.7	1	2.04
	2.8	1	2.04
	3.0	8	16.32
	3.5	1	2.04
	4.0	3	6.12
	5.0	1	2.04
	6.8	1	2.04
	7.2	1	2.04
	7.3	2	4.08
	7.8	1	2.04
	<8.0	8	16.32
	8.0	1	2.04
	9.0	2	4.08
	Total	49	100
Test results >300 mg/L	452.9	1	14.29
	464.0	1	14.29
	513.0	1	14.29
	576.0	1	14.29
	727.9	1	14.29
	836.0	1	14.29
	1136.9	1	14.29
	Total	7	100.00
Test results < 8.0 mg/L	<5.0	8	36.36
	5.0	11	50.00
	5.3	1	4.55
	5.4	1	4.55
	5.9	1	4.55
	Total	22	100.00

#### 7.4.4. Comparison of PoCT and pathology laboratory test results for albumin/creatinine ratio (ACR)

As an indication of the order of magnitude of the ACR results, the average result across both PoCT and pathology laboratory tests is 2.89mg/mmol. Table 84 gives results for the ACR relating to

absolute differences between PoCT and pathology laboratory test results, overall. These results are reported in mg/mmol.

The estimated bias over all geographic regions is  $-0.1513\text{mg/mmol}$ . This means that, on average, PoCT results are  $0.1513\text{mg/mmol}$  below the corresponding pathology laboratory test result. For ACR results the true bias lies between  $-0.2730$  and  $-0.0296\text{mg/mmol}$  (95% CI).

Across all geographic regions, the 95% limits of agreement are  $-2.0488, 1.7461\text{ mg/mmol}$ . ACR results obtained using PoCT devices are expected to be between  $2.0488\text{mg/mmol}$  lower and  $1.7461\text{mg/mmol}$  higher than the corresponding pathology laboratory result approximately 95% of the time. Figure 14 shows that differences in results of around  $2\text{mg/mmol}$  in either direction are common, with larger differences also possible.

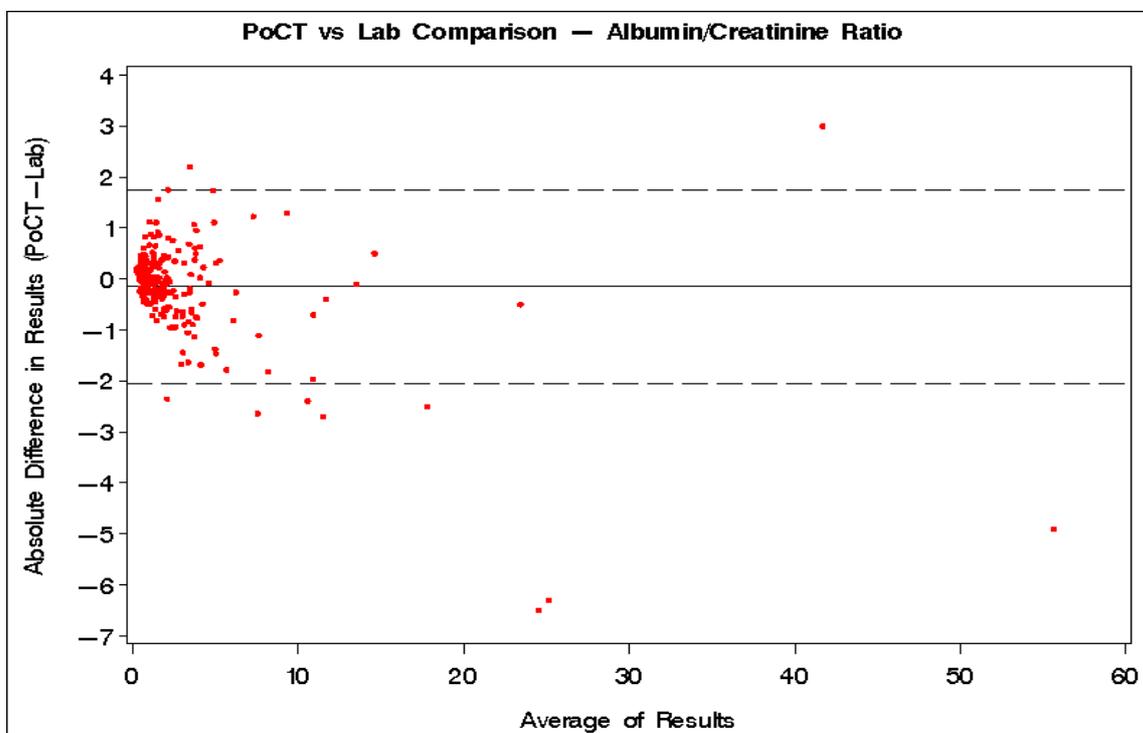
The results for the ACR relating to relative differences between PoCT and pathology test results overall are shown in Table 84.

**Table 84: Mean absolute difference in ACR test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
Overall	-0.1513	-0.2730	-0.0296	-2.0488	1.7461	243

The results for the ACR relating to relative differences between PoCT and pathology laboratory test results are shown in Appendix 18. These results are reported as percentage differences relative to the pathology laboratory test result.

**Figure 14: Absolute difference in results vs average of results for ACR over all geographic regions**



Regression analysis shows that there is a significant linear trend in the bias. When all regions are considered, the correlation coefficient is  $-0.14697$ , indicating a weak negative linear trend. As the average of the PoCT and pathology laboratory test results increases by one unit, the bias

decreases by an estimated 0.0787 units ( $p=0.0438$ ). The 95% confidence interval for the true change in bias is -0.1553, -0.0022 units. This means that when the average of the results increases by one unit, the bias decreases by between 0.1553 and 0.0022 units (95% CI).

Only 243 (79.9%) of the 304 matched PoCT and pathology laboratory test results reported in Table 76 for the ACR could be used in the above analysis. For the remaining 61 matched results, 52 could not be used because the PoCT result was outside of the measurable range of the testing device, 5 could not be used because the pathology laboratory test result was outside of range and for the remaining 4 cases, both the PoCT and pathology laboratory test results were outside of range.

As the ACR is a ratio of two other measurements made by the device, an out of range result for the ACR indicates that the urine albumin result, the urine creatinine result, or both results are out of range. As a consequence, an ACR falling outside the measurable range can mean different things depending on the two individual results and thus, no meaningful comparison with pathology laboratory test results is possible for the ratio when the PoCT or pathology laboratory test result falls outside the measurable range.

#### 7.4.5. Comparison of PoCT and pathology laboratory test results for total cholesterol

To give an idea of the order of magnitude of the total cholesterol results, the average result across both PoCT and pathology laboratory tests is 4.50mmol/L. Table 85 gives results for total cholesterol relating to absolute differences between PoCT and pathology laboratory test results overall. These results are reported in mmol/L.

The estimated bias is -0.2645mmol/L. This indicates that, on average, PoCT results are 0.2645mmol/L below the corresponding pathology laboratory test result. We can be 95% confident that the true bias falls between -0.2930 and -0.2361mmol/L.

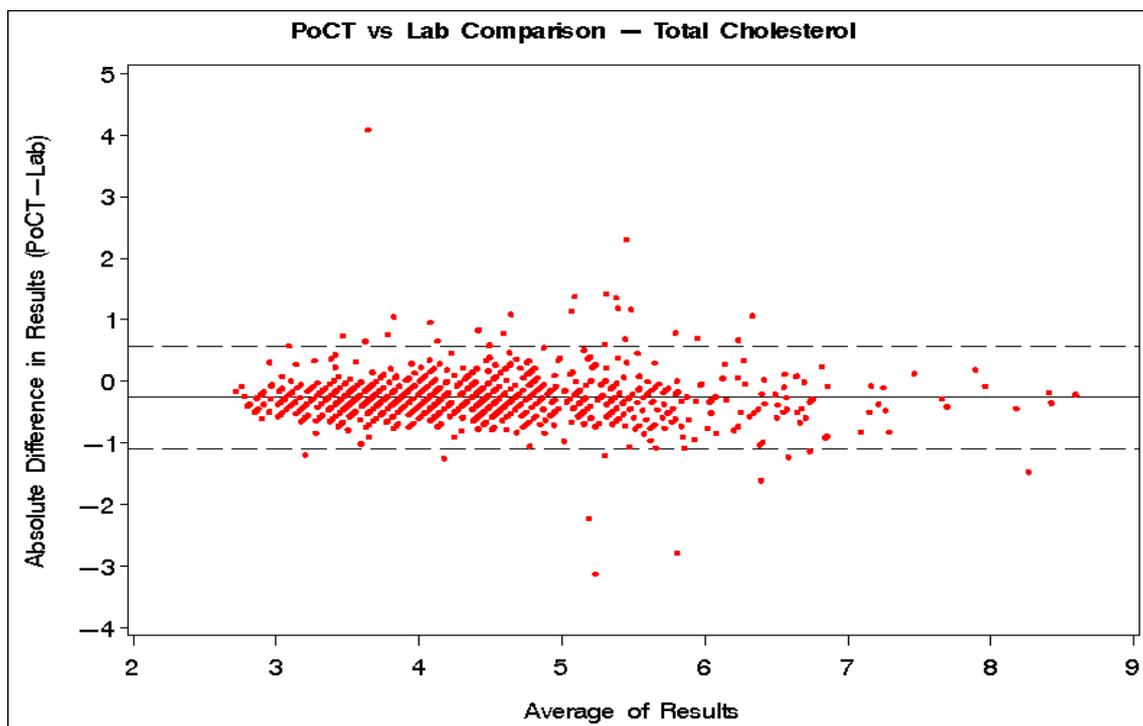
The 95% limits of agreement over all regions are -1.0931, 0.5641 mmol/L. Total cholesterol results obtained using a PoCT device will fall between 1.0931mmol/L below and 0.5641mmol/L above the corresponding pathology laboratory test result approximately 95% of the time. Figure 15 is a plot of the absolute difference in results for total cholesterol against the average of the results across all geographic regions.

**Table 85: Mean absolute difference in total cholesterol test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
Overall	-0.2645	-0.2930	-0.2361	-1.0931	0.5641	847

The results for total cholesterol relating to relative differences between PoCT and pathology laboratory test results are provided in Appendix 18.

**Figure 15: Absolute difference in results vs average of results for total cholesterol over all geographic regions**



Regression analysis revealed no significant linear relationship between the bias and the average of the PoCT and pathology laboratory test results ( $p=0.2300$  for all regions combined).

Out of the 864 matched PoCT and pathology laboratory test results for total cholesterol reported in Table 76, 847 (98.0%) were used in the above analysis. The remaining 17 matched tests could not be used due to the PoCT result falling below 2.6mmol/L, which is the minimum result the PoCT device is able to detect. Table 86 shows the pathology laboratory test results that were obtained for these tests.

**Table 86: Pathology laboratory test results for PoCT test results <2.6mmol/L**

Lab result	Frequency	%
2.4	2	11.76
2.5	1	5.88
2.6	2	11.76
2.7	4	23.53
2.8	2	11.76
2.9	4	23.53
3.1	1	5.88
3.5	1	5.88
Total	17	100.00

#### 7.4.6. Comparison of PoCT and pathology laboratory test results for HDL-C

The average HDL-C result across both PoCT and pathology laboratory tests can be used to give an indication of the magnitude of the total cholesterol results and is 1.29mmol/L. Results for HDL-C relating to absolute differences between PoCT and pathology laboratory test results are given in Table 87. These results are reported in mmol/L.

The estimated bias over all geographic regions is  $-0.0694$ mmol/L. This means that, on average, PoCT results are 0.0694mmol/L below the corresponding pathology laboratory test result. For HDL-C the true bias will lie between  $-0.0846$  and  $-0.0543$ mmol/L (95% CI).

Across all geographic regions, the 95% limits of agreement are  $-0.4899$ ,  $0.3510$  mmol/L. HDL-C results obtained using PoCT devices are expected to be between 0.4899mmol/L lower and 0.3510mmol/L higher than the corresponding pathology laboratory result approximately 95% of the time.

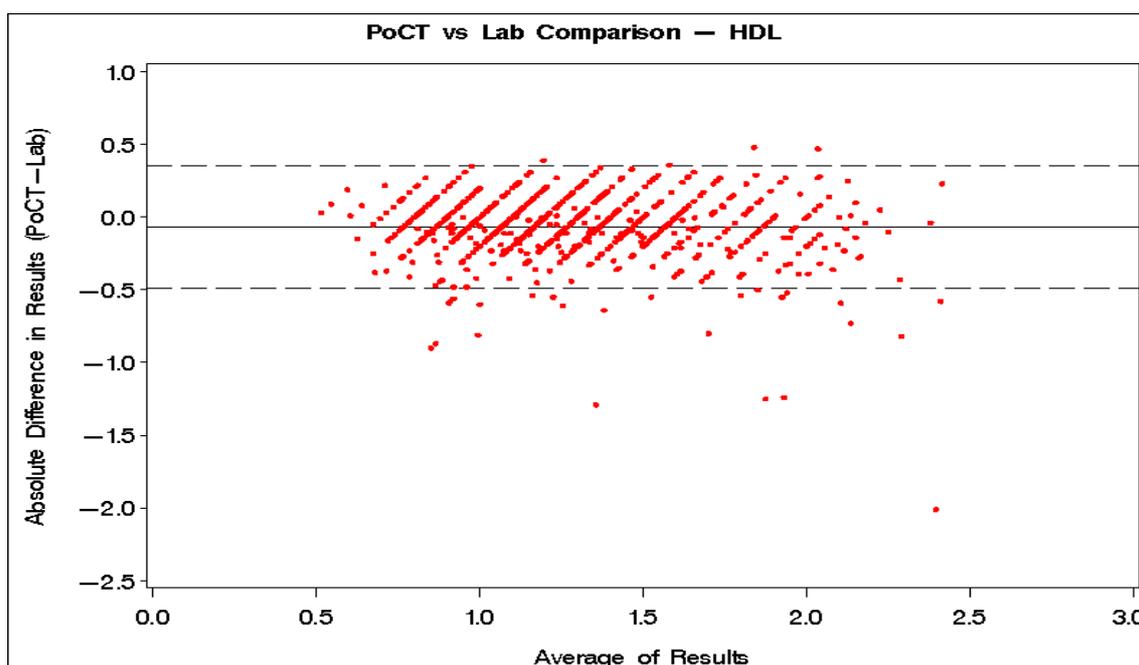
The plot in Figure 16 shows the absolute difference in results for HDL-C plotted against the average of the results across all geographic regions. Both positive and negative differences were observed, with a number of relatively large negative differences occurring.

**Table 87: Mean absolute difference in HDL-C test results and 95% limits of agreement by geographic location**

Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
		-0.0846	-0.0543	-0.4899	0.3510	
Overall	-0.0694	-0.0846	-0.0543	-0.4899	0.3510	772

The results for HDL-C relating to relative differences between PoCT and pathology laboratory test results are provided in Appendix 18. No significant linear relationship between the bias and the average of the PoCT and pathology laboratory test results was found using linear regression analysis ( $p=0.0615$  for all regions combined).

**Figure 16: Absolute difference in results vs average for HDL-C over all geographic regions**



There were 772 (99.2%) matched PoCT and pathology laboratory test results for HDL-C out of the 778 reported in Table 76 used in the above analysis. Table 88 gives the results for the five pairs of tests that could not be included, due to the fact that the PoCT result was less than 0.4mmol/L, the lower limit of the analytical range of the device. There was also one PoCT result which was greater than the upper limit of 2.6mmol/L. The corresponding pathology laboratory test result was 2.2mmol/L.

**Table 88: Pathology laboratory test result for PoCT HDL-C results <0.4mmol/L**

Lab result	Frequency	%
0.49	1	20.00
0.52	1	20.00
0.7	1	20.00
0.9	1	20.00
1.0	1	20.00
Total	5	100.00

#### 7.4.7. Comparison of PoCT and pathology laboratory test results for triglycerides

To give an indication of the order of magnitude of triglycerides results, the average result across both PoCT and pathology laboratory tests is 1.83mmol/L. In Table 89, results are given for triglycerides relating to absolute differences between PoCT and pathology laboratory test results. These results are reported in mmol/L.

An estimated bias of 0.2014mmol/L was observed across all geographic regions. This means that PoCT results are 0.2014mmol/L above the corresponding pathology laboratory test result on average. A 95% confidence interval for the true bias is 0.1618, 0.2411 mmol/L.

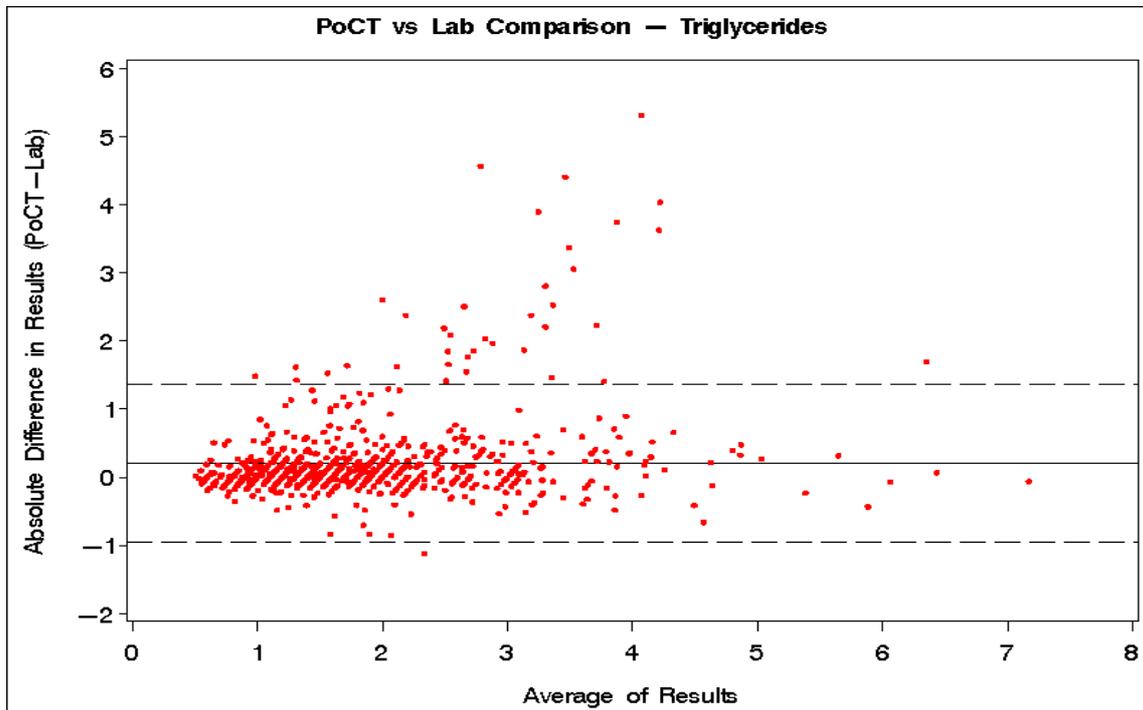
The overall 95% limits of agreement are -0.9540, 1.3569 mmol/L. In approximately 95% of cases, the triglycerides result from PoCT will be between 0.9540mmol/L lower and 1.3569mmol/L higher than the corresponding result from pathology laboratory testing.

Figure 17 is a plot of the absolute difference in results for triglycerides vs. the average of the results across all geographic regions. A number of relatively large positive differences occurred; however, the majority of differences are closer to zero.

**Table 89: Mean absolute difference in triglycerides test results and 95% limits of agreement**

Geographic location	Mean absolute difference (bas)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
		0.1618	0.2411	-0.9540	1.3569	
Overall	0.2014	0.1618	0.2411	-0.9540	1.3569	848

**Figure 17: Absolute difference in results vs average of results for triglycerides over all geographic regions**



The results for triglycerides relating to relative differences between PoCT and pathology laboratory test results are in Appendix 18. These results are reported as percentage differences relative to the pathology laboratory test result.

Results of the regression analysis revealed that there is a significant linear trend in the bias. When all regions are considered, the correlation coefficient is 0.0997, indicating a very weak positive linear trend. As the average of the PoCT and pathology laboratory test results increases by 1mmol/L, the bias increases by an estimated 0.1667mmol/L ( $p < 0.0001$ ). The 95% confidence interval for the true increase in bias is 0.0972, 0.2361 mmol/L. This means when the average of the results increases by 1mmol/L, the bias increases by between 0.0972 and 0.2361 mmol/L (95% CI).

There are 861 matched PoCT and pathology laboratory test results for triglycerides reported in Table 76. Of these, 848 (98.5%) were used in the above analysis. The remaining 13 matched tests could not be used due to the PoCT result falling outside the measurable range of the PoCT device. The pathology laboratory test results matched to PoCT results falling below the lower limit of 0.5mmol/L or above the upper limit of 7.3mmol/L are given in Table 90 and Table 91 respectively.

**Table 90: Laboratory results for PoCT triglycerides results <0.5mmol/L**

Lab result	Frequency	%
0.4	1	11.11
0.5	4	44.44
0.56	1	11.11
0.6	1	11.11
0.8	1	11.11
1.6	1	11.11
Total	9	100.00

**Table 91: Laboratory results for PoCT triglycerides results >7.3mmol/L**

Lab result	Frequency	%
6.91	1	25.00
8.7	1	25.00
12.2	1	25.00
15.9	1	25.00
Total	4	100.00

#### 7.4.8. Concordance analysis of pathology results and PoCT results

The number of paired results included in this analysis equals the number of matched tests in Table 76. Overall the agreement of results for the same patient obtained by the PoCT device and pathology laboratory ranged from 77% - 98% (Table 92). The discordant results for INR, HbA1c, urine albumin, ACR, total cholesterol, triglycerides and HDL-C were: 392/1677 (23.3%), 53/498 (10.6%), 8/320 (2.5%), 32/304 (10.5%), 131/864 (15.1%), 91/861 (10.5%) and 111/778 (14.2%) respectively. These results provide an indication of the percentage of test results where a clinical decision may have been altered depending on whether the test was from the laboratory or PoCT. The Bland Altman analyses (Sections 7.4.1 to 7.4.7) can provide detail regarding the likely differences between results and the level of agreement by test and by method of testing.

**Table 92: Agreement and disagreement of in range test results for the same patient by PoCT and pathology laboratory**

Test	Test result in target range				Total
	Agree		Disagree		
	Freq	%	Freq	%	
INR	1285	76.62	392	23.38	1677
HbA1c	445	89.36	53	10.64	498
Urine albumin	312	97.50	8	2.50	320
ACR	272	89.47	32	10.53	304
Total cholesterol	733	84.84	131	15.16	864
Triglycerides	770	89.43	91	10.57	861
HDL-C	667	85.73	111	14.27	778

#### 7.4.9. Clinically relevant agreement – INR results

For all patients, the proportion (95% CI) of dual INR measurements that satisfied the expanded and narrow criteria were 91.35% (79.91, 92.66) and 88.79% (87.18, 90.26) respectively (Table 93).

**Table 93: Percentage of agreement of dual INR measurements (CoaguChek S, laboratory) by using clinically relevant agreement criteria**

Agreement criteria	Urban (95% CI)	Rural (95% CI)	Remote (95% CI)	Combined results (95% CI)
	N=728	N=406	N=543	N=1677
Narrow	89.70 (87.62, 91.81)	88.67 (85.18, 91.58)	87.66 (8.60, 93.09)	88.79 (87.18, 90.26)
Expanded	91.62 (89.37, 93.53)	91.63 (88.49, 94.13)	90.79 (88.04, 93.09)	91.35 (89.91, 92.66)

In the analysis of the difference in dual INR results, the mean difference in the INR values for laboratory INR ranges of <2.0, 2.0-3.0, 3.1-4.0, >4.0 were 0.07, 0.00, -0.05, and -0.08 respectively. The percentage of dual INR measurements within 0.5 INR units for laboratory INR ranges of <2.0, 2.0-3.0, 3.1-4.0 and >4.0 was 94%, 90%, 69% and 67% respectively (Table 94).

**Table 94: Agreement of dual INR measurements as a function of increasing INR for all patients**

INR Range	Dual measurements	
	Mean difference (INR units)	Percentage within 0.5 INR units
<2.0	0.07	93.64
2.0-3.0	0.00	89.74
3.1-4.0	-0.05	69.10
> 4.0	-0.08	67.27
Overall	0.00	86.23

## 7.5. DISCUSSION

To answer the research question of whether it is safe to perform PoCT in a general practice setting the Trial looked at whether the results obtained from PoCT devices for each patient closely agreed with results obtained for the same patient from pathology laboratory testing. The 95% limits of agreement using the Bland and Altman method were calculated for each test. The clinical significance of these results was then determined by clinical review. The Trial concluded that the mean difference in results and the 95% limits of agreement were clinically acceptable for all tests.

Interpretation of the significance of the 95% limits of agreements is difficult. While the Bland and Altman method is widely used, it provides only a description of the results. With no pre-determined acceptable limit of agreement for any of the tests analysed, it is difficult to determine the significance of the Trial results. The relatively wide limits of agreement found in this Trial can to some extent be explained by the large number of laboratories participating in the Trial each using a range of different methods with their own analytical performance characteristics. This factor would be expected to contribute to the increase in the width of the limits of agreement. As Bland and Altman conclude it would be very improbable that different methods would agree exactly<sup>77</sup> and in

this Trial it was deemed that the mean difference in results and the 95% limits of agreement between the PoCT and laboratory result would not compromise clinical decisions and patient safety. Four studies devoted to INR testing have assessed Bland Altman plots between PoCT and laboratory results in the general practice setting. The results from these studies found the difference between PoCT and laboratory results to be clinically acceptable<sup>16, 17, 62, 76</sup> and the one study which reported the 95% limits of agreement showed results within acceptable limits<sup>16</sup> supporting Trial findings. No studies were found that have investigated the 95% limits of agreement between PoCT and laboratory results for diabetes or hyperlipidaemia testing, in a general practice setting.

Analysis describing agreement of PoCT and pathology laboratory results in terms of whether the results fell within or outside the target range showed that the percentage of tests in agreement ranged from 77%-98%. Under the assumption that a GP would only change patient management if a test result was 'outside target range', the results indicate that between 2%-23% of clinical decisions could have been different depending on the method of testing. However, in this analysis 'outside target range' may have only been 0.1 units outside (e.g. for HbA1c target range = 7.0%, value obtained = 6.9%) which may not have resulted in any change in patient management.

The INR results showed the largest discordance (23%); however, patient safety was not compromised as there were no serious adverse events, such as thromboembolic complications or life threatening haemorrhage identified as attributable to the Trial. Hobbs et al.<sup>63</sup> who evaluated the reliability of INR using PoCT devices in comparison with results obtained from the laboratory concluded that up to 53% of tests would have resulted in a different dose of warfarin being given depending on the method of INR determination. They reported one possible reason for the discordance between PoCT and laboratory results as being that the laboratory or practices did not meet the QA standards.

The accuracy of the PoCT devices as compared with conventional laboratory methods to measure INR patients was assessed using clinically relevant criteria. Based on this analysis it can be concluded that the PoCT device for INR measurement achieved clinically acceptable levels of accuracy. That is, it is unlikely to result in over or under dosing of warfarin. Using the agreement criteria developed by Anderson et al.<sup>106</sup> and Douketis et al.<sup>19</sup> there was a high level of agreement (approximately 90%) between the PoCT device and laboratory method.

The Trial found the PoCT device to be 91% accurate against expanded agreement criteria and 89% accurate against narrow criteria. This compares favourably with results from other studies which have used the same or older CoaguChek devices. Anderson et al.<sup>106</sup> found the device to be 96% accurate against expanded criteria and Douketis et al.<sup>19</sup> found the CoaguChek to be 90% accurate against expanded criteria and 86% against narrow criteria. Shiach et al.<sup>18</sup> found 98% and 97% agreement against expanded and narrow criteria respectively. In two Australian studies using CoaguChek S, the same device used in the Trial, agreement was found to be 90% against expanded criteria and 88% against narrow criteria in an outpatient clinic, and 93% against expanded criteria and 90% against narrow criteria in rural practice.<sup>15, 17</sup>

The Trial found 86% of dual measurements were within 0.5 INR units, which is similar to that found by Jackson et al.<sup>15</sup> (83%), Jackson et al.<sup>17</sup> (88%) and Douketis et al.<sup>19</sup> (79%). The Trial's results on the percentage of dual measurements within 0.5 units achieved similar results for the lower result ranges, but the Trial achieved much higher measurements of agreement in the higher INR ranges than other studies.<sup>15, 17, 19</sup>

From a clinical perspective, the margin of error for the PoCT device is most important in the INR range of 1.5 to 3.5 because decision about warfarin dosing will be influenced by relatively small differences in the INR between a PoCT device and a laboratory method. The risk of stroke increases sharply when INR falls below 2.0. The results from the Trial indicate that the PoCT device is very accurate for INR results less than 3.0. The mean difference between the PoCT INR and laboratory INR was less than 0.1 units. This is similar for INR values greater than 3.0.

Based on the results obtained from the clinically relevant agreement analysis, the PoCT device provided acceptable levels of accuracy when compared with laboratory results for INR. However,

the increased level of inaccuracy of the device at INR values above 3.5 or 4.0 may require the need for guidelines in the use of the device at these levels, as suggested by Jackson et al.<sup>15</sup>

The review by clinicians indicated that, as with INR, the wide limits of agreement for the other tests were not considered clinically significant.

### *Limitations*

The key limitation with this analysis was the poor adherence to the protocol which resulted in a percentage of laboratory and PoC test results that could not be matched. A number of possible reasons for unmatched results have been identified including: non-compliance with Trial protocol, loss to follow-up, specialist care and electronic downloads from laboratories. In each case, the Trial attempted to minimise this as much as possible.

Several practices involved in the Trial did not follow the Trial protocol regarding pathology testing. This resulted in them not undertaking a corresponding pathology test when undertaking a PoC test in Phase I of the Trial. Where this had been identified, the Trial Manager requested that they commence pathology laboratory testing immediately. However, prior PoCT results did not have matching laboratory results, and therefore there are missing laboratory results for some PoCT results.

Several GPs did not place the pink sticker on the pathology request form, which was designed to alert the pathology laboratories that the patient was involved in the Trial and that a copy of the test results should be forwarded to the Trial Manager. This was followed up by the Trial Manager and results were obtained from the pathology laboratories or practices where possible.

The number of HDL-C pathology results from the laboratories is low as this test needed to be specifically requested and this did not always occur. Pathology laboratories do not automatically provide an HDL-C when a lipid study is ordered. This occurred mainly in Victoria.

Lack of matching of PoCT and laboratory results has also resulted from a mismatch of date of testing of the laboratory results and the date on the PoCT internal request/result forms. This problem had been identified in one practice where the date was recorded on the request/result form prior to the patient's appointment. If the patient failed to attend the appointment the date was not changed on the form when the appointment was re-scheduled. While this was identified in one practice, it may also have occurred in other practices and reduced the number of exact matches.

Similarly, patients may have elected to have the laboratory test on a different day to the PoC test and so there was mismatch of results. While practices and patients were strongly encouraged to undertake both tests on the same day, it was not possible to ensure that this occurred with every patient. This seems a likely explanation for the low number of matching ACR results, as this test is required to be undertaken after fasting.

Mismatches between PoCT and laboratory results may also have occurred because a patient failed to attend the pathology laboratory or the practice for their pathology test as requested.

In some cases the patient had seen a specialist who requested a pathology blood test just prior to their visit to the GP. The practice then undertook a PoC test but did not impose a repeated pathology test. This resulted in the lack of a match between PoCT and pathology results.

Difficulties arose with the receipt of pathology results from the pathology providers in an electronic format. Some pathology laboratories did not activate the transfer of pathology results for identified patients until some months after the Trial's commencement date. Where possible this was rectified by the Trial Manager, but in some cases it was not possible to obtain the data retrospectively and therefore resulted in missing information.

In matching the electronic pathology test with the PoCT, the test codes used by each pathology provider were also used to identify the relevant tests and then to match them with a PoCT result. However, some tests were provided by the pathology provider under several different test codes. For example, total cholesterol can be requested as part of a lipids study test request but is also

provided in the group of test results under a complete blood examination request. This meant that a test sent to the Trial Manager as part of the complete blood examination did not have a PoCT match.

## **7.6. CONCLUSION**

The Trial found relatively wide limits of agreement which can be partly explained by the impact of multiple pathology laboratories for comparison with the PoCT results, rather than one reference laboratory. However, the methodology utilised reflects the real world, where practices utilise a number of pathology laboratories.

There are currently limited methods to assess the clinical relevance of agreements. INR is the only condition where there has been research in this area and a standard approach developed. This is likely because of the potential for adverse events. For the other tests used in the Trial, no such methods exist and therefore this requires review of limits of agreement and then judgement by clinicians as to what is clinically acceptable. This was the approach used in the Trial for HbA1c, urine albumin, ACR, total cholesterol, HDL-C and triglycerides. One conclusion from this Trial is the need to develop a method to assess clinically relevant agreements for these tests. Overall, all PoC test results were deemed to be clinically acceptable.



## 8. SAFETY OF PoCT IN GENERAL PRACTICE PART 4 – SERIOUS ADVERSE EVENTS AND INCIDENTS

### SUMMARY OF THE CHAPTER

This chapter describes the methodology and results of the analysis of the serious adverse events (SAEs) and incidents reported during the Trial, which formed part of the assessment of the safety of PoCT. SAEs were monitored by a Safety Subcommittee which assessed and made a recommendation to the Trial Management Committee regarding the likelihood or otherwise that a particular SAE was related to the Trial.

Weighted estimates of the number of SAEs, the number and percentage of patients experiencing one or more SAE and the number of SAEs per 10,000 person-years were calculated both overall and by treatment group. Descriptive analysis of Trial incidents was also undertaken.

The key findings of the chapter are:

- no SAE reviewed was assessed to be attributable to PoCT
- for all three conditions, the number of SAEs per 10,000 person-years for the intervention (1319) group was lower than for the control (1446) group
- overall, the proportion of patients experiencing one or more SAE was the same for both the intervention (13%) and control (13%) groups
- a larger number of incidents was recorded by the Trial Management Group from patients and practices in the intervention group and that number reduced over the period of the Trial
- most calls to the QC/QA hotline related to interpretation and recording of QC results
- 15 test error codes were recorded during the Trial and these errors related to pre-analytical or operative factors.

The key conclusion:

- based on the results, it can be concluded that PoCT did not result in a higher number of SAEs.

### 8.1. INTRODUCTION

Reporting of SAEs is an essential component of most randomised control trials.<sup>107</sup> Serious adverse events monitoring is an important part of assessing the safety of any new intervention. A key aspect of the Trial was to ensure that an effective quality management program was developed and implemented, firstly to assure quality and safety of PoCT undertaken by participating practices and secondly to ensure the viability of Trial processes and procedures. Requirements of the quality management program were outlined in the Trial Design<sup>25</sup> and included identification, reporting and management of SAEs and incidents.

In addition to SAEs, as part of the Trial Design, the Trial Management Group, Device Group and Quality Assurance Group were required to maintain a log of incidents throughout the PoCT Trial. This chapter outlines the methods, results and discussion of these two areas.

## 8.2. AIMS AND OBJECTIVES

The aim of this chapter is to address the research question: Is it safe to perform PoCT in a general practice setting focusing on serious adverse events and incidents. The objectives are:

- to determine if the number of SAEs reported in PoCT patients per person-year is the same as or fewer than the number of SAEs reported in control patients per person-year
- to determine if the proportion of PoCT patients who experience one or more serious adverse event is the same as or less than the proportion of control patients who experience one or more SAE
- to assess the type of incidents reported by each participant group – GPs, Device Operators and patients.

## 8.3. METHODS

### 8.3.1. Serious adverse events

The definition of SAEs used in the Trial is provided in Appendix 19.

SAE data were collected and reported using two different methodologies and both were reported to and reviewed by the Safety Subcommittee.

The first and standard methodology involved a combination of reports made to the Trial Management Group direct by practice staff using the appropriate SAE reporting form (see Appendix 20). This method also involved SAEs reported to the Trial by patients or the families of patients, in which case documentation to confirm the SAE was sought from the practice. This is referred to as Method 1.

During the Trial it became clear that there was under-reporting of SAEs using Method 1 with over-representation of particular practices and within the intervention group. Following discussions with the Safety Subcommittee and the national PoCT Steering Group it was determined that data should be sought using a different methodology. Given that a case note audit (CNA) was required for a different aspect of the Trial, it was therefore decided to use this process to gather the additional data which would then be used to confirm or otherwise the suspected under-reporting. This is referred to as Method 2.

For both methods of reporting SAEs, reports made by practice staff were reviewed on receipt by the Trial Manager and subsequently circulated to the Safety Subcommittee as soon as deemed reasonable in the judgement of the Trial Manager. Details were taken of SAEs reported by patients or the families of patients and confirmation of the event was subsequently sought from the patient's GP, together with the required SAE assessment of causation on the required form. SAEs identified through the CNA process were documented and confirmation again sought from the patient's GP together with the required SAE assessment of causation on the required form.

Reporting of SAEs for patients on anticoagulant therapy was extended one month beyond the end of Phase II of the Trial to ensure all SAEs that could have resulted from the Trial were included in the analysis. Collection of SAEs for patients with diabetes or hyperlipidaemia ceased at the end of Phase II (28 February 2007).

#### 8.3.1.1. *Role of the Safety Subcommittee*

The Safety Subcommittee monitored all reported SAEs and made recommendations to the Trial Management Committee regarding the likelihood or otherwise that a particular SAE was related to the Trial. The Safety Subcommittee was established as per the guidelines for good practice for clinical trials by the Medical Research Council in the United Kingdom<sup>108</sup> and the National Health and Medical Research Council's ethical conduct in human research.<sup>109</sup>

The Safety Subcommittee also developed the stopping rules for the Trial. These are outlined in Appendix 21.

Based on detail provided in reported SAEs, the Safety Subcommittee considered whether a particular event was attributable to the patient's participation in the Trial, subsequently forming a recommendation based on the information available as to whether the SAE was likely to have been related to the Trial intervention. This was possible with the inclusion of detail to identify which treatment group the patient belonged to and the condition for which the patient was enrolled in the Trial.

This recommendation was then submitted to the Trial Management Committee for consideration and decision as to whether to stop or continue the Trial if it was determined that a specific event or series of events was identified as arising from the Trial intervention. If a specific SAE were to result in death, an urgent report would be issued immediately by the Trial Manager to the Safety Subcommittee. If the Safety Subcommittee were to make a recommendation to stop or alter the Trial intervention, an urgent Trial Management Committee meeting would then be called.

In the event that a change to the Trial or the Trial intervention was recommended for patient safety reasons, the Chair/Principal Investigator of the Trial Management Committee was required to act to implement the change as expeditiously as possible.

#### 8.3.1.2. *Statistical analysis*

Statistical analyses were planned for the number of SAEs per person-year and the proportion of patients experiencing one or more SAEs based on data collected on all patients using Method 1. However, a comparison of data collected using Methods 1 and 2 provided evidence of severe under-reporting by Method 1. The PoCT Management Committee agreed that it would be more appropriate for analysis to be restricted to case note audit patients, combining data collected by Methods 1 and 2, for the purposes of assessing safety.

By using data collected on case note audit patients by both methods, more SAEs would be captured. However, the combined data would still be incomplete. Method 2 only involved a review of case notes for consultations relating to test results, rather than all consultations (since the primary purpose for conducting the case note audit was to collect information on GP actions relating to test results). Given the limitations of the data, only descriptive analyses were performed, as the results of statistical tests may not accurately reflect any potential differences between treatment groups in the outcomes of interest.

Weighted estimates of the number of SAEs, the number and percentage of patients experiencing one or more SAEs and the number of SAEs per 10,000 person-years were calculated by treatment group and type of SAE, both overall and by condition. The number of SAEs per 10,000 person-years provides the most relevant and appropriate description of the data since it takes into account the difference in the number of participants in each treatment group and the fact that different participants were in the study for different periods of time.

For details on patient selection for the case note audit and calculation of sampling weights, see Chapter 1 (section 1.13). The results of the analysis of Method 1 are provided in Appendix 22.

#### 8.3.2. Incidents

Descriptive analysis was undertaken using the log of incidents that was maintained by each group participating in the Trial: the Trial Management Group, the Device Group and the Quality Assurance Group. The Safety Subcommittee was provided with regular incident report summaries by each of the groups. These reports were reviewed and further information sought where incidents were not resolved or where further action was required. In the case of ongoing issues, clarification was sought from the relevant provider regarding the cause and potential solution/s.

### 8.3.2.1. Trial Management Group

Incidents were reported in two ways to the Trial Manager with both logged on the Trial's Management Information System. Incidents were reported under the following categories:

- practice reported incidents and
- telephone reported incidents.

The Trial Manager defined six categories of incidents which were used to define all incidents reported as outlined in Table 95.

**Table 95: Definitions of incidents for PoCT Trial**

Type of Incident	Description
Patient related	<p>Patient related incidents refer to those incidents related to a patient that occur at or during the course of the Point of Care test. This may include the patient fainting, pain from finger prick etc.</p> <p>It also includes incidents related to personal aspects of the patient such as change of address or notification by a relative of a death.</p> <p>A patient related incident is not and does not include a serious adverse event.</p>
Operator related	<p>Operator related incidents refer to those incidents involving the Device Operator that occur during the course of undertaking a Point of Care test. This may include the inability of the operator to obtain the required blood sample, repeated device errors.</p>
Device related	<p>Device related incidents refer to any problems or difficulties experienced with the PoCT device. These incidents must be logged on the Test Error Log Sheet and referred to the Device Group.</p>
Quality control/Quality assurance related	<p>Quality control/quality assurance incidents relate to any problems or difficulties in performing the QC/QA processes or problems with materials, delivery or results.</p>
Trial related	<p>Trial related incidents refer to those incidents or queries around aspects of the Trial management such as patient recruitment, withdrawal, data collection processes or Trial procedures.</p>
Other incidents not elsewhere defined	<p>Any other incidents not covered in the five categories above including incidents such as power failure that prevent testing from being undertaken.</p>

Practice related incident reports were completed by participating practices for an incident relating to the Trial that occurred in the practice. Practices were required to complete a brief report on the incident that was then forwarded to the Trial Manager. In some instances a Test Error Log Sheet would also be completed and faxed to the Device Group.

Additionally, practices and patients were given access to a free 1800 telephone number which diverted to each of the three Trial groups. All telephone calls from practices and patients to the Management Group were logged as incidents. These incidents were grouped into categories.

Incidents relating to the devices or quality control and quality assurance were forwarded to the relevant groups when necessary.

### 8.3.2.2. *Device and QAP Groups*

#### *Device Group*

##### *Hotline calls*

The 1800 telephone hotline was manned by a member of the PoCT Device Working Group from 8am to 8pm Monday to Friday and from 8am to 1pm Saturday mornings.

A telephone help desk register was established, which logged all telephone communications conducted between practices and the PoCT Device Working Group. Incoming calls were categorised according to whether they related to a device, reagent, QC, consumables or training issue. A record of the summary of the problem, the action taken to address the problem and follow-up action required to resolve the problem were also recorded.

##### *Test Error Logs*

A Test Error Log Sheet was devised to record specific error codes displayed on PoCT devices when such an event occurred. These Log Sheets were provided for all practices at the commencement of the live phase of the Trial. Device Operators were required to complete the Test Error Log Sheet and immediately fax it to the PoCT Device Group every time a test error occurred. The PoCT Device Group maintained a log of all test error codes.

##### *Device Events*

All device events were required to be immediately reported to the PoCT Device Group via the telephone hotline. These events were then logged by the Device Group. An Industry Escalation Procedure was developed by the PoCT Device Group to cater for the situation whereby a series of similar device events were reported in a short time frame, necessitating urgent industry action. However this procedure was not required during the Trial.

##### *QAP Group*

Serious adverse events and incidents for the external quality assurance programs were monitored by the RCPA Quality Assurance Program Pty Ltd. Two methods were used:

- review of the practice external quality assurance (EQA) and internal quality control (IQC) results. Review meetings were held with the Device Group to review all quality management results on a fortnightly or monthly basis as the results were returned. This was an indicator of the practice staff competency and a secondary indicator of the adequacy of patient results
- helpdesk support hotline calls were logged and reviewed.

## **8.4. RESULTS**

### 8.4.1. Evidence of under-reporting of SAEs using practice reporting (Method 1)

The Safety Subcommittee at its meeting in March 2007 to review practice reported SAE data noted that there was a higher level of reporting of SAEs by intervention practices and that this had been consistent throughout the Trial. Of the intervention practices reporting SAEs, one had reported 60 (33%) and another 21 (11.6%) of the total 181 reported events. It was this inconsistent rate of reporting that prompted data to be sought using a different method.

The case notes of over 1,000 randomly selected patients of 18 randomly selected practices were audited. Table 96 shows that, for audited patients, a total of 199 SAEs were reported and of these 156 (78.39%) were identified by the CNA process. Of the 101 SAEs reported for control patients, 84% of their reported SAEs were identified through the CNA process and of the 98 SAEs reported for intervention patients, 72% of their SAEs were identified through the CNA process.

**Table 96: Method of SAE identification among case note audit patients by treatment group**

Method of SAE identification	Treatment group					
	Control		Intervention		Total	
	N	%	N	%	N	%
Identified by practice	16	15.84	27	27.55	43	21.61
Identified by case note audit	85	84.16	71	72.45	156	78.39
Total	101	100.00	98	100.00	199	100.00

These data confirm that, for these patients, more SAEs were identified as a result of the CNA, and that a higher percent of SAEs were identified in this way for control patients than for intervention patients.

The CNA also identified additional SAEs across all the categories that had not been identified by practices using Method 1 (Table 97). More SAEs were identified through the CNA process than were reported by the practice except in the case of death for both treatment groups.

**Table 97: Serious adverse events by treatment group for case note audit patients**

Type of SAE	Method of SAE identification	Treatment group				Total	
		Control		Intervention		Total	
		N	%	N	%	N	%
Death	By practice	9	75.00	7	100.00	16	84.21
	By Case Note Audit	3	25.00	0	0	3	15.79
	Total	12	100.00	7	100.00	19	100.00
Inpatient hospitalisation or prolongation of existing hospitalisation	By practice	5	6.49	16	26.23	21	15.22
	By Case Note Audit	72	93.51	45	73.77	117	84.78
	Total	77	100.00	61	100.00	138	100.00
Life threatening	By Case Note Audit	0	0	2	100.00	2	100.00
	Total	0	0	2	100.00	2	100.00
Newly diagnosed cancer	By practice	1	33.33	0	0	1	25.00
	By Case Note Audit	2	66.67	1	100.00	3	75.00
	Total	3	100.00	1	100.00	4	100.00
Other important medical event	By practice	1	12.50	4	15.38	5	14.71
	By Case Note Audit	7	87.50	22	84.62	29	85.29
	Total	8	100.00	26	100.00	34	100.00
Permanent or significant disability or incapacity	By Case Note Audit	1	100.00	1	100.00	2	100.00
	Total	1	100.00	1	100.00	2	100.00
Total		101	100.00	98	100.00	199	100.00

It is apparent from the data that more SAEs were identified as a result of the CNA, and that a higher percentage of SAEs was identified in this way for control patients than for intervention patients. Following this analysis, the decision was made that the CNA data relating to SAEs was more likely to reflect the true status of SAEs for the PoCT Trial, although this method also had limitations. Therefore the decision was made to use the CNA data for the analysis of SAEs and that

weighted estimates would be used so that the results could be applied to the entire Trial population.

#### 8.4.2. Assessment of SAEs by Safety Sub-Committee

The PoCT Safety Sub-committee assessed 384 SAEs obtained either through practice reporting or through the CNA to determine if the events related to the PoCT Trial. The results of the assessments are shown in Table 98.

**Table 98: Outcome of SAEs assessed by the PoCT safety sub-committee**

Outcome of safety sub-committee assessment	Control		Intervention		Total	
	N=139		N=252		N=391	
	Freq	%	Freq	%	Freq	%
Not assessed	4	2.9	3	1.2	7	1.8
Unlikely to be related to the Trial	135	97.1	249	98.8	384	98.2

Nearly all the SAEs (98.2%) were deemed unlikely to be related to the Trial. A total of seven SAEs were not assessed by the sub-committee because the details were unobtainable from the practice as the records had been archived or because the practices were unable to provide details to the Trial Manager by the deadline for data analysis.

#### 8.4.3. Serious adverse events reported using weighted estimates based on the case note audit

A summary of SAEs based on the CNA weighted estimates for the entire study population is shown in Table 99. Overall 939 SAEs were estimated for the study population and of these 390 were in the control group and 549 were in the intervention group. The most common estimated SAEs were inpatient hospitalisations (69.72%) followed by other important medical events (17.86%). Other important medical events included: day admission for procedures such as gastroscopy, colonoscopy, cataract surgery, angiogram, and other events such as motor vehicle accident, plus emergency department visits for general sickness such as abdominal pain, and vomiting. Life threatening events included: cardiac event, shortness of breath, and hypoglycaemia. The least common estimated SAE was permanent disability or significant disability or incapacity (1.11%).

**Table 99: Type of SAE by treatment group (weighted estimates)**

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N	%	N	%	N	%
Death	41	10.42	41	7.45	82	8.68
Inpatient hospitalisation or prolongation of existing hospitalisation	305	78.11	350	63.75	655	69.72
Life threatening	0	0.0	11	2.03	11	1.19
Newly diagnosed cancer	10	2.58	3	0.63	14	1.44

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N	%	N	%	N	%
Other important medical event	31	7.86	137	24.97	168	17.86
Permanent or significant disability or incapacity	4	1.03	6	1.17	10	1.11
Total	390	100.00	549	100.00	939	100.00

There were some differences in the type of estimated SAE by treatment group. A higher percentage of inpatient hospitalisations were estimated for the control group (78.11%) compared to the intervention group (63.75%) while the intervention group was estimated to have a higher percentage of other important medical events (24.97%) compared to the control group (7.86%).

Of the SAEs estimated for the control group, 257 patients (13.1%) experienced 390 estimated events (Table 100). Of those estimated for the intervention group, 405 patients (12.5%) experienced 549 estimated SAEs, with a total of 662 (13.3%) patients estimated to have experienced 939 events throughout the Trial (Table 100).

Hospitalisation was estimated as the most frequently occurring event experienced by patients participating in the Trial. An estimated 473 (9.53%) patients were hospitalised 655 times and of these 214 (10.9%) were in the control group and 260 (8.64%) were in the intervention group.

**Table 100: Patients experiencing one or more SAEs by treatment group and type of SAE (weighted estimates)**

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N=1958		N=3010		N=4968	
	N	%	N	%	N	%
Death	41	2.08	41	1.36	82	1.64
Inpatient hospitalisation or prolongation of existing hospitalisation	214	10.9	260	8.64	473	9.53
Life threatening	0	0.0	11	0.37	11	0.22
Newly diagnosed cancer	10	0.51	3	0.12	14	0.27
Other important medical event	31	1.57	127	4.21	157	3.17
Permanent or significant disability or incapacity	4	0.21	6	0.21	10	0.21
Any SAE	257	13.1	405	13.5	662	13.3

Overall, the estimated rate of occurrence of SAEs per 10,000 person-years for all events is slightly higher for the control group patients (1446.06) compared with the intervention group patients (1319.90) (Table 101). The rate of occurrence of death, hospitalisation and newly-diagnosed cancer is higher for control group patients; however, the rate of occurrence of other important medical events and life threatening events was higher in the intervention group.

**Table 101: Number of SAEs per 10,000 person-years by treatment group and type of SAE (weighted estimates)**

Type of SAE	Control	Intervention	Total
Death	150.69	98.29	118.92
Inpatient hospitalisation or prolongation of existing hospitalisation	1129.47	841.47	954.83
Life threatening	0.00	26.81	16.26
Newly diagnosed cancer	37.24	8.33	19.71
Other important medical event	113.71	329.53	244.58
Permanent or significant disability or incapacity	14.95	15.47	15.26
Total	1446.06	1319.90	1369.56

#### 8.4.3.1. Anticoagulant therapy

Within the group of patients on anticoagulant therapy, there were 358 estimated SAEs, with the most common type of SAE being inpatient hospitalisation (62.41%), followed by other important medical events (21.64%) (Table 102). There were no events classified as life threatening for either treatment group. There were some differences between the treatment group and type of SAEs. Overall, there were more SAEs in the intervention group (183) compared to the control group (174). A higher proportion of SAEs within the control group were inpatient hospitalisations (67.14%) compared with the intervention group (57.90%), while the intervention group had no events related to newly diagnosed cancer or permanent or significant disability.

**Table 102: Type of SAE by treatment group for anticoagulant therapy (weighted estimates)**

Type of SAE	Treatment Group				Total	
	Control		Intervention		Total	
	N	%	N	%	N	%
Death	24	13.80	25	13.41	49	13.60
Inpatient hospitalisation or prolongation of existing hospitalisation	117	67.14	106	57.90	223	62.41
Life threatening	0	0	0	0	0	0
Newly diagnosed cancer	4	2.50	0	0	4	1.22
Other important medical event	25	14.24	53	28.69	77	21.64
Permanent or significant disability or incapacity	4	2.31	0	0	4	1.13
Total	174	100.00	183	100.00	358	100.00

Of the SAEs estimated for patients on anticoagulant therapy, 235 (21.7%) patients experienced one or more SAEs (Table 103). Of those estimated for the intervention group, 129 patients (18.6%)

experienced 183 events, with 106 (27.6%) of control patients on anticoagulant therapy experiencing one or more events (Table 103). For patients on anticoagulant therapy the most frequently occurring SAE was inpatient hospitalisation and this was repeated across treatment groups. Anticoagulant therapy patients in the control group had more hospitalisations than patients in the intervention group (79 times versus 65 times).

**Table 103: Patients on anticoagulant therapy experiencing one or more SAE by treatment group and type of SAE (weighted estimates)**

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N=388*		N=694*		N=1082*	
	N	%	N	%	N	%
Death	24	6.21	25	3.54	49	4.50
Inpatient hospitalisation or prolongation of existing hospitalisation	79	20.5	65	9.43	145	13.4
Life threatening	0	0.0	0	0.0	0	0.0
Newly diagnosed cancer	4	1.13	0	0.0	4	0.40
Other important medical event	25	6.41	53	7.57	77	7.16
Permanent or significant disability or incapacity	4	1.04	0	0.0	4	0.37
Any SAE	106	27.3	129	18.6	235	21.7

\*Note: The case note audit patient selection was not stratified by condition so these numbers are estimates based on the case note audit patients, rather than actual numbers of anticoagulant therapy patients in the study.

For patients on anticoagulant therapy, the estimated rate of occurrence of SAEs per 10,000 person-years for all events was higher in the control group (3308.36 events) than in the intervention group (2018.08 events) (Table 104). For all events, except life threatening and other important events, patients on anticoagulant therapy in the control group had a higher number of occurrences per 10,000 person years than patients in the intervention group. The only exception was other important medical events which occurred at a higher number in the intervention group (Table 104).

**Table 104: Number of SAEs per 10,000 person-years by treatment group and type of SAE for patients on anticoagulant therapy**

Type of SAE	Control	Intervention	Total
Death	456.71	270.59	339.04
Inpatient hospitalisation or prolongation of existing hospitalisation	2221.26	1168.54	1555.72
Life threatening	0.00	0.00	0.00
Newly diagnosed cancer	82.77	0.00	30.44
Other important medical event	471.19	578.95	539.31
Permanent or significant disability or incapacity	76.43	0.00	28.11
Total	3308.36	2018.08	2492.63

#### 8.4.3.2. Diabetes

Within the group of patients with diabetes, there were 372 estimated SAEs, with the most common type of SAE being inpatient hospitalisation (64.54%), followed by other important medical events (17.55%) (Table 105). There were no events classified as life threatening or permanent or significant disability for the control group. There were some differences between treatment group and type of SAEs. Overall, for patients with diabetes, there were more SAEs in the intervention group (222) compared to the control group (149). A higher percentage of SAEs within the control group were in-patient hospitalisations (80.59%) compared with the intervention group (53.76%), while the intervention group (25.19%) had a higher percentage of events classified as other important medical events than the control group (6.18%) (Table 105).

**Table 105: Type of SAE by treatment group for diabetes (weighted estimates)**

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N	%	N	%	N	%
Death	10	6.50	26	11.59	36	9.55
Inpatient hospitalisation or prolongation of existing hospitalisation	120	80.59	120	53.76	240	64.54
Life threatening	0	0.0	11	5.01	11	3.00
Newly diagnosed cancer	10	6.73	3	1.56	14	3.63
Other important medical event	9	6.18	56	25.19	65	17.55
Permanent or significant disability or incapacity	0	0.0	6	2.89	6	1.73
Total	149	100.00	222	100.00	372	100.00

Of the SAEs estimated for patients with diabetes, 277 (14.2%) of patients experienced one or more SAE (Table 106). Of those estimated for the intervention group, 172 patients with diabetes (14.7%) experienced 222 events while 105 (13.5%) of control patients with diabetes experienced 149 events. For patients with diabetes, the most frequently occurring SAE was inpatient hospitalisation and this was repeated across treatment groups. A higher percentage of patients with diabetes in the control group (10.7%) were hospitalised than patients in the intervention group (7.49%). A higher percentage of patients with diabetes in the intervention group had events which were life threatening, death, disability and incapacity and other important medical events.

**Table 106: Patients with diabetes experiencing one or more SAE by treatment group and type of SAE (weighted estimates)**

Type of SAE	Treatment group					
	Control		Intervention		Total	
	N=775*		N=1173*		N=1947*	
	N	%	N	%	N	%
Death	10	1.25	26	2.20	36	1.82
Inpatient hospitalisation or prolongation of existing hospitalisation	83	10.7	88	7.49	171	8.76
Life threatening	0	0.00	11	0.95	11	0.57
Newly diagnosed cancer	10	1.30	3	0.30	14	0.69
Other important medical event	9	1.19	56	4.78	65	3.35
Permanent or significant disability or incapacity	0	0.00	6	0.55	6	0.33
Any SAE	105	13.5	172	14.7	277	14.2

*\*Note: The case note audit patient selection was not stratified by condition so these numbers are estimates based on the case note audit patients, rather than actual numbers of diabetes patients in the study.*

For patients with diabetes, the estimated rate of occurrence of SAEs per 10,000 person-years for all events was higher in the control group (1421.54 events) than in the intervention group (1378.14 events) (Table 107). For all events, except newly diagnosed cancer and inpatient hospitalisation, patients with diabetes in the intervention group had a higher number of occurrences per 10,000 person years than patients in the intervention group (Table 107).

**Table 107: Number of SAEs per 10,000 person-years by treatment group and type of SAE for patients with diabetes**

Type of SAE	Control	Intervention	Total
Death	92.44	159.75	133.20
Inpatient hospitalisation or prolongation of existing hospitalisation	1145.69	740.88	900.55
Life threatening	0.00	69.08	41.83
Newly diagnosed cancer	95.62	21.45	50.71
Other important medical event	87.79	347.13	244.84
Permanent or significant disability or incapacity	0.00	39.85	24.13
Total	1421.54	1378.14	1395.26

### 8.4.3.3. Hyperlipidaemia

Within the group of patients with hyperlipidaemia, there were 621 estimated SAEs, with the most common type of SAE being inpatient hospitalisation (71.59%), followed by other important medical events (16.28%) (Table 108). There were no events classified as life threatening for the control group. There were some differences between treatment group and type of SAEs. Overall, for patients with hyperlipidaemia, there were more SAEs in the intervention group (376) compared to the control group (245). A higher percentage of SAEs within the control group were inpatient hospitalisations (82.87%) compared with the intervention group (64.23%), death (10.67%) and newly diagnosed cancer (4.10%). The intervention group had a higher percentage of events classified as other important medical events (25.36%) than the control group (2.37%) (Table 108). No patients with hyperlipidaemia experienced an event which resulted in permanent or significant disability.

**Table 108: Type of SAE by treatment group for hyperlipidaemia (weighted estimates)**

Type of SAE	Treatment group				Total	
	Control		Intervention			
	N	%	N	%	N	%
Death	26	10.67	31	8.24	57	9.20
Inpatient hospitalisation or prolongation of existing hospitalisation	203	82.87	241	64.23	445	71.59
Life threatening	0	0.0	5	1.26	5	0.76
Newly diagnosed cancer	10	4.10	3	0.92	14	2.18
Other important medical event	6	2.37	95	25.36	101	16.28
Permanent or significant disability or incapacity	0	0.0	0	0.0	0	0.0
Total	245	100.00	376	100.00	621	100.00

Of the SAEs estimated for patients with hyperlipidaemia, 445 (11.8%) of patients experienced one or more SAEs (Table 109). Of those estimated for the intervention group, 284 patients with hyperlipidaemia (12.1%) experienced 376 events, while 161 (11.2%) of control patients with hyperlipidaemia experienced 245 events. For patients with hyperlipidaemia, the most frequently occurring SAE was inpatient hospitalisation and this was repeated across treatment groups. A higher percentage of patients with hyperlipidaemia in the intervention group (3.6%) had an other important medical event compared to patients in the control group (0.40%). A higher percentage of patients with hyperlipidaemia in the control group had events which resulted in hospitalisation.

**Table 109: Patients with hyperlipidaemia experiencing one or more SAE by treatment group and type of SAE (weighted estimates)**

Type of SAE	Treatment group					
	Control		Intervention		Total	
	N=1441*		N=2343*		N=3784*	
	N	%	N	%	N	%
Death	26	1.82	31	1.32	57	1.51
Inpatient hospitalisation or prolongation of existing hospitalisation	135	9.35	189	8.06	324	8.55
Life threatening	0	0.00	5	0.20	5	0.12
Newly diagnosed cancer	10	0.70	3	0.15	14	0.36
Other important medical event	6	0.40	85	3.63	91	2.4
Permanent or significant disability or incapacity	0	0.00	0	0.00	0	0.00
Any SAE	161	11.2	284	12.1	445	11.8

\*Note: The case note audit patient selection was not stratified by condition so these numbers are estimates based on the case note audit patients, rather than actual numbers of hyperlipidaemia patients in the study.

For patients with hyperlipidaemia, the estimated rate of occurrence of SAEs per 10,000 person-years for all events was higher in the control group (1224.04 events) than in the intervention group (1156.94 events) (Table 110). Patients with hyperlipidaemia in the intervention group had a higher number of other important medical events and events that were life threatening per 10,000 person years. However, patients with hyperlipidaemia in the control group had higher numbers of events per 10,000 person years for newly diagnosed cancer, death and inpatient hospitalisation.

**Table 110: Number of SAEs per 10,000 person-years by treatment group and type of SAE for patients with hyperlipidaemia**

Type of SAE	Control	Intervention	Total
Death	130.57	95.28	108.74
Inpatient hospitalisation or prolongation of existing hospitalisation	1014.31	743.13	846.60
Life threatening	0.00	14.52	8.98
Newly diagnosed cancer	50.16	10.66	25.73
Other important medical event	29.01	293.35	192.48
Permanent or significant disability or incapacity	0.00	0.00	0.00
Total	1224.04	1156.94	1182.55

#### 8.4.4. Trial management incidents

##### 8.4.4.1. Practice reported incidents

A summary of the practice reported incidents by treatment group, for the duration of the Trial, is shown in Table 111. The majority of practice reported incidents related to the Trial (59.91%), with device related incidents (15.35%) and quality control/quality assurance incidents (10.23%) being the next largest group of incidents reported. As expected the majority of the incidents (87.42%) came from the intervention group. A total of 326 (69.5%) of these incidents were received via the telephone.

**Table 111: All practice reported incidents by treatment group**

Type of incident	Treatment group				Total	
	Control		Intervention			
	N	%	N	%	N	%
Device related	0	0	72	17.56	72	15.35
Operator related	0	0	24	5.85	24	5.12
Other incident	3	5.08	7	1.71	10	2.13
Patient related	3	5.08	31	7.56	34	7.25
Quality control/quality assurance	0	0	48	11.71	48	10.23
Trial related	53	89.83	228	55.61	281	59.91
Total	59	100.00	410	100.00	469	100.00

##### 8.4.4.2. Patient incidents

As shown in Table 112, a total of 922 incidents were received from patients and of these 899 (97.50%) were received via the phone. A majority of the incidents were either queries relating to questionnaires (51.84%) or patient related problems pertaining to the Trial (47.18%). Queries relating to the questionnaires were mainly for clarification regarding some of the questions, requesting another questionnaire or advising that the participant was overseas. Patient related problems included general enquiries about the Trial, notifying change of address, advising that a relative participating in the Trial had died or requesting to withdraw from the Trial.

**Table 112: All patient incidents**

Type of incident	Freq	%
Trial procedures	5	0.54
Other	4	0.43
Patient related problems	435	47.18
Questionnaires	478	51.84
Total	922	100.00

A summary of the patient reported incidents by treatment group is shown in Table 113. This data only includes patients who were assigned to a treatment group and could be identified. A total of 524 incidents were reported for patients by treatment group where their patient ID was recorded. The majority of incidents related to questionnaires (71.95%) and patient related problems pertaining to the Trial (26.91%). Overall the intervention group reported more (61.40%) incidents/queries than the control group (38.93). A larger percentage of queries in the control group related to the questionnaires (75.00%) compared to the intervention group (70.00%) while patients in the intervention group had a slightly larger number of patient related problems (28.44%) compared to the control group (24.51%) (Table 113).

**Table 113: All patient incidents by treatment group (where defined)**

Type of incident	Control		Intervention		Total	
	Freq	%	Freq	%	Freq	%
Trial procedures	0	0.0	4	1.25	4	0.76
Other incidents	1	0.49	1	0.31	2	0.38
Patient related	50	24.51	91	28.44	141	26.91
Questionnaires	153	75.00	224	70.00	377	71.95
Total	204	100.00	320	100.00	524	100.00

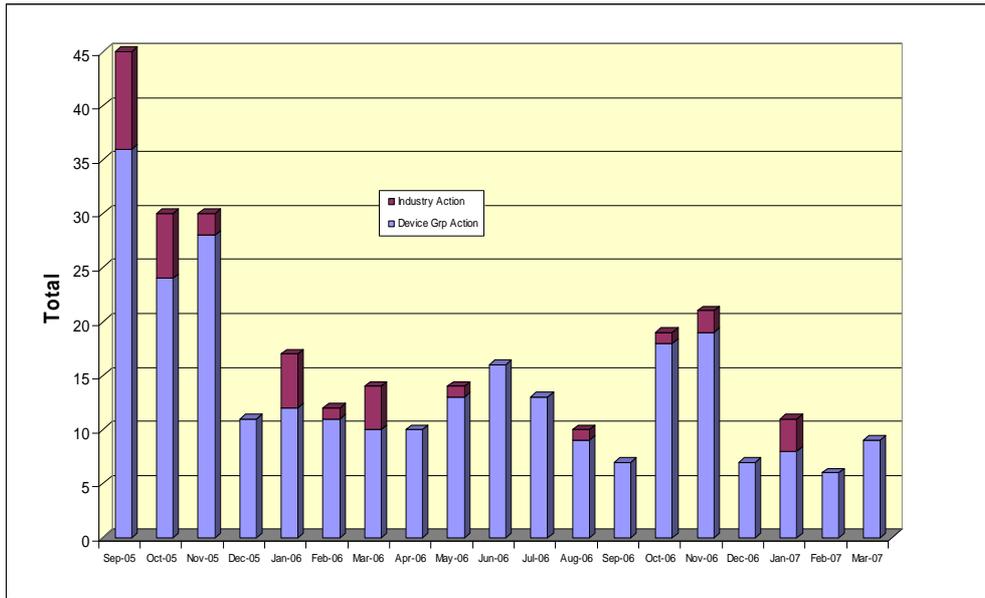
#### 8.4.5. Device Group incidents

##### 8.4.5.1. Summary of calls to telephone help desk support line

Across the live phase of the Trial (1 September 2005 to 28 February 2007), a total of 302 calls were received by the PoCT Device Working Group via the 1800 telephone help desk support line. Eighteen calls (6%) were received out of hours. Thirty five calls (12%) required additional help from industry partners to resolve the issue, but no calls warranted enactment of the industry escalation procedure established for the Trial. A monthly breakdown of the 302 calls received by the telephone help desk is shown in (Figure 18).

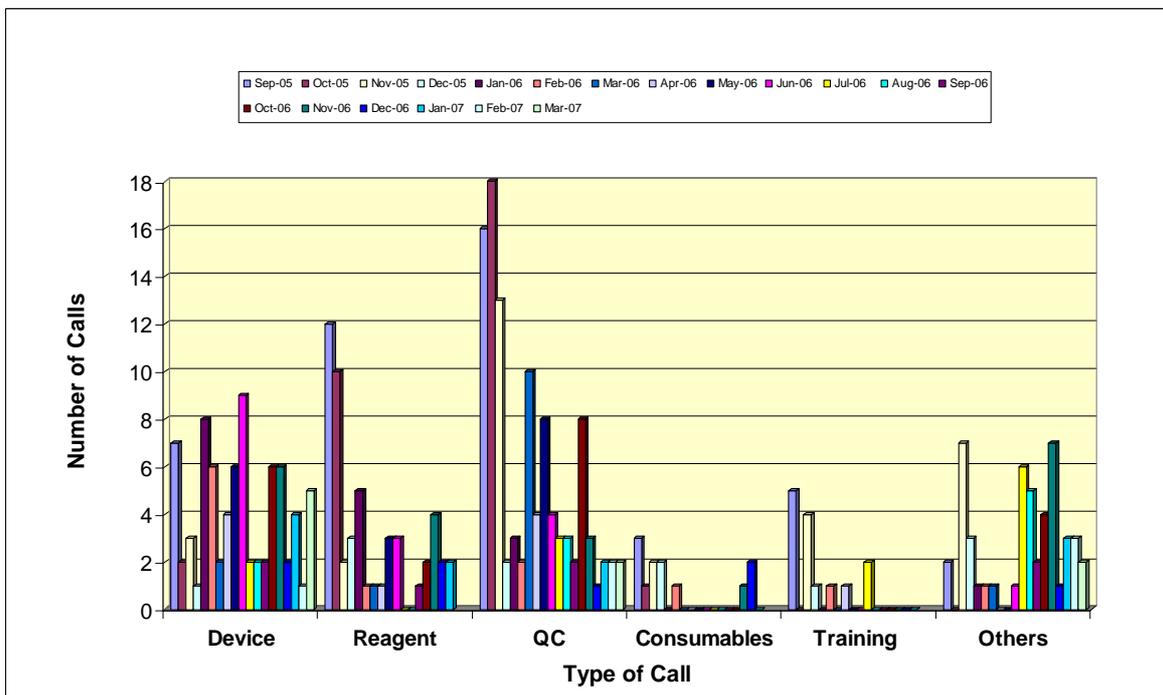
Most calls (106, 34%) related to QC issues, notably processes concerning the appropriate interpretation and recording of QC results. Seventy eight calls were received regarding device issues. Fifty two calls were received in relation to reagents, particularly delivery of start-up reagents at the beginning of the live phase of the Trial. In the remaining categories 14 calls concerned training, 12 were about consumables and 49 related to miscellaneous issues (Figure 19).

**Figure 18: Breakdown of help desk calls by month**



A breakdown of the number of calls by category is shown in Figure 19.

**Figure 19: Breakdown of help desk calls by category**



8.4.5.2. Test error logs

The total number of test error codes reported by practices to the PoCT Device Working Group was 15 for the DCA 2000, 20 for the Cholestech LDX and 23 for the CoaguChek S. A summary of these test error codes is provided in Table 114.

**Table 114: Test error codes reported on each PoCT device**

PoCT device	Test	Specific test error code	Number
DCA 2000	HbA1c	107	3
		105	2
		104	1
		102	3
		11	1
		90	1
		Not reported	2
	ACR	305	1
		313	1
Cholestech LDX	Lipids	Reaction not occur	5
		Tray time out	1
		Sample error	3
		Mag read error	4
		Temp out of range	6
		14	1
CoaguChek S	INR	Test strip icon	1
		Error	3
		Test strip blood drop icon	6
		Sample error	10
		Unknown error	1
		Code chip error	1
		Battery	1

Most errors related to pre-analytical or operator factors.

The DCA 2000 error codes mainly concerned:

- cartridges being exposed to too much heat or used before they had warmed to room temperature after being taken out of the fridge
- the capillary blood sample being allowed to dry out prior to analysis or excess blood being applied to the sample holder.

The Cholestech LDX errors mainly related to:

- insufficient sample being collected
- the analyser being used outside its specified temperature range (maximum 30 degrees Celsius) due to poor environmental conditions within the practice itself. Prolonged heat wave conditions were experienced in rural/remote Australia when these 'temp out of range' errors were reported.

The CoaguChek S errors mainly concerned:

- insufficient sample being collected

- difficulty in applying the sample to the device's application area, which was a significant issue for some operators particularly early in the Trial.

During the Trial, Device Operators were also required to complete a PoCT Incident Report when a test (or device) error occurred and return this form to the Trial Management Group. It is possible therefore that the number of test errors reported to the PoCT Device Group was less than the number reported to the Trial Management Group, as practices were likely to have returned only one form rather than duplicating paperwork.

#### 8.4.5.3. Device events

Across the live phase of the Trial:

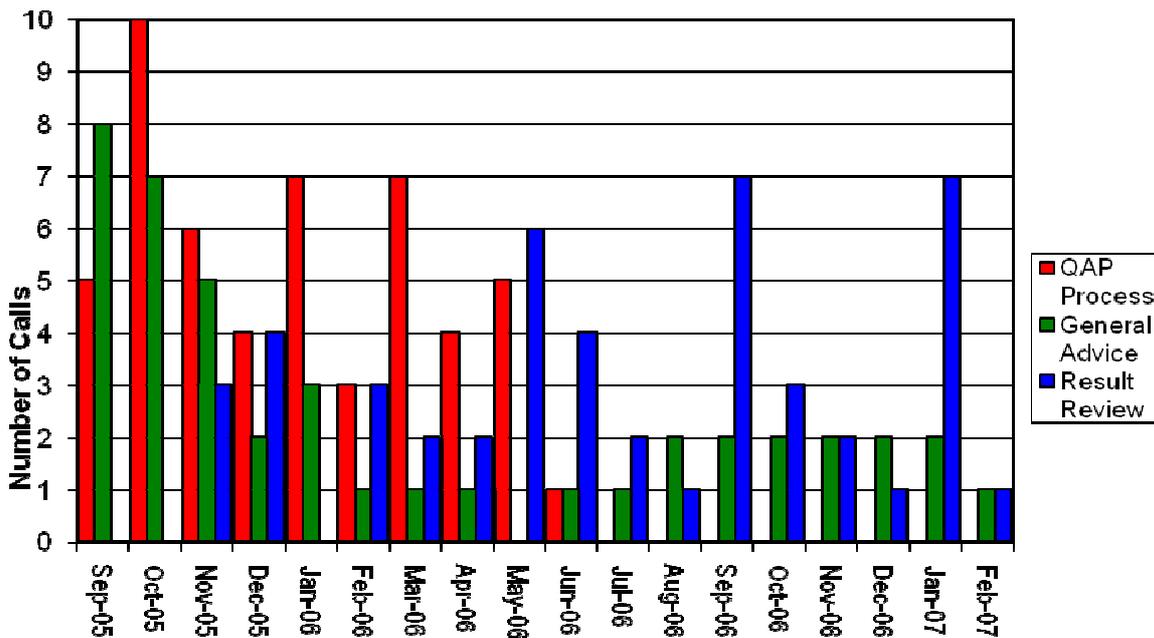
- one DCA 2000 was replaced due to mechanical failure
- three Cholestech LDX devices were replaced due to persistent 'mag read errors', which related to the device not being able to successfully read the calibration information encoded on the brown magnetic strip of the lipid reagent cassette
- four CoaguChek S devices were replaced; two due to code chip errors, one due to a power supply problem and one due to the very minor issue of a dirty electrical connection
- one set of devices was also destroyed when an urban practice unfortunately burnt to the ground as a result of arson in March 2006.

#### 8.4.6. QAP Group incidents

The QAP Group used the same review meetings as outlined by the Device Group to review the incidents reported to them.

During the Trial a total of 143 hotline calls were received by the QAP Group (Figure 20). By type, 52 (36%) calls concerned how to perform the external quality assurance program, 48 (34%) were for reviewing practice results and 43 (30%) were for general advice.

**Figure 20: Total number of calls to QA help desk by type**



During the early stages of the Trial the hotline phone calls were enquiries on how to perform the external quality assurance program and general advice. As the practices gained confidence the calls changed to assisting the practices to review their results.

## 8.5. DISCUSSION

### *Serious adverse events*

All of the SAEs that the PoCT Safety Sub-committee assessed were deemed not attributable to the PoCT Trial. Thus PoCT can be deemed safe in terms of SAEs. The analysis based on estimations of the SAEs showed the most common type of SAE was inpatient hospitalisation or other important medical event. This reflected the conditions and age of the patients participating in the Trial.

The analysis of the proportion of patients experiencing one or more SAEs was similar for the intervention and control groups. A larger proportion of control patients on anticoagulant therapy experienced one or more SAEs, while for diabetes and hyperlipidaemia, the intervention patients experienced a slightly higher proportion of SAEs. When analysed in terms of SAEs per 10,000 person years it showed that across all SAEs, and by the three conditions, the number of SAEs per 10,000 person years was lower in the intervention group than in the control group. This is deemed the most appropriate analysis for comparison across treatment groups as it takes into account the different number of participants in each group and the fact that participants were in the study for different periods of time.

### *Comparison of data collection methodologies*

The methodology of obtaining SAEs for the Trial relied on the practices to report SAEs encountered by the patients or relayed to the Trial Manager directly by patients or their families, a method used in a number of studies. The amount of under-reporting using this method was tested when SAE data were obtained from the CNA. This raises doubts about the validity of this methodology of SAE reporting in general practice.

A review of the literature has found very little published on the difficulty of obtaining and monitoring serious adverse events and incidents through RCTs in general practice. By comparison, there are a substantial number of studies reporting on adverse events in RCTs relating to drug trials and secondary care. What has been reported relates primarily to reporting and monitoring incidents (adverse events and near-misses) in general within general practice. Some studies have either focused on qualitative descriptions looking at GP and nurses' attitudes<sup>110</sup> or motivators and barriers to incident reporting<sup>111</sup>, while others have included observational studies<sup>112</sup> looking at types of incidents reported or developing techniques<sup>113, 114</sup> for collecting adverse event data. Under-reporting of adverse events is a common theme running through the studies. Reasons for not reporting adverse events identified in the studies include time constraints, lack of clarity about what should be reported, complexity of reporting and confusion about who should report. Another issue reported in the literature is the lack of communication between secondary and primary care. GPs are not always aware that a patient has had an event outside of their practice that needs reporting to the trial managers. According to Kidd and Veale<sup>115</sup> '*failure to provide hospital discharge information to GPs is a longstanding and fundamental flaw in the [health] system*'. Anecdotal evidence from Device Operators participating in the Trial raised this issue at a refresher workshop when discussing notification of serious adverse events.<sup>116</sup> Due to lack of formal communication channels between the hospital and general practice, patients were often admitted to hospital with the GP and practice staff being unaware of it for some time.

What is clear from this analysis of SAE reporting is that future studies occurring in general practice need to identify a more appropriate methodology for obtaining SAE data that does not rely on the reporting from practice staff. A review of medical records seems to provide a more reliable method, but this is costly and time consuming.

## *Incidents*

For the Trial Management Group, a larger proportion of the practice and patient related incidents reported came from the intervention group. The incidents reduced over the period of the Trial, with the majority of incidents reported in the first six months of the Trial (Phase I), as found by the other Trial groups. For patients, incidents mainly related to queries around the questionnaires. For practices, the majority of incidents related to Trial issues around the protocol, recruitment of patients and so on. The use of the 1800 telephone number was useful in providing direct access to three groups involved in the Trial.

There were no major external quality assurance incidents in the Trial. There was some confusion with some of the practices about which sample numbers to test in the first week of the trial but the practices soon learnt to follow the supplied sample and date schedule.

## *Limitations*

One of the key limitations with this analysis, choice of methodology for collection of SAEs, has been discussed above. The use of the CNA data to generate weighted estimates for the study population is also not without limitations. The main purpose of the CNA was to obtain data on the process of care actions undertaken by a GP upon receipt of a test result. This required the auditors to only review consultations relating to test results and so not all records were thoroughly scrutinised. Therefore it is likely that the SAE data obtained from the CNA also under-reported the number of SAEs.

Another limitation relates to the categories used to define SAEs. These categories are fairly broad and do not allow more detailed categorisation of SAEs that may be more pertinent for some conditions. For example, many studies investigating the management of anticoagulant therapy assess safety in terms of haemorrhagic and thromboembolic incidents.<sup>8</sup> However, it was not feasible to drill down the SAEs to this level of reporting for each type of condition examined.

## **8.6. CONCLUSION**

The Trial identified a flaw in the methodology used to collect SAEs and introduced a second method. Although the CNA methodology also had flaws the two methods provided a more sound and thorough approach which will provide a direction for future studies which require SAE reporting in general practice. The assessment of the SAEs by the PoCT Safety Subcommittee deemed none of the SAEs to be attributable to the PoCT Trial.

The results of the analysis of SAEs in terms of per 10,000 person-years showed that the intervention group had a lower rate of SAEs than the control group overall and by type of condition. Therefore, PoCT did not result in a higher number of SAEs and in terms of SAEs it is safe to perform PoCT in a general practice setting.



## 9. CLINICAL EFFECTIVENESS OF PoCT IN GENERAL PRACTICE

### SUMMARY OF THE CHAPTER

This chapter describes the methodology and results of the analysis focused on clinical effectiveness. Four main areas of interest were investigated: therapeutic control, impact on patient care and patient compliance with disease management.

Non-inferior analyses (the same or better) were used to measure therapeutic control and patient compliance with disease management. Descriptive analysis of the process of care actions, prescribing patterns and lifestyle activities were also undertaken. Various data sources were used in the analysis; test results, Medicare data, case note audit data and medicine and lifestyle questionnaires.

The key findings of the chapter are:

- at a patient level PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing for HbA1c ( $p < 0.0001$ ), urine albumin ( $p = 0.0040$ ), ACR ( $p = 0.0367$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p = 0.0001$ ), but not for INR ( $p = 0.2389$ ) and HDL-C ( $p = 0.7723$ )
- at a test level PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing for INR ( $p = 0.0008$ ), HbA1c ( $p < 0.0001$ ), urine albumin ( $p = 0.0005$ ), ACR ( $p = 0.0129$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p < 0.0001$ ), but not for HDL-C ( $p = 0.7862$ )
- PoCT was found to be non-inferior (the same or better) compared to pathology laboratory testing in relation to the proportion of patients showing an improvement in their test result from baseline for HbA1c ( $p < 0.0001$ ), total cholesterol ( $p < 0.0001$ ) and triglycerides ( $p = 0.0001$ )
- PoCT patients had significantly more GP visits ( $p = 0.0126$ ) and more testing
- GPs using PoCT recorded more process of care actions than control GPs for all conditions if tests were within target range. Fewer differences were found between actions undertaken by intervention GPs compared to control GPs if tests were outside target range
- PoCT had little impact on GP prescribing patterns for all three conditions
- PoCT was found to be non-inferior (the same or better) to pathology laboratory testing in relation to the proportion of MARS-5 questionnaire responses indicating compliance with disease management (medication compliance)
- in terms of lifestyle activities few differences were found between treatment groups.

The key conclusions:

- in terms of therapeutic control, PoCT was found to be the same or better than pathology laboratory testing for most tests, therefore PoCT can assist GPs in better management of some chronic conditions
- the results also suggest that having an immediate test result is beneficial for patients in terms of medication compliance.

## 9.1. INTRODUCTION

PoCT in general practice has the potential to provide better monitoring of chronic conditions, improved therapeutic control, more rational prescribing, better clinical decisions within the consultation timeframe, greater patient compliance with pathology requests, and fewer visits to the doctor.<sup>3, 4, 45</sup> However, there is a lack of evidence around several of these benefits, particularly those relating to clinical outcome. Some evidence is available on the role of PoCT in improving control in the areas of glycaemic control,<sup>6, 45</sup> cholesterol and lipids,<sup>7</sup> and oral anticoagulant control.<sup>8</sup>

There has been an increase in the use of oral anticoagulant therapy, such as warfarin, for the prevention and treatment of venous or arterial thrombosis and embolism. While providing greater health benefits there are high risks to having the therapy.<sup>28</sup> Careful monitoring of INR (international normalised ratio) levels is required to ensure they are kept within a safe therapeutic range. Deviation from the therapeutic range can have adverse effects and lead to thromboembolism and haemorrhage.<sup>34</sup> Studies have shown that the immediate availability of an INR result improves time spent in therapeutic range<sup>8, 117</sup> and decreases serious adverse events.<sup>8</sup>

There is strong evidence that improving therapeutic control even slightly in patients with either Type 1 or Type 2 diabetes will prevent or delay the onset of complications<sup>118, 119</sup> and lower healthcare costs.<sup>120</sup> Studies have shown that the immediate availability of an HbA1c result at the time of a consultation increases the frequency of intensification of therapy and lowered HbA1c levels in patients with Type 2 diabetes.<sup>6, 45, 58</sup> Testing for microalbuminuria is important in diabetes management to prevent the development of nephropathy and cardiovascular disease. It is estimated that 30% to 50% of patients will develop microalbuminuria and urinary ACR is recommended as the initial screening test. Microalbuminuria can be measured by either a urine albumin test (timed) or an albumin/creatinine ratio (first morning sample) test. While microalbuminuria can be measured using PoCT devices, no evidence exists on its effectiveness in the general practice setting.

One of the major risk factors for coronary heart disease (CHD) is hyperlipidaemia. Evidence has shown that reducing cholesterol levels reduces CHD advancement, morbidity and mortality for people at high risk of CHD events.<sup>46</sup> Lowering lipid levels in those people at highest risk has also been shown to be cost-effective.<sup>31</sup> There is limited evidence that results available at the time of a consultation reduces lipid levels although research suggests that PoCT can lead to improved management.<sup>44, 65</sup>

Pathology results provided by PoCT at the time of a consultation provide the GP with an opportunity to discuss the test results with the patient immediately and implement any changes to improve the management of their condition. PoCT could lead to increased visits to the GP because of earlier identification of abnormal test results which influences the patient earlier, and ensures all processes of care are maintained. This could demonstrate that GPs are adhering to clinical management guidelines (see Appendix 2 to Appendix 4). An increase in the number of GP visits can lead to more processes of care which have the potential to improve therapeutic control and health outcomes. More visits may be costly in the short-term but cost savings could be gained in the long-term with reduced hospitalisations, complications and premature death.

In order to assess the impact of PoCT on GP management of patients the Trial measured the processes of care undertaken for each pathology test received. The availability of a test result during the consultation has been shown to assist the GP to treat and manage patients<sup>44</sup>, although research in this area is limited.

Chronic disease in Australia accounts for more than 70 percent of the healthcare burden due to death, disability and reduced quality of life.<sup>121</sup> Chronic disease is increasingly being managed by GPs who play a key role in implementing good disease management and identifying and preventing complications of disease. However, it is necessary that the patient acts upon the GP's advice and treatment for improvements in patient health outcomes to be achieved. Disease management is defined as: 'a system of co-ordinated healthcare interventions and

communications for populations with conditions in which patient self care efforts are significant'.<sup>122</sup> Disease management includes many health related actions where patients are expected to actively contribute in managing their condition. For the purpose of the Trial disease management refers to patient compliance to medication and assessment of diet and exercise activities.

It has been widely reported in the literature that non-compliance to medication is substantial with an estimated 30-40% of patients failing to take medications as prescribed.<sup>35</sup> It is well known that poor medication compliance compromises the effectiveness of treatment and is influenced by a complex multi-factorial set of variables (number of medications, duration of disease, age and patient attitudes, beliefs and perception of illness).<sup>36,37</sup> There are many methods available to measure how patients take their medicines including direct measures such as drug assays of blood or urine or indirect measures such as patient self report (questionnaires, diaries, interviews) and review of prescription records and claims.<sup>123</sup> No single measure is seen as the gold standard with a combination of methods thought of as the most effective.<sup>124</sup> Patient self report is an inexpensive and easily obtained measure of compliance in the primary care setting. However, it is recognised that self report is susceptible to overestimates of compliance<sup>38</sup> with reports of low compliance more accurate than reports of high compliance.<sup>125,126,127</sup> Medication compliance rates are higher among patients with acute conditions compared to patients with a chronic condition.<sup>36,128</sup> Improving patient compliance to disease management is critical to reduce serious adverse health outcomes.

## **9.2. AIMS AND OBJECTIVES**

The aim of this part of the Trial was to address the research question: Is the effectiveness of PoCT the same or better than the same tests using pathology laboratory testing? The objectives were improved therapeutic control, impact on patient care (in terms of prescribing, clinical decisions and number of visits to the GP) and patient compliance with disease management. The hypotheses related to these areas are listed below. For impact on patient care the focus was the processes of care that the GP undertakes upon receipt of a pathology test result via PoCT or laboratory and a number of outcome measures were determined. These included: number of GP visits per person-year; process of care actions undertaken by the GP; and patterns of prescribing. For patient compliance, disease management refers to medication compliance using the Medication Adherence Reporting Scale (MARS-5).

The four hypotheses addressed in this chapter are as follows:

### *Therapeutic control*

Hypothesis 1a: The proportion of PoCT patients who have pathology results within the target range is the same as or greater than the proportion of control patients who have pathology results within the target range.

Hypothesis 1b: The proportion of PoCT patients who have any reduction (HbA1c, total cholesterol and triglycerides) or any increase (HDL-C) in test results from baseline is the same as or greater than the proportion of control patients who have any reduction (HbA1c, total cholesterol and triglycerides) or any increase (HDL-C) in test results from baseline.

Hypothesis 2: The proportion of total tests within the target range in PoCT practices is the same as or greater than the proportion of total tests within the target range in control practices.

### *Impact on patient care*

Hypothesis 3: The number of GP visits for PoCT patients per person-year is different to the number of GP visits for control patients per person-year.

## *Patient compliance with disease management*

Hypothesis 4: The proportion of MARS-5 questionnaire responses indicating compliance with disease management in PoCT practices is the same as or greater than the proportion of MARS-5 questionnaire responses indicating compliance with disease management in control practices.

In addition to medication compliance, assessment of diet and exercise was also investigated, termed here as lifestyle activities.

### **9.3. METHODS**

#### 9.3.1. Therapeutic control

To measure therapeutic control, two approaches were taken. Firstly, the proportion of patients within target range (point prevalence) and secondly, the proportion of tests within the target range for each of the three condition groups was analysed. The former is the primary outcome measure for the Trial. The target ranges used for the three conditions are based on clinical guidelines as outlined in Table 4.

For intervention practices, patients' test results were recorded on a specifically designed request/result form, with copies forwarded to the Trial Manager every month. The test results were entered into a specially designed database by the Data Management & Analysis Centre (DMAC). For control practices, test results were collected from the various pathology laboratories through either hard copy reports or weekly electronic downloads of results for those patients identified as participating in the Trial. This was achieved with a PoCT Trial identification sticker adhered to the pathology laboratory test request form. Again, these test results were entered into a database by DMAC.

The outcome of interest for Hypothesis 1a was whether the last test result was within or outside the target range. Test results were collected from multiple sources and were combined to give a single test result per patient per day for each type of test (see Appendix 23 for the rules on combining test results) so that the last test result could be selected. This last result was then defined as being within or outside the target range according to the target ranges specified above.

The outcome of interest for Hypothesis 1b was any reduction (HbA1c, total cholesterol and triglycerides) or any increase (HDL-C) in the test results from baseline. The last test result together with the baseline result, as defined in Hypothesis 1a, was used as the outcome measure.

For Hypothesis 2 the outcome of interest was whether the test result was within or outside the target range and all tests performed during Phase I and Phase II were considered. Test results were collected from multiple sources and were combined to give a single test result per patient per day for each type of test (see Appendix 23 for the rules on combining test results). Each test result was then defined as being within or outside the target range according to the target ranges as defined in Table 4.

#### 9.3.2. Impact of PoCT on patient care

To measure the impact of PoCT on patient care, a number of outcome measures were determined. These included: number of GP visits per person-year; process of care actions undertaken by the GP; and patterns in prescribing.

##### 9.3.2.1. GP visits

The outcome of interest for Hypothesis 3 was the number of GP visits during the length of the Trial. Information on all GP visits was obtained from Medicare Australia for the period 1 September 2005 to 28 February 2007. Medicare Benefits Schedule (MBS) service claims and Pharmaceutical Benefits Scheme (PBS) data were requested from Medicare Australia (application 2005/CO04042). Data were requested on an individual patient and an individual GP basis and included all GP visits,

patient episode initiations, laboratory tests, specialist referrals, allied health services, multidisciplinary care plans/case conferences, completion of annual cycle of care for patients with diabetes mellitus and pharmaceutical scripts dispensed for the duration of the Trial. The Trial also requested data relating to the scheduled fee, the benefit and actual charge that consenting patients paid for health care services (Appendix 24). Data were not requested for all patients due to some patients refusing consent to release Medicare information, the practice/patient had withdrawn from the Trial or patients were found to be ineligible prior to the data request being submitted.

Of the 4968 patients in the Trial, Medicare data were requested for 4706 patients. Medicare Australia experienced difficulties with the data matching process and so was not able to identify 168 of these patients. Reasons for the matching difficulties were identified as the patient supplying incorrect information to the Trial relating to Medicare number and/or position number on the card, or date of birth. Data for 4538 patients were received; however, two of these patients had withdrawn since the data request was submitted and did not consent to the use of their Medicare data (although they did consent to use of their other data). Thus Medicare data for 4536 patients was available for analysis.

It was assumed that each patient had only one GP visit per date (although some patients had multiple charges per date). For patients with Medicare data but no data on GP visits, the number of GP visits was assumed to be zero. For patients with no Medicare data, the number of GP visits was set to 'missing'. The nature of the missing data was investigated and there was evidence to suggest that the data were not missing completely at random. Multiple imputation was used to impute the missing values using the regression method after applying a log transformation to the number of GP visits. Analysis was performed on each of 10 completed datasets and the results were combined.

The number of tests per person-year was calculated separately for each type of test by treatment group for Phase II (Table 146). This takes into account the difference in number of participants in each group, and the fact that different participants had been in the study for different periods of time. PoCT and laboratory test results that had been received by the Trial for Phase II were used in the analysis.

#### 9.3.2.2. *Processes of care and prescribing patterns*

Descriptive analysis relating to the number of process of care actions, including appropriate prescribing, performed by the GP is reported separately for test results within the target range (well controlled) and outside the target range (poorly controlled) by type of test at 18 months.

Data were collected through the case note audit on a sample of patients. Medical records were reviewed and the GP's processes of care documented by identification of specific pre-selected indicators for diabetes management, lipid management and INR management. The minimum number of processes of care was based on the guidelines developed for diabetes management; management of patients on anticoagulant therapy and lipid management (see Appendix 2 to Appendix 4).<sup>28-31</sup> Actions included review of the test result by the GP, medication review, medication changes, lifestyle advice given, referrals, blood pressure readings and follow-up testing. Actions varied depending on whether a test result was within or outside therapeutic range. The list of actions documented for each condition based on current guidelines is provided in Appendix 25.

A total of five auditors were trained in the data collection process. The reliability of auditors was assessed using a sample of patient notes and results compared. Following this, one-on-one training occurred with each auditor to ensure standardised data collection. Data was systematically collected from the patient's medical records and the information was entered on to data collection sheets. A data collection sheet was designed for each test undertaken in the Trial (INR, HbA1c, lipids and microalbuminuria) based on evidence-based guidelines (Appendix 26).

### 9.3.3. Patient compliance with disease management

Compliance in the Trial has been defined as 'the extent to which a person's behaviour (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice'.<sup>p1129</sup> Disease management in the Trial has been defined as patient medication compliance (using the MARS-5) and the extent to which a patient performed lifestyle (specifically diet and exercise) behaviours during the previous seven days. Patient compliance with medication and lifestyle activities was assessed by a self-administered questionnaire as required by the Trial Design. Copies of the questionnaire can be found in Appendix 27.

The questionnaire had two sections. The first section focused on patient medication compliance and patient beliefs and attitudes towards medicines in general and medicines prescribed for their condition. The second section focused on lifestyle activities, in particular diet and exercise.

#### 9.3.3.1. Medication compliance

Medication compliance was measured using the Medication Adherence Reporting Scale (MARS-5). This is a five item scale asking patients to rate the frequency with which they engaged in each of five aspects of non-adherent behaviour, e.g. altering the dose or forgetting to take their medicine. Scores for each of the five items are combined to give a scale score ranging from 5 to 25, where higher scores indicate higher levels of reported compliance. On the advice of the PoCT Management Committee an additional question was added to the end of the MARS-5 and is scored in the same manner (Table 115).

**Table 115: MARS-5 with additional question**

	<b>Your own way of using your medicines</b>	<b>Always</b>	<b>Often</b>	<b>Sometimes</b>	<b>Rarely</b>	<b>Never</b>
M1	I forget to take them					
M2	I alter the dose					
M3	I stop taking them for a while					
M4	I decide to miss out a dose					
M5	I take less than instructed					
	I take more than instructed					

Since 1996, the MARS has been used in studies across a variety of illnesses and in several countries.<sup>39,40,41,42</sup> The MARS-5 has been found to have good reliability and validity.<sup>43</sup>

Patients were also asked to comment about their beliefs and attitudes towards medicines in general and medicines prescribed for their condition. Past research has shown that levels of medication compliance are associated with patient beliefs about the necessity of taking medication.<sup>130</sup> Responses to each statement were scored on a 5 point Likert scale (strongly agree to strongly disagree).

Responses to each question in the MARS-5 (including the additional question) were separated into three groups, the compliant group (those who answered 'never' to the question) or the non-compliant group (those who answered 'always', 'often', 'sometimes' or 'rarely' to the question) and the missing group (those who did not answer the question).

Non-compliance can be classified as intentional or unintentional. Patients who intentionally do not comply have made the decision consciously. Intentional non-compliers, in this Trial, were those patients who responded to the statements that they always, often, sometimes or rarely 'altered the dose', 'stopped taking them for a while', 'decided to miss out a dose', and 'took less than instructed' or 'took more than instructed'. Patients who unintentionally do not comply, would like to but could not for some reason (e.g. forgetting to take their medicine). Unintentional non-compliers, in this Trial, were those patients who responded with always, often, sometimes or rarely to the statement 'I forget to take them'.

#### 9.3.3.2. *Lifestyle activities*

Finally, patients were asked to complete questions about their diet and exercise regime during the last seven days. Patients were asked to tick from a list of eight dietary items where one or more option could be chosen. The dietary items patients could select included: 'low fat diet', 'low salt diet', 'diabetic diet', 'cholesterol lowering diet', 'low carbohydrate diet', 'other weight loss diet', 'other diet' or 'I did not follow a special diet'. Patients were also asked to report on how many of the previous seven days they had participated in a specific exercise session (such as swimming, jogging) other than what they would do around the house or as part of their work, and on how many of the previous seven days they had participated in thirty minutes of other physical activity such as walking, cleaning the house, gardening but not including a specific exercise session. For both these questions patients could tick one response ranging from 0-7 days.

#### 9.3.3.3. *Medicines and Lifestyle Questionnaire pilot*

The questionnaire was piloted using patients from one general practice located on the Yorke Peninsula, South Australia. The practice was not involved in the Trial but was using PoCT devices. They invited fifteen patients (treated for diabetes, hyperlipidaemia or anticoagulant therapy) to complete the questionnaire and provide feedback regarding any item that was not clear, confusing or could be improved on. Twelve patients completed the questionnaire and feedback sheet and any modifications were made prior to mail out. The Trial Management Committee also provided feedback regarding the questionnaire and again any modifications were made prior to mail out.

#### 9.3.3.4. *Survey mail out*

All patients were sent a Medicines and Lifestyle Questionnaire twice during the Trial (first questionnaire was sent on the 10/04/2006 and the second questionnaire on the 03/01/2007). The Dillman Method<sup>87</sup> was used which included:

- initial mail out of the Medicines and Lifestyle Questionnaire to all patients
- follow-up reminder using a flyer to all patients
- final reminder to non-responders with a copy of the questionnaire.

#### 9.3.3.5. *Response rate*

The response rates for each questionnaire are outlined in Table 16 and Table 117. The response rate is calculated on all patients who were sent the questionnaire and excludes patients who withdrew or died prior to the dissemination of the Medicines and Lifestyle Questionnaires. An overall response rate of 94.13% was achieved for the first Medicines and Lifestyle Questionnaire and 93.35% for the second Medicines and Lifestyle Questionnaire.

**Table 116: Response rate first Medicines and Lifestyle Questionnaire**

Responded	Treatment Group				Total	
	Intervention		Control			
	N	%	N	%	N	%
Yes	2626	93.75	1828	94.67	4454	94.13
No	175	6.25	103	5.33	278	5.87
Total	2801	100.00	1931	100.00	4732	100.00

**Table 117: Response rate second Medicines and Lifestyle Questionnaire**

Responded	Treatment Group				Total	
	Intervention		Control			
	N	%	N	%	N	%
Yes	2469	92.54	1772	94.51	4241	93.35
No	199	7.46	103	5.49	302	6.64
Total	2668	100.00	1875	100.00	4543	100.00

Ninety percent of control patients and 86% of intervention patients completed both first and second questionnaires.

#### 9.3.4. Statistical analysis

##### 9.3.4.1. Therapeutic control

Some patients did not have any test result data. There was also a substantial amount of missing data on the pre-specified baseline covariates to be adjusted for in the analysis. The nature of the missingness was investigated and there was evidence to suggest that the missing data were not missing completely at random. Multiple imputation was used to impute the missing values for both the baseline covariates and the last test result, except in the case of urine albumin and albumin creatinine ratio where imputation was used to impute whether the test result was inside or outside target range rather than the actual test result. A variety of methods was used depending on the type of variable requiring imputation; the discriminant function method was used for categorical variables, the logistic regression method was used for binary variables and the Markov Chain Monte Carlo (MCMC) method was used to produce a monotone missing data pattern for continuous variables, followed by the regression method to fill in the remaining missing values. Analysis was performed on each of 10 completed data-sets and the results were combined.

For Hypothesis 1, the analysis was performed separately for each type of test using an identity binomial model with allowance for clustering at the practice level. Where the identity binomial model failed to converge, a logistic regression model with allowance for clustering at the practice level was used instead. Where a logistic regression model was used, parameter estimates were used to calculate the proportion of patients within the target range and the proportion of tests within target range for each treatment group as well as the difference between treatment groups. Appropriate variances were determined using the delta method so that a statistical test for non-inferiority could be conducted. Both unadjusted and adjusted analyses (with adjustment for baseline covariates as specified in the evaluation protocol) were performed.

For Hypothesis 2, again the analysis was performed separately for each type of test. Since a random effects generalised linear model with allowance for clustering at the practice and patient level failed to converge for each type of test, the analysis method used for Hypothesis 1 was also used for Hypothesis 2.

In order to conclude that PoCT is non-inferior to pathology laboratory testing in relation to the proportion of patients within the target range and the proportion of tests within target range, the lower limit of the 90% confidence interval for the difference in proportions (intervention – control) must be greater than the minimum difference for non-inferiority (defined by -0.07, e.g. -7%). Alternatively, the p-value must be <0.05.

#### 9.3.4.2. *Impact of PoCT on patient care*

##### *GP Visits*

The analysis was performed using a log Poisson model with allowance for clustering at the practice level. Both unadjusted and adjusted analyses (with adjustment for age at consent and gender) were performed. In order to conclude that PoCT is different to pathology laboratory testing in relation to the number of GP visits, the 95% confidence interval for the rate ratio (intervention/control) must not contain one. Alternatively, the p-value must be <0.05.

##### *Processes of care and prescribing patterns*

The analysis was based on weighted estimates and applied to the entire study population. Details of the CNA selection process and calculation of weights is described in Section 1.13.

Descriptive analysis relating to the number of process of care actions performed by the GP on receipt of a test result over the study period is reported separately for test results. The actions are grouped according to whether the test result was within the target range (well controlled) and outside the target range (poorly controlled). Target range was based on those identified in the guidelines for each condition shown in Table 4. For the conditions where there were multiple tests (hyperlipidaemia and microalbuminuria), the results were classified as within target range if all of the associated tests were within target range or outside target range if any one test was outside target range. Process of care actions are reported as a percentage of tests where an action was performed.

For diabetes only, the actions which form part of the diabetes annual cycle of care<sup>29</sup>, the results are reported as the number of actions per person-year by treatment group. This takes into account the difference in number of participants in each group, and the fact that different participants have been in the Trial for different periods of time. In the diabetes annual cycle of care, GPs should complete a number of care actions over a 12 month period. Therefore, by presenting the data as actions per person-year allowed the Trial to determine if the GPs under-took these items over a 12 month period. A value of 1 for this analysis indicates that the action was being performed once per person-year as recommended by the diabetes guidelines.

For prescribing patterns, descriptive analysis is reported on the type of medication, changes in medication and the strength and dosage of the change by the GP. Again this data is grouped into test results within target range and test results outside target range. Prescribing information is reported as a percentage of tests where an action was performed. Data were only included in this analysis if a GP consultation had occurred.

In this analysis change in medication can refer to an alternative or additional medication being prescribed or a change in the current medication (dosage and/or strength). Dosage refers to the number of times medication is taken (e.g. twice daily) and strength refers to the amount of medication taken (e.g. 10mg).

### *Patient compliance with disease management*

The statistical analysis to answer Hypothesis 4 was completed on the MARS-5 and did not include the additional question. The MARS-5 score was heavily skewed, with many patients reporting that they were fully compliant and obtaining the maximum score of 25. It was decided to dichotomise the data for the analysis, such that a MARS-5 score of 25 would be considered compliant and a MARS-5 score below 25 would be considered non-compliant (binary outcome). This method of dichotomising the data for analysis has been used in other studies using the MARS-5.<sup>41,131</sup> Furthermore, a systematic review of studies showing that adherence measures have indicated that low adherence is suggested if one or more doses are missed and that if a patient admits to missing medication they will over-estimate the actual rate of compliance (by an average of 17% in one study).<sup>123, 132</sup>

The outcome was defined for each questionnaire where all five questions in the MARS-5 were completed and hence each patient could have up to two outcomes corresponding to the two questionnaires disseminated. Interest is thus in the proportion of questionnaire responses indicating compliance with disease management (medication compliance), rather than the proportion of patients, since some patients may have been classed as compliant based on their responses to one of the questionnaires but non-compliant based on their responses to the other questionnaire.

The null hypothesis ( $H_0$ ) is that the proportion of MARS-5 questionnaire responses indicating compliance with disease management is worse (e.g. lower) in the intervention group compared to the control group. The alternative hypothesis ( $H_A$ ) is that the proportion is the same or better (e.g. higher) in the intervention group compared to the control group, where the non-inferiority criteria defines what is meant by 'the same'.

The non-inferiority criteria is 10% of the control group estimate (as specified in the evaluation protocol), with the control group estimate a proportion rather than a difference in means. Thus, in order to reject the null hypothesis and conclude that PoCT is non-inferior to pathology laboratory testing in relation to the proportion of MARS-5 questionnaire responses indicating compliance with disease management, the lower limit of the 90% confidence interval for the difference in proportions (intervention – control) must be greater than the minimum difference for non-inferiority (defined by -10% of the proportion in the control group). Alternatively, the p-value must be <0.05.

The analysis was performed using a mixed model ANOVA with allowance for clustering at both the practice and patient level. Statistical inference was based on the normal approximation to the binomial distribution. Both unadjusted and adjusted analyses (with adjustment for age at consent and gender) were performed. Analyses were carried out using SAS version 9.1.3 (Cary, NC, USA).

The adjusted analysis was also repeated with a questionnaire effect (first or second questionnaire) as well as an interaction between treatment group and questionnaire to test for evidence of effect modification by questionnaire. *Post hoc* tests were performed to examine the effect of treatment group separately for each questionnaire.

### *Patient compliance missing data*

Not all patients were included in the analysis due to missing outcome data (patient did not answer either questionnaire or did not complete all MARS-5 questions). There were a higher percentage of patients excluded from the analysis in the intervention group compared to the control group (14.12% and 8.27% respectively). This was generally due to the larger number of intervention practices that withdrew from the Trial and hence these patients were not sent questionnaires (Table 118). The nature of the missingness was investigated and the missing outcomes are not expected to bias the results. Analysing the MARS-5 responses by geographic location showed that there was a higher percentage of patients excluded from the analysis in the remote intervention group (23.41%) compared to the remote control group (8.94%). As noted for the treatment group analysis, this was largely due to a higher number of intervention practices withdrawing from the Trial in a remote location (4 remote intervention practices compared to 2 remote control practices, refer to Chapter 3).

**Table 118: Patient inclusion in the MARS-5 analysis by treatment group**

MARS-5 Analysis	Treatment Group				Total	
	Intervention		Control			
	N	%	N	%	N	%
Included in the analysis	2585	85.88	1796	91.73	4381	88.18
Excluded due to missing outcome data	425	14.12	162	8.27	587	11.82
Total	3010	100.00	1958	100.00	4968	100.00

9.3.4.3. *Descriptive analysis for lifestyle activities*

Descriptive statistics were completed for diet and lifestyle activities and are reported by treatment group and for each geographic region.

**9.4. RESULTS**

9.4.1. Therapeutic control

9.4.1.1. *INR Tests*

Across both treatment groups the median number of INR tests was higher in the intervention group compared to the control group (15 versus 12), while the median INR test result was the same for both groups (Table 119). For 8.47% of patients, no test result data was available, while 30.40% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was similar between treatment groups.

**Table 119: INR results by treatment group**

Characteristic	Intervention	Control	Total
	N=572	N=372	N=944
Last INR result: median (IQ range)	2.5 (2.2-2.9)	2.5 (2.1-2.9)	2.5 (2.1-2.9)
Number of INR tests: median (IQ range)	15.0 (6.5-20.0)	12.0 (6.0-18.0)	14.0 (6.0-19.0)

Hypothesis 1 – Last INR Test Result in Target Range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of anticoagulant therapy patients with INR results within the target range ( $p=0.2389$ ) cannot be concluded (Table 120). Based on the adjusted analysis, the percentage of patients within the target range was lower in the intervention group (57.01%) compared with the control group (61.47%), with a difference of -4.45%. The results of the unadjusted analysis confirm these findings.

**Table 120: Hypothesis 1 - PoCT leads to the same or better INR control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-inferiority	P-value
57.01	61.47	-4.45	-10.36, 1.46	-7.00	0.2389

Hypothesis 2 – All INR Test Results in Target Range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of INR tests within the target range (p=0.0008) can be concluded (Table 121). Based on the adjusted analysis, the percentage of INR tests within the target range was lower in the intervention group (55.76%) compared with the control group (57.60%), with a difference of -1.84%. The results of the unadjusted analysis confirm these findings.

**Table 121: Hypothesis 2 - PoCT leads to the same or better INR control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
55.76	57.60	-1.84	-4.51, 0.84	-7.00	0.0008

9.4.1.2. *Diabetes Tests (HbA1c, urine albumin and albumin/creatinine ratio)*

HbA1c

Across both treatment groups the median number of HbA1c tests performed was the same and the median HbA1c test result was similar between groups, though slightly lower in the intervention group (Table 122). For 19.06% of patients, no test result data was available, while 38.84% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the intervention group compared to the control group.

**Table 122: HbA1c results by treatment group**

Characteristic	Intervention	Control	Total
	N=1182	N=785	N=1967
Last HbA1c result: median (IQ range)	6.7 (6.2-7.4)	7.0 (6.5-7.8)	6.9 (6.3-7.6)
Number of HbA1c tests: median (IQ range)	2.0 (1.0-3.0)	2.0 (1.0-3.0)	2.0 (1.0-3.0)

### Hypothesis 1a – Last HbA1c test result in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of diabetes patients who have shown an improvement from baseline and are within the target range ( $p < 0.0001$ ) can be concluded (Table 123). Based on the adjusted analysis, the percentage of patients within target range was higher in the intervention group (65.48%) compared to the control group (56.18%) with a difference of 9.31%. The results of the unadjusted analysis confirm these findings.

**Table 123: Hypothesis 1a - PoCT leads to the same or better HbA1c control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
65.48	56.18	9.31	2.89, 15.73	-7.00	<0.0001

### Hypothesis 1b – Any reduction compared to baseline

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing ( $p < 0.0001$ ) can be concluded (Table 124). Based on the adjusted analysis, the percentage of patients with a reduction in their HbA1c test from baseline was higher in the intervention group (57.33%) compared to the control group (44.91%) with a difference of 12.42%.

**Table 124: Hypothesis 1b - PoCT leads to the same or better HbA1c control - any reduction compared to baseline (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
57.33	44.91	12.42	6.48, 18.36	-7.00	<0.0001

### Hypothesis 2 – All HbA1c test results in target range

The hypothesis that PoCT is non-inferior (i.e. the same or better) compared to pathology laboratory testing in relation to the proportion of HbA1c tests within the target range ( $p < 0.0001$ ) can be concluded (Table 125). Based on the adjusted analysis, the percentage of HbA1c tests within the target range was higher in the intervention group (64.11%) compared with the control group (54.74%), with a difference of 9.36%. The results of the unadjusted analysis confirm these findings.

**Table 125: Hypothesis 2 - PoCT leads to the same or better HbA1c control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
64.11	54.74	9.36	4.04, 14.69	-7.00	<0.0001

## Urine albumin

Across both treatment groups the median number of urine albumin tests performed was the same (Table 126). For 43.31% of patients, no test result data was available, while 53.48% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the control group compared to the intervention group.

**Table 126: Urine albumin tests by treatment group**

Characteristic	Intervention	Control	Total
	N=1182	N=785	N=1967
Number of urine albumin tests: median (IQ range)	1.0 (1.0-2.0)	1.0 (1.0-1.0)	1.0 (1.0-2.0)

### Hypothesis 1 – Last urine albumin test result in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of diabetes patients with urine albumin results within the target range ( $p=0.0040$ ) can be concluded (Table 127). Based on the adjusted analysis, the percentage of patients within target range was higher in the intervention group (74.96%) compared with the control group (67.99%) with a difference of 6.97%. The results of the unadjusted analysis confirm these findings.

**Table 127: Hypothesis 1 - PoCT leads to the same or better urine albumin control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
74.96	67.99	6.97	-1.76, 15.70	-7.00	0.0040

### Hypothesis 2 – All urine albumin test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of urine albumin tests within the target range ( $p=0.0005$ ) can be concluded (Table 128). Based on the adjusted analysis, the percentage of urine albumin tests within target range was higher in the intervention group (74.50%) compared with the control group (66.37%) with a difference of 8.13%. The results of the unadjusted analysis confirm these findings.

**Table 128: Hypothesis 2 - PoCT leads to the same or better urine albumin control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
74.50	66.37	8.13	0.49, 15.78	-7.00	0.0005

### Albumin/creatinine ratio (ACR)

Across both treatment groups the median number of ACR tests performed was the same (Table 129). For 44.03% of patients, no test result data was available, while 54.25% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the control group compared to the intervention group.

**Table 129: ACR tests by treatment group**

Characteristic	Intervention	Control	Total
	N=1182	N=785	N=1967
Number of albumin/creatinine ratio tests: median (IQ range)	1.0 (1.0-2.0)	1.0 (1.0-1.0)	1.0 (1.0-2.0)

### Hypothesis 1 – Last ACR test result in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of diabetes patients with ACR results within the target range ( $p=0.0367$ ) can be concluded (Table 130). Based on the adjusted analysis, the percentage of patients within target range was higher in the intervention group (77.39%) compared with the control group (74.18%) with a difference of 3.21%. The results of the unadjusted analysis confirm these findings.

**Table 130: Hypothesis 1 - PoCT leads to the same or better ACR control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-inferiority	P-value
77.39	74.18	3.21	-6.20, 12.62	-7.00	0.0367

### Hypothesis 2 – All ACR test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of ACR tests within the target range ( $p=0.0129$ ) can be concluded (Table 131). Based on the adjusted analysis, the percentage of ACR tests within target range was higher in the intervention group (77.01%) compared with the control group (72.62%) with a difference of 4.39%. The results of the unadjusted analysis confirm these findings.

**Table 131: Hypothesis 2 - PoCT leads to the same or better ACR control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-inferiority	P-value
77.01	72.62	4.39	-4.05, 12.82	-7.00	0.0129

9.4.1.3. Lipid tests (total cholesterol, HDL-C and triglycerides)

Total cholesterol

Across both treatment groups the median number of total cholesterol tests performed was the same and the median total cholesterol test result was similar, though slightly lower in the intervention group (Table 132). For 24.25% of patients, no test result data was available, while 35.77% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the intervention group compared to the control group.

**Table 132: Total cholesterol results by treatment group**

Characteristic	Intervention	Control	Total
	N=2356	N=1463	N=3819
Last total cholesterol result: median (IQ range)	4.3 (3.8-4.9)	4.5 (4.0-5.2)	4.4 (3.8-5.0)
Number of total cholesterol tests: median (IQ range)	1.0 (1.0-2.5)	1.0 (1.0-2.0)	1.0 (1.0-2.0)

Hypothesis 1a – Last total cholesterol test result in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of hyperlipidaemia patients with total cholesterol results within the target range ( $p < 0.0001$ ) can be concluded (Table 133). Based on the adjusted analysis, the percentage of patients within target range was much higher in the intervention group (38.65%) compared with the control group (21.62%) with a difference of 17.02%. The results of the unadjusted analysis confirm these findings.

**Table 133: Hypothesis 1a - PoCT leads to the same or better total cholesterol control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-inferiority	P-value
38.65	21.62	17.02	13.00, 21.05	-7.00	<0.0001

Hypothesis 1b – Any reduction compared to baseline

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing ( $p < 0.0001$ ) can be concluded (Table 134). Based on the adjusted analysis, the percentage of patients with a reduction in their total cholesterol test from baseline was much higher in the intervention group (74.23%) compared with the control group (57.38%) with a difference of 16.85%.

**Table 134: Hypothesis 1b - PoCT leads to the same or better total cholesterol control - any reduction compared to baseline (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
74.23	57.38	16.85	12.27, 21.43	-7.00	<0.0001

Hypothesis 2 – All total cholesterol test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of total cholesterol tests within the target range ( $p < 0.0001$ ) can be concluded (Table 135). Based on the adjusted analysis, the percentage of total cholesterol tests within target range was much higher in the intervention group (34.90%) compared with the control group (20.91%) with a difference of 13.98%. The results of the unadjusted analysis confirm these findings.

**Table 135: Hypothesis 2 - PoCT leads to the same or better total cholesterol control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
34.90	20.91	13.98	10.78, 17.19	-7.00	<0.0001

*High Density Lipoprotein (HDL-C)*

Across both treatment groups the median number of HDL-C tests performed was the same and the median HDL-C test result was similar (Table 136). For 25.77% of patients, no test result data was available, while 44.75% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the intervention group compared to the control group.

**Table 136: HDL-C results by treatment group**

Characteristic	Intervention	Control	Total
	N=2356	N=1463	N=3819
Last HDL-C result: median (IQ range)	1.2 (1.0-1.4)	1.3 (1.1-1.5)	1.2 (1.0-1.5)
Number of HDL-C tests: median (IQ range)	1.0 (1.0-2.0)	1.0 (1.0-2.0)	1.0 (1.0-2.0)

Hypothesis 1a – Last HDL-C test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of hyperlipidaemia patients with HDL-C results within the target range ( $p = 0.7723$ ) cannot be concluded (Table 137). Based on the adjusted analysis, the percentage of patients within target range is lower in the intervention group (73.48%) compared

with the control group (82.72%) with a difference of -9.24%. The results of the unadjusted analysis confirm these findings.

**Table 137: Hypothesis 1a - PoCT leads to the same or better HDL-C control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
73.48	82.72	-9.24	-14.19, -4.29	-7.00	0.7723

Hypothesis 1b – Any increase compared to baseline

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing (p=0.5822) cannot be concluded (Table 138). Based on the adjusted analysis, the percentage of patients with an increase in their HDL-C test from baseline was lower in the intervention group (29.02%) compared with the control group (36.68%) with a difference of -7.66%.

**Table 138: Hypothesis 1b - PoCT leads to the same or better HDL-C control - any increase compared to baseline (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
29.02	36.68	-7.66	-12.86, -2.45	-7.00	0.5822

Hypothesis 2 – All HDL-C test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of HDL-C tests within the target range (p=0.7862) cannot be concluded (Table 139). Based on the adjusted analysis, the percentage of HDL-C tests within target range is lower in the intervention group (74.45%) compared with the control group (83.54%) with a difference of -9.09%. The results of the unadjusted analysis confirm these findings.

**Table 139: Hypothesis 2 - PoCT leads to the same or better HDL-C control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
74.45	83.54	-9.09	-13.43, -4.75	-7.00	0.7862

### Triglycerides

Across both treatment groups the median number of triglyceride tests performed was the same and the median test result was also the same (Table 140). For 24.82% of patients, no test result data was available, while 37.94% of patients were missing test result data and/or one or more baseline covariates and hence required imputation to fill in the missing values. The percentage of patients with missing data was higher in the intervention group.

**Table 140: Triglyceride results by treatment group**

Characteristic	Intervention	Control	Total
	N=2356	N=1463	N=3819
Last triglycerides result: median (IQ range)	1.6 (1.2-2.2)	1.6 (1.2-2.1)	1.6 (1.2-2.2)
Number of triglycerides tests: median (IQ range)	1.0 (1.0-3.0)	1.0 (1.0-2.0)	1.0 (1.0-2.0)

Hypothesis 1a – Last Triglyceride test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of hyperlipidaemia patients with triglyceride results within the target range (p=0.0001) can be concluded (Table 141). Based on the adjusted analysis, the percentage of patients within target range was higher in the intervention group (70.86%) compared with the control group (68.84%) with a difference of 2.02%. The results of the unadjusted analysis confirm these findings.

**Table 141: Hypothesis 1a - PoCT leads to the same or better triglyceride control (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
70.86	68.84	2.02	-2.02, 6.06	-7.00	0.0001

Hypothesis 1b – Any decrease compared to baseline

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing (p=0.0001) can be concluded (Table 142). Based on the adjusted analysis, the percentage of patients with a decrease in their triglyceride test from baseline was higher in the intervention group (54.89%) compared with the control group (51.07%) with a difference of 3.82%.

**Table 142: Hypothesis 1b – PoCT leads to the same or better triglyceride control - any reduction compared to baseline (adjusted analysis)**

Percentage of patients in target range (intervention)	Percentage of patients in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
54.89	51.07	3.82	-0.91, 8.55	-7.00	0.0001

Hypothesis 2 – All Triglyceride test results in target range

The hypothesis that PoCT is non-inferior (e.g. the same or better) compared to pathology laboratory testing in relation to the proportion of triglyceride tests within the target range (p<0.0001) can be concluded (Table 143). Based on the adjusted analysis, the percentage of triglyceride tests within target range was higher in the intervention group (67.04%) compared with the control group (65.38%) with a difference of 1.66%. The results of the unadjusted analysis confirm these findings.

**Table 143: Hypothesis 2 - PoCT leads to the same or better triglyceride control (adjusted analysis)**

Percentage of test results in target range (intervention)	Percentage of test results in target range (control)	Difference (intervention - control)	90% confidence interval for difference	Minimum difference for non-Inferiority	P-value
67.04	65.38	1.66	-1.78, 5.09	-7.00	<0.0001

#### 9.4.2. Impact of PoCT on Patient Care

##### 9.4.2.1. GP visits

There were missing data on GP visits for 8.70% of patients and so their data needed to be imputed. There were a higher percentage of patients requiring data imputation in the intervention group compared to the control group (10.17% and 6.44% respectively); however, this was largely due to patients from the intervention practices withdrawing from the Trial prior to patient details being sent to Medicare Australia.

Based on the adjusted analysis, the number of GP visits per person-year was higher in the intervention group (11.66 visits per year) compared to the control group (9.97 visits per year), with a rate ratio of 1.17 (intervention vs. control) and a 95% confidence interval for the rate ratio of (1.03, 1.32) (Table 144). Intervention patients had a significantly higher number of GP visits per person-year ( $p=0.0126$ ). The results of the unadjusted analysis confirm these findings.

**Table 144: GP visits per person-year by treatment group (adjusted analysis)**

GP visit rate per year (intervention)	GP visit rate per year (control)	Rate ratio (intervention vs. control)	95% confidence interval for rate ratio	P-value
11.66	9.97	1.17	1.03-1.32	0.0126

An analysis of the Medicare Australia GP visit data by condition provides some insight into visits for the three conditions (Table 145). While this data has some limitations – not all patients had a GP visit – it does help to explain the variation across treatment groups. The descriptive statistics based on the raw data relating to GP visits provides evidence that patients on anticoagulant therapy were the driving force behind the higher number of GP visits per person-year for the intervention group. For patients with diabetes and hyperlipidaemia the overall difference was similar between both treatment groups.

**Table 145: Number of GP visits per person-year by treatment group**

Conditions	Intervention	Control	Total
INR	19.22	13.60	17.01
Diabetes	11.11	10.51	10.86
Hyperlipidaemia	10.99	9.65	10.47

For INR testing the total number of tests per person-year for Phase II is higher in the intervention group (12.0) compared to the control group (9.3). The total number of tests per person-year for

HbA1c in Phase II is slightly higher for the intervention group (1.8) compared to the control group (1.5). For both ACR and urine albumin testing the total number of tests per person-year was higher in the intervention group (1 for both tests) compared to control patients (0.4 each). The total number of tests per person-year for total cholesterol, triglycerides and HDL-C was higher in the intervention group (1.3 each) compared to the control group (0.9 each).

**Table 146: Number of tests per person-year for Phase II by treatment group**

Test	Number of tests per person-year (intervention)	Number of tests per person-year (control)
INR	12.0603	9.3251
HbA1c	1.76558	1.46324
ACR	0.95995	0.38340
Urine albumin	0.96396	0.42935
Total cholesterol	1.27357	0.90251
HDL-C	1.25251	0.85935
Triglyceride	1.27256	0.88478

#### 9.4.2.2. Processes of care actions

A total of 1126 patients (22.7%) out of 4968 patients in the PoCT Trial had their notes reviewed for process of care actions analysis. Reflecting the number of patients recruited by condition, the largest percentage of patients audited had hyperlipidaemia and the smallest number of patients audited was on anticoagulant therapy (Table 147).

**Table 147: Patients selected and number of tests examined for case note audit by condition**

Condition	Patients selected for audit		Estimated tests based on the audit	
	Freq	%*	Freq	%
Anticoagulant therapy	248	22.0	20076	61.9
Diabetes	437	38.8	5477	16.9
Hyperlipidaemia	856	76.0	6857	21.2
Total	1126		32410	100.0

\* not add up to 100% as patients have multiple conditions

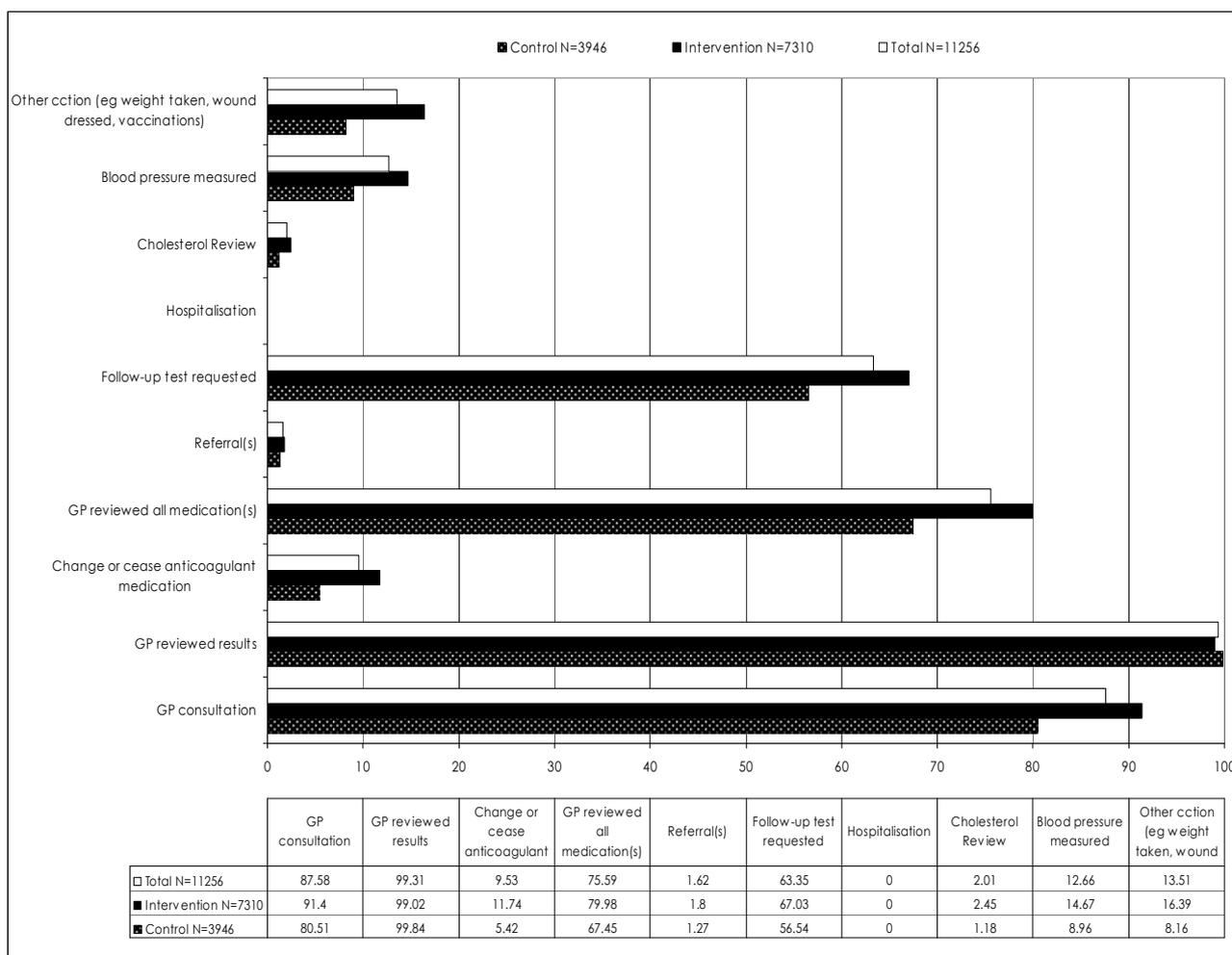
The number of tests were estimated for the study population, with a total of 32,410 tests examined (Table 147). The largest number of consultations examined was for patients on anticoagulant therapy (61.9%) followed by hyperlipidaemia (21.2%) and diabetes (16.9%).

## Anticoagulant Therapy

For the patients on anticoagulant therapy, a total of 11256 (56.06%) tests were within target range and 8820 (43.93%) tests were outside target range.

For the tests that were within target range, the most common action by the GP was a review of the test results which occurred for nearly every test (99.31%) (Figure 21). For 87.58% of test results there was also a GP consultation, either face-to-face or by phone. For 75.59% of the tests the GP reviewed the medication (anticoagulant medication or other types of medication), with only 9.53% of tests leading to a change or cessation of anticoagulant medication (Figure 21). For nearly two-thirds of test results examined, the GP requested a follow-up test. The least common actions for INR test results within range were cholesterol review (2.01%) and referrals to specialists or dietician (1.62%) and no test result resulted in hospitalisations (Figure 21). When analysed by treatment group, apart from reviewing of the results by the GP and hospitalisation, patients in the intervention group with tests within range had a larger percentage of actions in all areas compared to the control group. Test results for patients in the intervention group had a larger number of actions relating to changes or cessation of anticoagulant medication, reviewing of all medications, requesting of follow-up tests, measurement of blood pressure and other actions (Figure 21 and Figure 22).

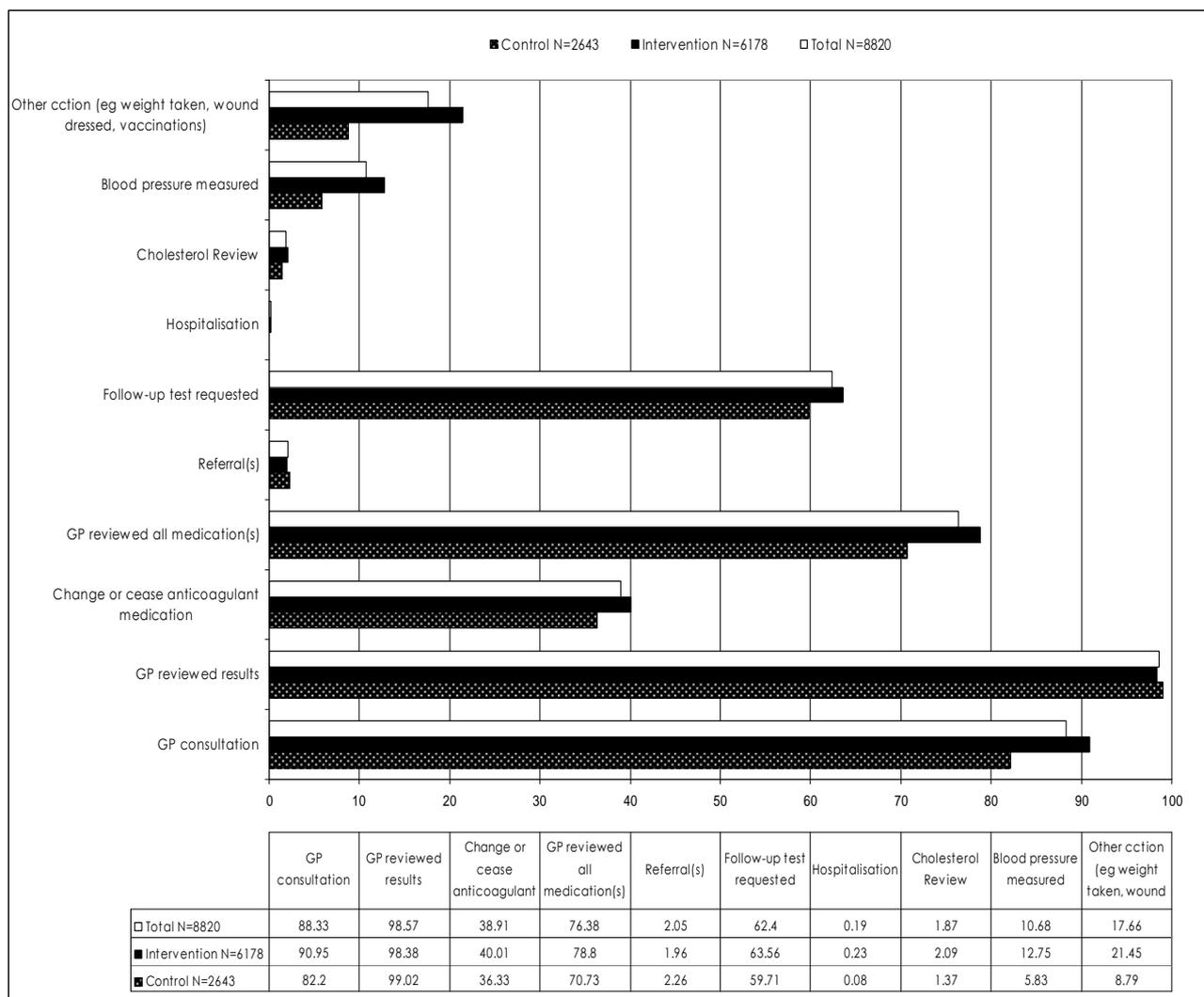
**Figure 21: Percentage of INR tests where action was performed by treatment group for patients on anticoagulant therapy when test result was within target range**



A smaller number of tests audited for patients on anticoagulant therapy were outside the target range (8820). The most common actions associated with tests outside the target range were the same as for tests within the target range – GP reviewed result (98.57%), GP consultation (88.33%), review of all medications (76.38%) and follow-up test request (62.4%) (Figure 22). When analysed by

treatment group, patients in the intervention group with tests outside therapeutic range had a larger percentage of actions across all items except for referrals, where the control group had a higher proportion (2.26%), and reviewing of results which was the same for both groups (Figure 22).

**Figure 22: Percentage of INR tests where action was performed by treatment group for patients on anticoagulant therapy when test result was outside target range**



In comparing the actions by the GP for tests within and outside target range, a much larger proportion of GPs changed or ceased anticoagulant medication if the test was outside range (38.91%) compared to when the test was within range (9.53%). There was also a larger percentage of hospitalisations for tests outside the target range (0.19%) where there were none for tests within target range (Figure 21 and Figure 22).

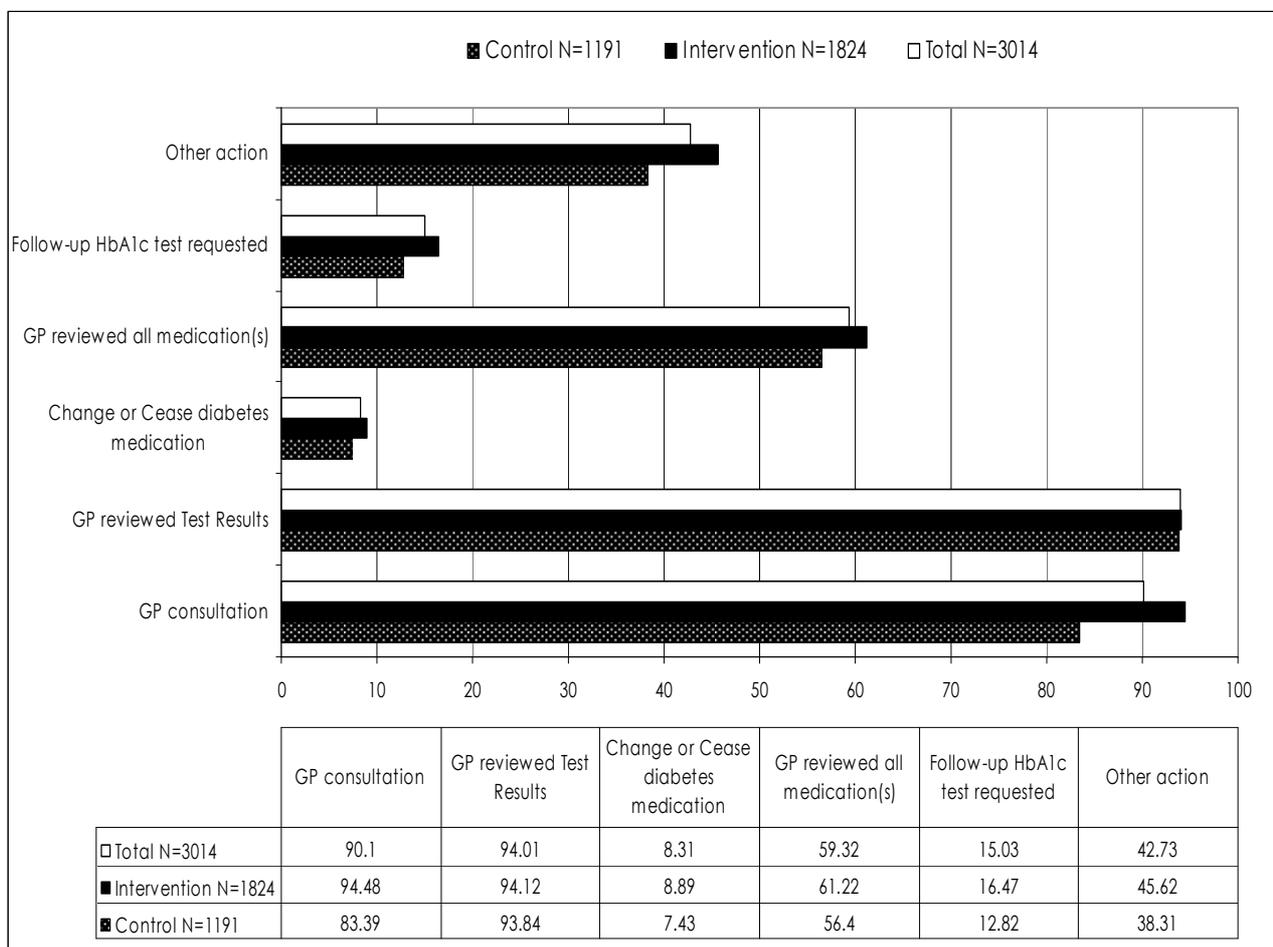
## Diabetes

For the patients with diabetes a total of 3014 (55.03%) HbA1c tests were within target range and 2463 (44.96%) tests were outside the target range.

For HbA1c test results within the target range, the most common process of care actions for patients with diabetes, which were not part of the diabetes annual cycle of care, were review of the results (94.01%), a GP consultation (91.10%) and a review of all medications (59.32%) (Figure 23). The least common action was change or cessation of medication (8.31%). When viewed by treatment group, the proportion of actions in all areas was greater in the intervention group than in the control group (Figure 23). More tests in the intervention group were associated with a GP

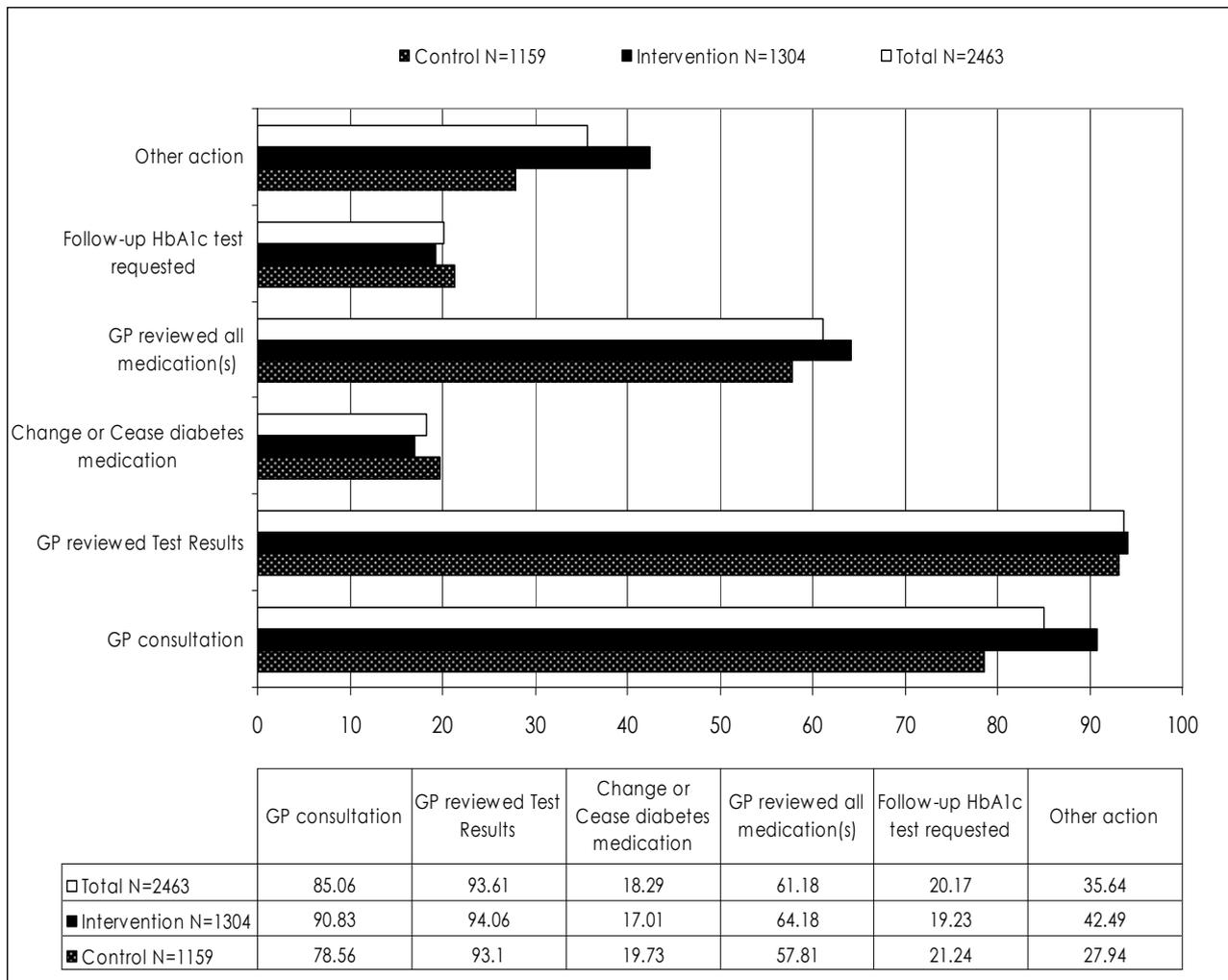
consultation (94.48%) compared with the control group (83.39%) as well as review of all medications (61.22%) and other actions (45.62%).

**Figure 23: Percentage of HbA1c tests where action was performed by treatment group for patients with diabetes and when test was within target range**



For HbA1c tests outside the target range, the most common actions were similar to those reported for the tests within range (Figure 24), being review of test results (93.61%), GP consultation (85.06%) and review of all medications (61.18%). When comparing treatment groups for tests outside target range, the intervention group had a larger proportion of actions in terms of GP consultations (90.83% versus 78.56%), review of all medications (64.18% versus 57.81%) and other actions (42.49% versus 27.94%) (Figure 24). However, the control group reported a slightly higher proportion of changes in medication (19.73 versus 17.01%).

**Figure 24: Percentage of HbA1c tests where action was performed by treatment group for patients with diabetes and when test was outside target range**



In comparing the actions by the GP for HbA1c tests within and outside target range, a much larger proportion of GPs changed or ceased diabetes medication if the test was outside target range (18.29%) compared to when the test was within range (8.31%). There was also a larger percentage of GP consultations and other actions for tests within target range compared with tests outside the target range, and a larger number of follow-up HbA1c tests requested for patients with tests outside target range compared with patients with tests within target range (20.17% versus 15.03%) (Figure 23 and Figure 24). However, there were a higher proportion of tests associated with a review of all medications (61.18%) for tests outside the target range compared with tests within target range (59.32%).

In terms of the actions related to the diabetes annual cycle of care, overall every action was not being performed within the 12 month period for patients whose test results were either within or outside the target range except for review of all medications, and the review of HbA1c levels (Table 148).

For patients with HbA1c test results within the target range, review of medications and review of HbA1c results for both control and intervention patients occurred at least once in a 12 month period. For control patients, lipid testing was also performed at least once in the 12 month period while for the intervention group, lipids were being tested only 0.93 times per person-year, which is slightly below the recommendation of once per year (Table 148). Review of HbA1c test results by the GP and review of all medications by the GP were the actions in the annual cycle of care most

often undertaken – 1.66 times per person-year and 1.70 times per person-year respectively (Table 148). Blood pressure measures were being undertaken 0.90 times per person-year for the control group and 0.80 times for the intervention group, which is slightly below the recommendation of once per year. Smoking, nutrition, alcohol and physical exercise (SNAP) actions were undertaken the least number of times per person-year out of all the annual cycle of care actions (Table 148).

**Table 148: Number of actions per person-year by treatment group for patients with diabetes and whether test was within or outside target range**

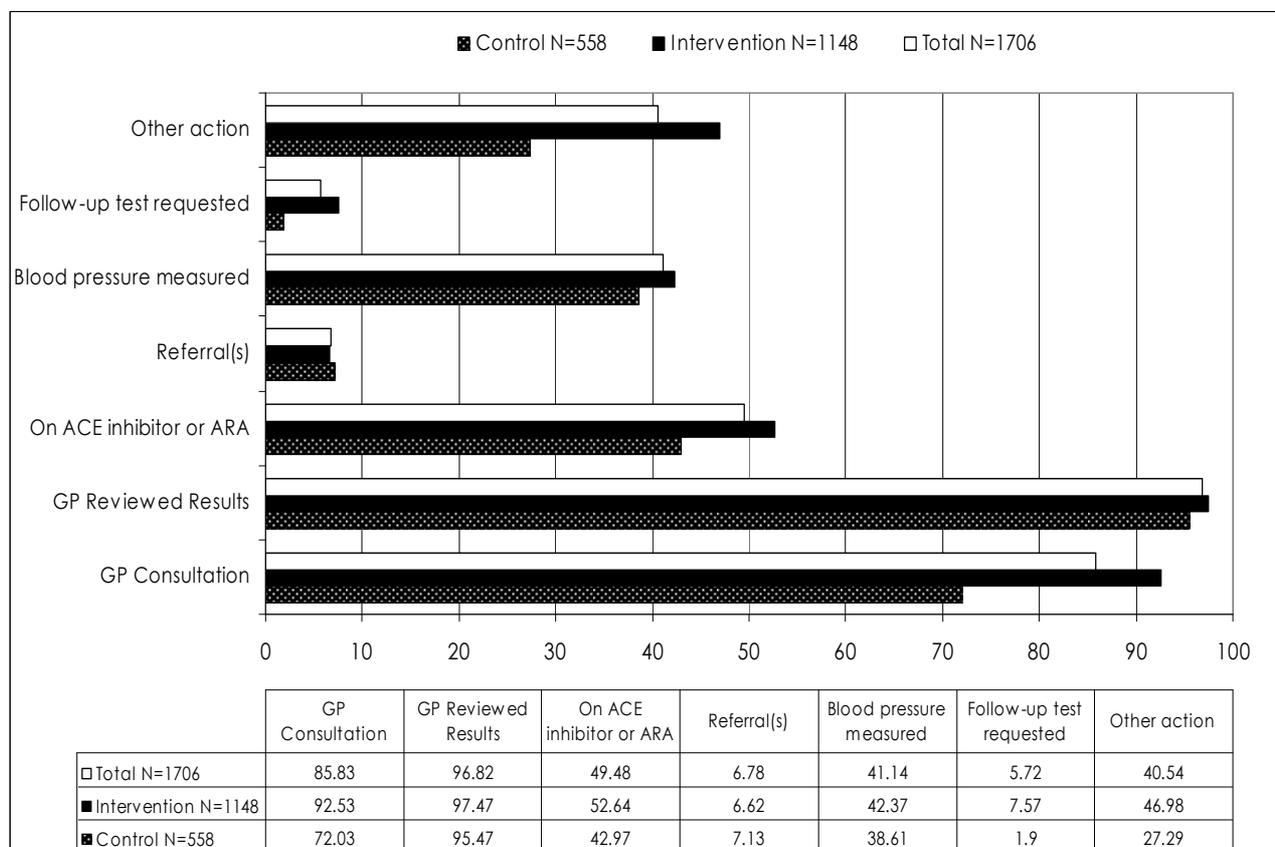
Process of care action	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
GP reviewed test results	1.68	1.65	1.66	1.86	1.58	1.70
GP reviewed all medications	1.01	1.08	1.05	1.16	1.08	1.11
SNAP (at least 3 out of 4 actions performed)	0.03	0.02	0.02	0.05	0.01	0.03
Referral(s)	0.11	0.16	0.14	0.20	0.17	0.18
BMI	0.25	0.31	0.29	0.11	0.30	0.22
Eye examination	0.16	0.18	0.17	0.07	0.22	0.16
Blood pressure measured	0.90	0.80	0.84	0.70	0.63	0.66
Feet examined	0.37	0.17	0.25	0.20	0.16	0.18
Lipids tested	1.00	0.93	0.96	0.92	0.75	0.83
Urine microalbumin tested	0.48	0.72	0.63	0.49	0.62	0.57
Self-care education provided	0.10	0.12	0.11	0.13	0.07	0.10

*Note: each action should be performed at least once per year as part of the diabetes annual cycle of care (e.g. receive a score of 1.0)*

For patients with diabetes, a total of 2401 tests were also taken for microalbuminuria – either ACR or urine albumin. Of these test results, 1706 (71.05%) indicated the patient did not have microalbuminuria and for 695 test results (28.95%) indicated that the patient had microalbuminuria.

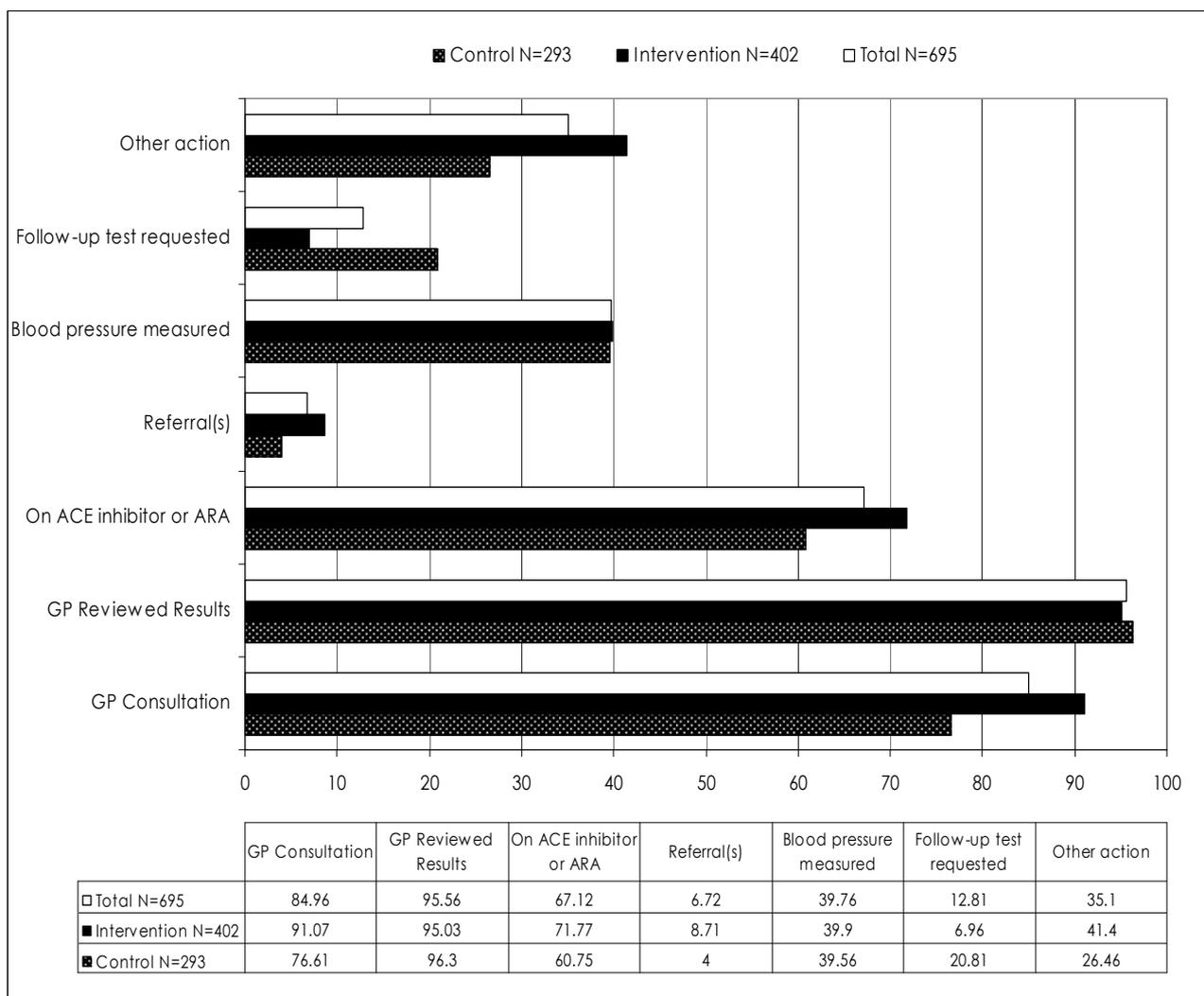
For ACR or urine albumin tests where microalbuminuria was not present, the most common actions were a review of all medications by the GP (97.47%), a GP consultation (92.53%), other actions (46.98%) or measurement of blood pressure (41.14%). For all actions except referrals, the intervention group had a larger proportion of actions undertaken compared to the control group (Figure 25).

**Figure 25: Percentage of microalbumin tests where action was performed by treatment group for patients with diabetes and where microalbuminuria is not present**



Where microalbuminuria was present (e.g. ACR or urine albumin outside target range), the most common actions by the GP were review of all patient medications (95.56%), a GP consultation (84.96%), measurement of blood pressure (39.76%) and other actions (35.10%) (Figure 26). For patients in the intervention group, there was a higher proportion of process of care actions relating to GP consultation (91.07% versus 76.61%), other actions (41.40% versus 26.46%) and referrals (8.71% versus 4.00%). However, for the control group, there were a much higher proportion of follow-up tests requested than in the intervention group (20.81% versus 9.69%) (Figure 26).

**Figure 26: Percentage of microalbumin tests where action was performed by treatment group for patients with diabetes and where microalbuminuria is present**

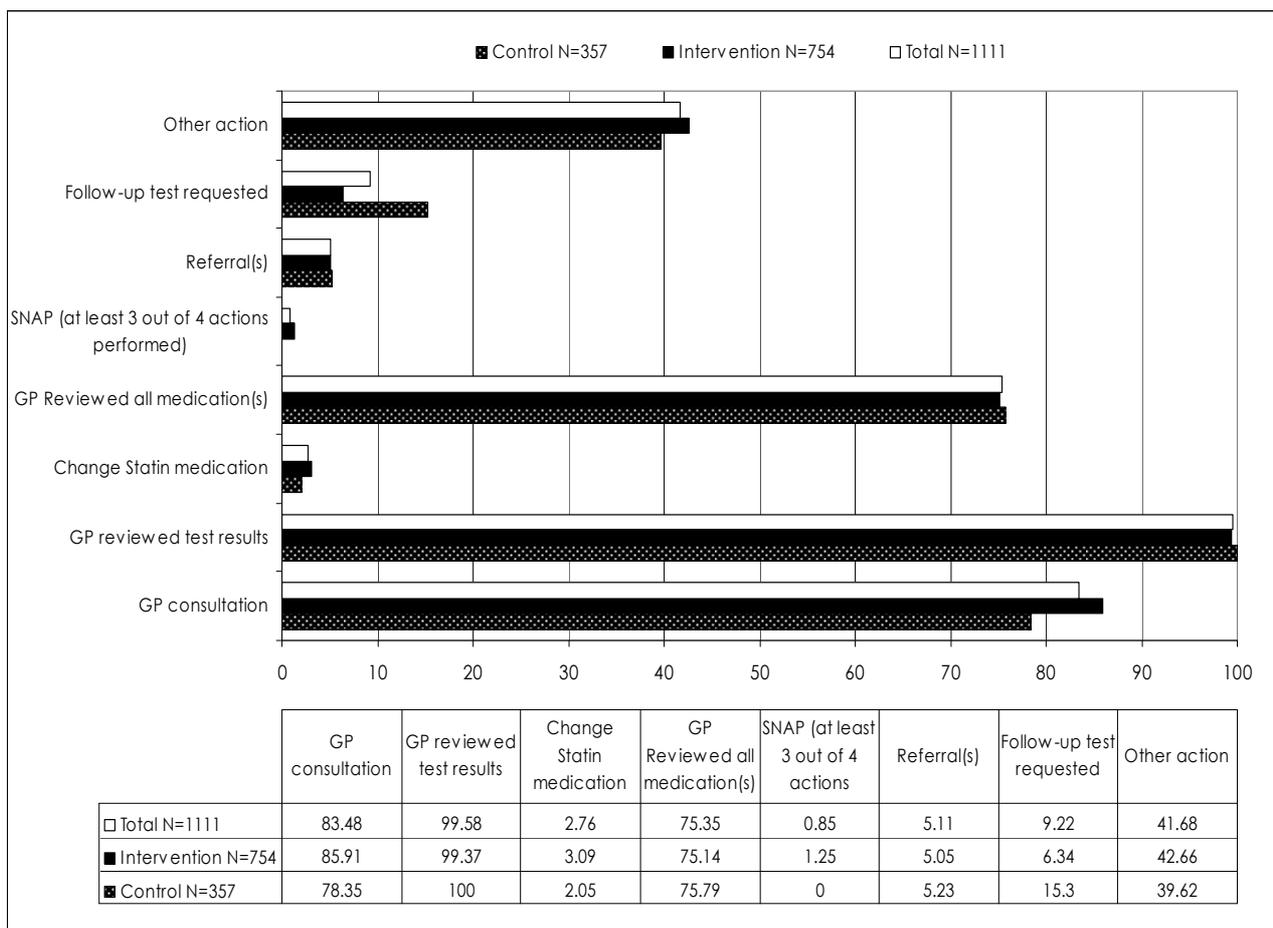


### Hyperlipidaemia

For the patients with hyperlipidaemia a total of 1111 (16.20%) tests were within target range and 5746 (83.79%) of tests were outside the target range.

For tests within target range, the most common process of care actions were review of test results (99.37%), a GP consultation (85.91%), review of all medications (75.14%) and other actions (41.68%). The least common process of care action was change in statin medication (2.76%). In comparing the control and intervention groups, the intervention group had a higher proportion of actions related to GP consultation, change in statin medication, SNAP and other actions (Figure 27). However, the control group had a higher proportion of follow-up tests requested.

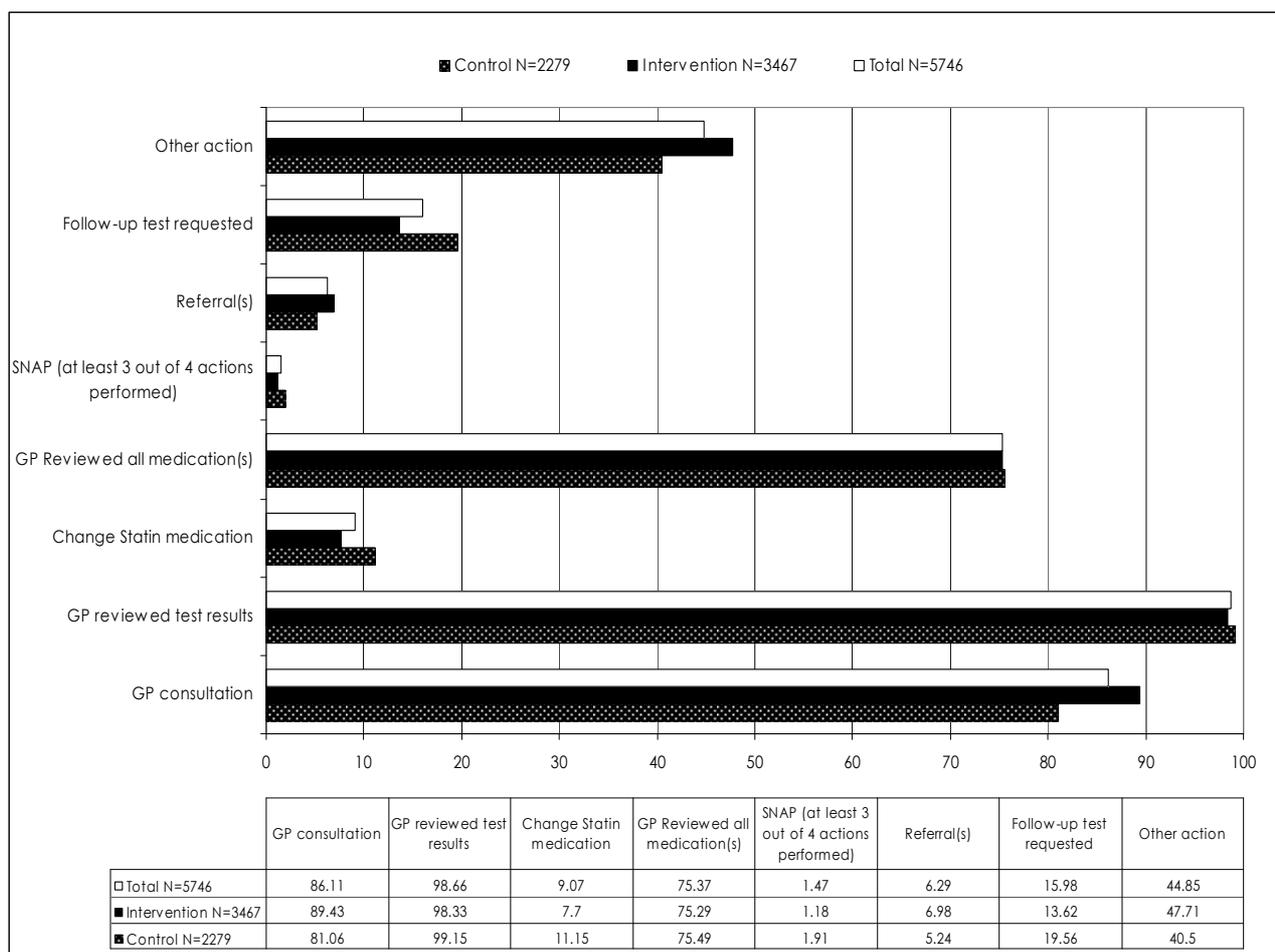
**Figure 27: Percentage of tests where action was performed by treatment group for patients with hyperlipidaemia and whether test was within target range**



A similar pattern was found in the tests outside the target range, although in the control group there was a higher proportion of change in statin medication (Figure 28).

In comparing the actions by the GP for tests within and outside target range, a larger proportion of GPs changed statin medication if the test was outside range (9.07%) compared to when the test was within range (2.7%), they referred more (6.29% versus 5.11%), completed more SNAP actions (1.47% versus 0.85%) and requested a follow-up lipid study test (15.98% versus 9.22%) (Figure 27 and Figure 28).

**Figure 28: Percentage of tests where action was performed by treatment group for patients with hyperlipidaemia and whether test was outside target range**



#### 9.4.2.3. Prescribing patterns

A total of 34,811 tests were examined in the case note audit, of which 87.30% were associated with a consultation with the GP either face-to-face or by telephone (Table 149). The largest group of tests examined was INR tests and the smallest was lipid tests, which reflected the frequency of testing.

**Table 149: Tests examined in the case note audit and tests associated with a GP consultation by condition**

Condition	Estimated tests based on the audit		Estimated tests associated with a GP consultations	
	Freq	%	Freq	%
Anticoagulant therapy - INR	20076	57.67	17649	87.91
Diabetes – HbA1c	5477	15.73	4811	87.84
Diabetes – Microalbuminuria	2401	6.90	2054	85.55
Hyperlipidaemia	6857	19.70	5875	85.68
Total	34811	100.0	30389	87.30

## Anticoagulant therapy

For patients on anticoagulant therapy, the most common medication prescribed was warfarin. A very small proportion of patients were on a combination of aspirin and warfarin, aspirin only or not on either medication (e.g. some patients enrolled in the Trial with Deep Vein Thrombosis which then resolved). In comparing differences in anticoagulant medication for patients whose test results were either within or outside the target range, a higher proportion of tests outside the target range had patients on a combination of warfarin and aspirin (2.53% versus 1.57%) or on neither drug (2.14% versus 0.70%) and the proportion was higher for patients in the intervention group. No patients whose test results were within target range were on aspirin only (Appendix 28).

In comparing differences in anticoagulant medication for patients whose test results were either within or outside the target range, a higher proportion of tests outside the target range had patients on a combination of warfarin and aspirin (2.53% versus 1.57%) or on neither drug (2.14% versus 0.70%) and the proportion was higher for patients in the intervention group. No patients whose test results were within target range were on aspirin only.

For INR test results within the target range, more changes in anticoagulation medication were made by the GP (10.54%). The most common change in medication was an increase or decrease in dosage (7.85 %) (Table 150). A different pattern in medication changes was found between the intervention and control groups. A higher proportion of changes in medication and changes in the strength and dosage of medication was found in the intervention group compared with the control group (Table 150).

For INR test results outside the target range, more changes in medications were made by the GP (41.74%), with the most common change being an increase or decrease in medication strength (34.39%) (Table 150). The type of medication change varied between the intervention and control groups. The intervention group was more likely to have an increase or decrease in medication while the control group was more likely to have an increase or decrease in medication strength (Table 150).

**Table 150: Percentage of consultations where medication changes were made by treatment group and whether test was within or outside target range**

Change in anticoagulant medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=3177	N=6681	N=9858	N=2172	N=5618	N=7791
Change in medication(s)	6.53	12.45	10.54	42.73	41.36	41.74
Increase/decrease in medication strength	5.36	9.04	7.85	38.38	32.85	34.39
Increase/decrease in medication dosage	0.61	2.35	1.79	2.79	6.47	5.45

## Diabetes

For patients with diabetes, the most common medication prescribed was metformin hydrochloride and gliclazide regardless of whether the test result was within or outside range (Table 151). No patients were on insulin lispro–protamine suspension, insulin zinc suspension or insulin zinc suspension crystalline.

In comparing differences in diabetes medication for HbA1c test results were either within or outside the target range, a higher proportion of patients with tests outside the target were on gliclazide (37.58% versus 25.58%), metformin hydrochloride (65.46% versus 51.29%), glimepiridie (4.58% versus 2.60%), insulin isophane (9.83% versus 3.43%) and insulin neutral–insulin isophane (7.50% versus 4.49%) (Table 151).

**Table 151: Percentage of tests by type of diabetes medication by treatment group and whether test was within or outside target range**

Type of Diabetes medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=993	N=1723	N=2716	N=910	N=1185	N=2095
Acarbose	0.00	0.53	0.34	0.00	0.00	0.00
Gilbenclamide	1.39	0.18	0.62	3.11	0.44	1.60
Gliclazide	25.42	25.67	25.58	44.12	32.56	37.58
Glimepiride	4.37	1.58	2.60	6.11	3.41	4.58
Glipizide	0.43	1.31	0.99	0.29	1.21	0.81
Metformin hydrochloride	52.58	50.55	51.29	67.59	63.82	65.46
Metformin hydrochloride with glibenclamide	0.36	1.36	0.99	1.02	4.50	2.99
Pioglitazone hydrochloride	1.89	0.60	1.07	2.12	1.77	1.92
Rosiglitazone maleate	1.23	2.88	2.28	5.64	4.47	4.98
Insulin aspart	0.00	0.23	0.15	1.62	7.85	5.14
Insulin aspart – protamine suspension	0.00	3.44	2.18	6.16	5.04	5.52
Insulin lispro	2.55	0.00	0.93	3.79	1.63	2.57
Insulin lispro – protamine suspension	0.00	0.00	0.00	0.00	0.00	0.00
Insulin isophane	4.07	3.06	3.43	8.61	10.77	9.83
Insulin neutral	5.17	0.46	2.18	2.63	3.19	2.95
Insulin neutral - insulin isophane	4.60	4.43	4.49	6.51	8.26	7.50
Insulin zinc suspension	0.00	0.00	0.00	0.00	0.00	0.00
Insulin zinc suspension crystalline	0.00	0.00	0.00	0.00	0.00	0.00
Other diabetes medication	0.43	0.00	0.16	0.24	6.70	3.89

A larger proportion of patients whose test results were outside target range were on multiple diabetes medications (52.89%) compared with patients whose test results were within the target range (24.52%) (Appendix 29). Patients with tests results within target range were more likely to be on one type of diabetes medication (47.69%) or on no diabetes medication (27.78%) compared with patients whose test results were outside the target range (Appendix 29).

For tests results within target range, a larger proportion of patients in the intervention group were on no diabetes medication (32.28%), while a larger proportion of patients in the control group was on one type of medication only (55.08%) (Appendix 29). For test results outside the target range, a higher proportion of patients in the control group were on multiple medications or no medications compared with the intervention group (Appendix 29).

For patients with test results within the target range, less than 10% of patients had a change in medication made by their GP. The most common change in medication was an increase or decrease in dosage (4.26%) and this pattern was similar across both the intervention and control groups (Table 152).

For patients whose test result was outside the target range, 21.50% had their diabetes medication changed by their GP. For those that did, this was mainly a change in strength (7.83%) rather than a change in dosage (5.87%) and this occurred only in the control group (Table 152). While patients within the control group had a higher proportion of changes in medication and changes in their diabetes medication dosage compared to the intervention group, the intervention patients had a higher proportion of diabetes medication strength changes (Table 152).

**Table 152: Percentage of tests where medication changes were made for patients with diabetes by treatment group and whether HbA1c test was within or outside target range**

Change in diabetes medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=993	N=1723	N=2716	N=910	N=1185	N=2095
Change in medication(s)	8.91	9.41	9.23	25.11	18.73	21.50
Increase/decrease in medication strength	2.72	3.75	3.37	7.49	8.08	7.83
Increase/decrease in medication dosage	3.24	4.85	4.26	7.62	4.52	5.87

The most common medication prescribed for patients diagnosed with microalbuminuria was an ACE inhibitor, while a small number of patients were on angiotensin receptor antagonist (ARA) medication. The most common ACE inhibitor medication was perindopril erbumine and ramipril and the most common ARA medication was avapro (Table 153).

**Table 153: Percentage of patients by type of diabetes medication by treatment group and whether microalbuminuria was present or not**

Type of microalbuminuria medication		Microalbuminuria not present			Microalbuminuria present		
		Control	Intervention	Total	Control	Intervention	Total
		N=402	N=1062	N=1462	N=225	N=366	N=590
ACE Inhibitor		33.69	31.21	31.89	55.96	38.75	45.30
	Captopril	0.00	0.61	0.44	0.96	0.00	0.37
	Enalapril Maleate	2.13	1.46	1.64	0.00	0.00	0.00
	Fosinopril Sodium	0.00	1.14	0.83	0.00	0.00	0.00
	Lisinopril	0.00	2.33	1.69	4.96	2.85	3.65
	Perindopril Erbumine	10.44	11.35	11.10	22.03	15.82	18.18
	Quinapril Hydrochloride	0.00	0.33	0.24	5.90	0.00	2.25
	Ramipril	13.63	8.63	10.00	18.58	11.28	14.06
	Trandolapril	1.09	3.30	2.69	1.95	1.67	1.78
	Other ACE inhibitor	6.41	2.06	3.26	1.58	7.12	5.01
ARA		24.88	26.66	26.17	23.34	42.91	35.46
	Atacand	4.84	7.68	6.90	1.80	12.24	8.27
	Avapro	6.58	13.66	11.72	12.44	24.79	20.09
	Cozaar	0.00	0.00	0.00	0.00	0.00	0.00
	Karvea	10.92	1.66	4.20	1.42	1.61	1.54
	Micardis	0.00	3.66	2.65	1.95	4.26	3.38
	Teveten	1.46	0.00	0.40	3.79	0.00	1.44
	Other ARA	1.09	0.00	0.30	1.95	0.00	0.74

Only a small percentage of tests resulted in a change in either ACE inhibitor or ARA medication, and this was greater for tests where microalbuminuria was present (4.99%) (Table 154). The change made to the medication was related to the strength of the medication, and a higher proportion of patients in the control group compared to the intervention group where microalbuminuria was present had these changes made (Table 154).

**Table 154: Percentage of ACR/UA tests where medication changes were made for patients with diabetes by treatment group and whether microalbuminuria was present or not**

Change in diabetes medication	Microalbuminuria not present			Microalbuminuria present		
	Control	Intervention	Total	Control	Intervention	Total
	N=402	N=1062	N=1462	N=225	N=366	N=590
Change in medication(s)	2.15	2.88	2.68	5.84	4.46	4.99
Increase/decrease in medication strength	2.15	2.51	2.41	5.84	0.00	2.22
Increase/decrease in medication dosage	0.00	0.00	0.00	0.00	0.00	0.00

#### Hyperlipidaemia

For patients with hyperlipidaemia, the most common medication prescribed was atorvastatin calcium and simvastatin (Table 155).

For patients with test results within target range, there were a larger proportion of patients in the intervention group on ezetimibe, gemfibrozil, fenofibrate, pravastatin sodium, and simvastatin than patients in the control group (Table 155). For patients with test results outside the target range, a larger proportion of control patients were prescribed fenofibrate, cholestyramine, gemfibrozil and simvastatin but a lower proportion was prescribed atorvastatin calcium and ezetimibe (Table 155).

A higher percentage of patients with tests within target range was on atorvastatin calcium (45.43%) compared with patients with test results outside the target range (38.86%). Only patients with test results outside the target range were on other lipid medicines (Table 155). No patients were on chlestipol hydrochloride or nicotinic acid.

**Table 155: Percentage of patients by type of lipid medication by treatment group and whether test was within or outside target range**

Type of lipid medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=280	N=648	N=927	N=1847	N=3100	N=4948
Atorvastatin calcium	48.47	44.00	45.43	32.51	43.04	38.86
Chlestipol hydrochloride	0.00	0.00	0.00	0.00	0.00	0.00
Cholestyramine	0.00	0.00	0.00	0.42	0.00	0.17
Ezetimibe	0.99	3.21	2.50	3.26	8.89	6.66
Fenofibrate	0.00	0.69	0.47	2.48	1.09	1.64

Type of lipid medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=280	N=648	N=927	N=1847	N=3100	N=4948
Fluvastatin sodium	0.00	0.00	0.00	0.00	0.87	0.53
Gemfibrozil	0.00	1.05	0.71	1.86	1.51	1.65
Nicotinic acid	0.00	0.00	0.00	0.00	0.00	0.00
Pravastatin sodium	2.85	8.58	6.74	7.03	7.26	7.17
Simvastatin	25.44	29.59	28.26	34.12	24.25	28.16
Other lipid medication	0.00	0.00	0.00	2.09	3.20	2.76

The majority of patients were on only one type of statin medication (Appendix 30). A larger proportion of patients whose test results were within target range were on one type of statin medication (94.77%) compared with patients whose test results were outside the target range (86.91%) and these patients were more likely to be on multiple medications (Appendix 30).

For patients whose test result was within target range, only 3.30% had their medication changed by their GP. For those who did, this was mainly a change in dosage (1.58%) rather than a change in strength (0.94%) and this occurred only in the intervention group (Table 156).

For patients whose test result was outside the target range, 10.53% had a change made in their medication by their GP, with a larger proportion of changes made in the control group. The most common change was a change in medication strength (4.29%) rather than a change in dosage (0.16%) and this was higher for the control group (Table 156).

**Table 156: Percentage of consultations where medication changes were made for patients with hyperlipidaemia by treatment group and whether test was within or outside target range**

Change in lipid medication	Tests within target range			Tests outside target range		
	Control	Intervention	Total	Control	Intervention	Total
	N=280	N=648	N=927	N=1847	N=3100	N=4948
Change in medication(s)	2.61	3.60	3.30	13.75	8.61	10.53
Increase/decrease in medication strength	0.00	1.34	0.94	5.28	3.69	4.29
Increase/decrease in medication dosage	0.00	2.26	1.58	0.43	0.00	0.16

### 9.4.3. Patient compliance with disease management

#### 9.4.3.1. Medication compliance (MARS-5) analysis by treatment group

Based on the adjusted analysis, the percentage of MARS-5 questionnaire responses indicating compliance with disease management (use of medicines), was higher in the intervention group (39.27%) compared to the control group (36.98%), with a difference of 2.29% and a 90% confidence interval for the difference of (-0.06, 4.64). Since the lower limit of the 90% confidence interval is greater than the non-inferiority limit of -3.70%, the hypothesis that PoCT is non-inferior to pathology testing in relation to the proportion of MARS-5 questionnaire responses indicating compliance with disease management ( $p < 0.0001$ ) can be concluded (Table 157). The results of the unadjusted analysis confirm these findings.

**Table 157: Compliance to disease management (use of medicines) by treatment group (adjusted analysis)**

Percent compliant (intervention)	Percent compliant (control)	Difference (intervention - control)	90% Confidence interval for difference	Minimum difference for non-inferiority	P-value
39.27	36.98	2.29	-0.06, 4.64	-3.70	<0.0001

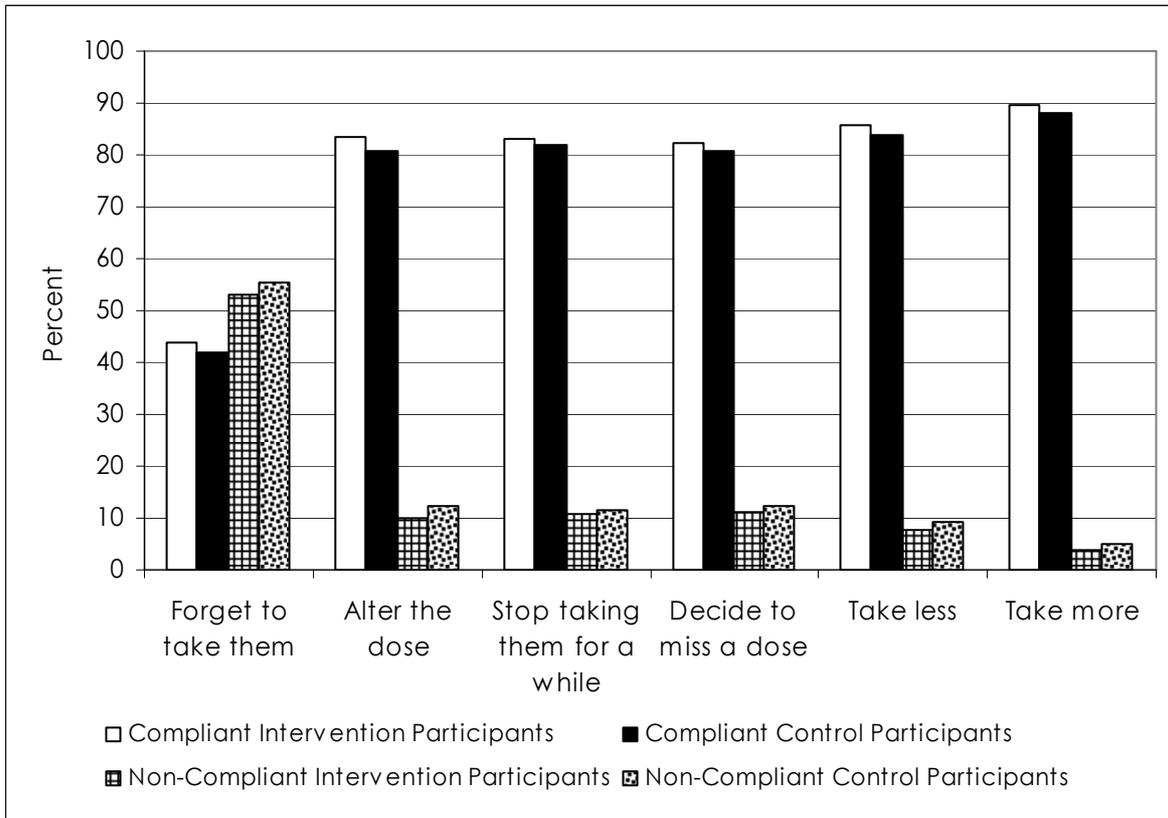
There was no evidence of effect modification by questionnaire ( $p=0.7558$ ), e.g. there was no evidence to suggest that the effect of treatment varies between the first and second questionnaire (see Appendix 31).

#### 9.4.3.2. Descriptive results of medication compliance using the MARS-5 (plus additional question)

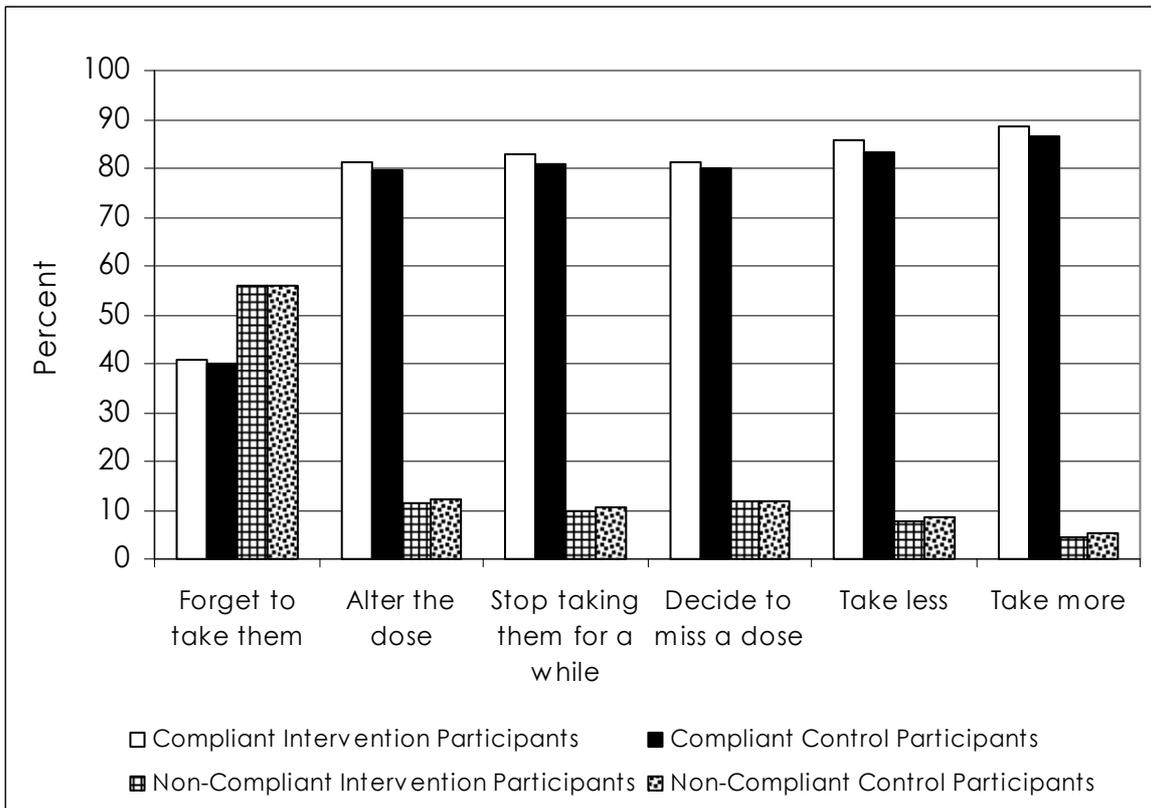
Descriptive data are presented by treatment group and geographic area. Responses to the MARS-5 (plus additional question) were similar between treatment groups, with the majority of patients reporting that they never altered the dose of their medicine(s), never stopped taking them for a while, never decided to miss a dose and did not take less or more than instructed (Figure 28 and Figure 29).

Interestingly, in the first questionnaire 55% of control patients and 53% of intervention patients reported that they forgot to take their medicine(s) to some degree and in the second questionnaire 56% of both control and intervention patients reported that they forgot. Results from the first questionnaire show that 12% of control patients and 10% of intervention patients reported that they altered the dose and in the second questionnaire this remained the same for control patients and increased to 12% of intervention patients. The first questionnaire showed that 12% of control patients and 11% of intervention patients stopped taking their medications for a while which decreased to 11% in the control group and 10% in the intervention group in the second questionnaire. Thirteen percent of control patients and 11% of intervention patients reported that they decided to miss out a dose, which decreased in the second questionnaire to 12% in the control group but increased to 12% for the intervention group. There were a smaller proportion of patients who reported taking less than instructed, with very little difference between questionnaires. Only 5% of control patients and 4% of intervention patients took more than instructed which increased in the second questionnaire in both groups (6% of control patients and 4.5% of intervention patients). The median MARS-5 score (regardless of treatment group) was 24.0 and the interquartile range was 23.0-25.0 in both the first and second questionnaires, indicating that patients generally reported a high level of compliance.

**Figure 29: MARS responses (first questionnaire) by treatment group**



**Figure 30: MARS responses (second questionnaire) by treatment group**



Results were similar when reviewing medication compliance by condition, treatment group and questionnaire (see Appendix 31). Only a small proportion of patients on anticoagulant therapy reported intentional medication non-compliance with approximately 49% forgetting to take their medicines. Over 50% of diabetes patients reported forgetting to take their medicines with approximately 10-15% of both treatment groups altering the dose, missing out a dose or stopping taking them for a while. Approximately 57% of hyperlipidaemia patients forgot to take their medicines with approximately 10% intentionally not complying.

MARS responses by geographic location show that in the first questionnaire 54% of control and 55% of urban intervention patients forgot to take their medication which increased in both groups in the second questionnaire (57% and 56% respectively). In both treatment groups the proportion of patients altering the dose was similar (12% of urban control patients and 10% of urban intervention patients) and did not change substantially in the second questionnaire. Eleven percent of patients in both urban treatment groups reported stopping their medication for a while and this decreased in both groups in the second questionnaire (9% control and 10% intervention). A similar proportion of both urban treatment groups decided to miss out a dose. Nine percent of patients in both urban treatment groups took less than instructed and 5% of patients in both groups took more medication than instructed (Table 158).

In the first questionnaire, 60% of rural control patients and 52% of rural intervention patients forgot to take their medication which decreased in the second questionnaire for control patients (54%) but slightly increased for intervention patients (53%). Thirteen percent of rural control patients compared to 10% of rural intervention patients altered their dose, 13% of rural control patients and 10% of intervention patients stopped taking their medication for a while. A higher proportion of rural control patients in the first questionnaire compared to rural intervention patients reported missing a dose (15% compared to 10%) which decreased in the second questionnaire for control patients (10%) but increased in intervention patients (11%). Ten percent of rural control patients compared to 6% of rural intervention patients took less medication than instructed which did not change in the second questionnaire and 4% of rural control patients compared to 3% of intervention patients took more medication than instructed which increased in the second questionnaire in both groups (6% and 5% respectively) (Table 159).

In the first questionnaire 54% of control patients and 53% of intervention patients located in a remote setting reported that they forgot to take their medicines which increased in the second questionnaire for both groups (55% and 59% respectively). Twelve percent of control patients compared to 10% of intervention patients altered the dose and this increased in both groups in the second questionnaire. Twelve percent of control patients and 11% of intervention patients stopped taking their medication for a while (this did not change in the second questionnaire for both groups), 12% of both groups decided to miss out a dose and this increased in the second questionnaire in both groups to 13%. Similar proportions of both remote treatment groups took less medication than instructed or took more medication than instructed (Table 160).

**Table 158: MARS responses for urban patients by treatment group and questionnaire**

Characteristic	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention N=848	Control N=789	Total N=1637	Intervention N=823	Control N=768	Total N=1591
I forget to take them						
Non-compliant	467 (55.1)	425 (53.9)	892 (54.5)	463 (56.3)	441 (57.4)	904 (56.8)
Compliant	357 (42.1)	345 (43.7)	702 (42.9)	343 (41.7)	304 (39.6)	647 (40.7)
Missing	24 (2.8)	19 (2.4)	43 (2.6)	17 (2.1)	23 (3.0)	40 (2.5)
I alter the dose						
Non-compliant	86 (10.1)	97 (12.3)	183 (11.2)	96 (11.7)	87 (11.3)	183 (11.5)
Compliant	712 (84.0)	641 (81.2)	1353 (82.7)	677 (82.3)	626 (81.5)	1303 (81.9)
Missing	50 (5.9)	51 (6.5)	101 (6.2)	50 (6.1)	55 (7.2)	105 (6.6)
I stop taking them for a while						
Non-compliant	90 (10.6)	83 (10.5)	173 (10.6)	84 (10.2)	72 (9.4)	156 (9.8)
Compliant	711 (83.8)	653 (82.8)	1364 (83.3)	685 (83.2)	640 (83.3)	1325 (83.3)
Missing	47 (5.5)	53 (6.7)	100 (6.1)	54 (6.6)	56 (7.3)	110 (6.9)
I decide to miss out a dose						
Non-compliant	101 (11.9)	95 (12.0)	196 (12.0)	92 (11.2)	91 (11.8)	183 (11.5)
Compliant	696 (82.1)	646 (81.9)	1342 (82.0)	679 (82.5)	623 (81.1)	1302 (81.8)
Missing	51 (6.0)	48 (6.1)	99 (6.0)	52 (6.3)	54 (7.0)	106 (6.7)
I take less than instructed						
Non-compliant	78 (9.2)	70 (8.9)	148 (9.0)	71 (8.6)	61 (7.9)	132 (8.3)
Compliant	723 (85.3)	666 (84.4)	1389 (84.9)	706 (85.8)	650 (84.6)	1356 (85.2)
Missing	47 (5.5)	53 (6.7)	100 (6.1)	46 (5.6)	57 (7.4)	103 (6.5)
I take more than instructed						
Non-compliant	42 (5.0)	38 (4.8)	80 (4.9)	34 (4.1)	34 (4.4)	68 (4.3)
Compliant	761 (89.7)	700 (88.7)	1461 (89.2)	739 (89.8)	677 (88.2)	1416 (89.0)
Missing	45 (5.3)	51 (6.5)	96 (5.9)	50 (6.1)	57 (7.4)	107 (6.7)
MARS-5 Total Score: median (IQR range)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)
MARS-5 plus additional question Total Score: median (IQR range)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)

**Table 159: MARS responses for rural patients by treatment group and questionnaire**

Characteristic	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention N=845	Control N=413	Total N=1258	Intervention N=808	Control N=398	Total N=1206
I forget to take them						
Non-compliant	18 (2.1)	9 (2.2)	27 (2.1)	32 (4.0)	20 (5.0)	52 (4.3)
Compliant	435 (51.5)	248 (60.0)	683 (54.3)	424 (52.5)	215 (54.0)	639 (53.0)
Missing	392 (46.4)	156 (37.8)	548 (43.6)	352 (43.6)	163 (41.0)	515 (42.7)
I alter the dose						
Non-compliant	41 (4.9)	27 (6.5)	68 (5.4)	61 (7.5)	40 (10.1)	101 (8.4)
Compliant	82 (9.7)	54 (13.1)	136 (10.8)	89 (11.0)	48 (12.1)	137 (11.4)
Missing	722 (85.4)	332 (80.4)	1054 (83.8)	658 (81.4)	310 (77.9)	968 (80.3)
I stop taking them for a while						
Non-compliant	43 (5.1)	23 (5.6)	66 (5.2)	64 (7.9)	41 (10.3)	105 (8.7)
Compliant	86 (10.2)	53 (12.8)	139 (11.0)	67 (8.3)	44 (11.1)	111 (9.2)
Missing	716 (84.7)	337 (81.6)	1053 (83.7)	677 (83.8)	313 (78.6)	990 (82.1)
I decide to miss out a dose						
Non-compliant	39 (4.6)	28 (6.8)	67 (5.3)	61 (7.5)	41 (10.3)	102 (8.5)
Compliant	88 (10.4)	62 (15.0)	150 (11.9)	90 (11.1)	38 (9.5)	128 (10.6)
Missing	718 (85.0)	323 (78.2)	1041 (82.8)	657 (81.3)	319 (80.2)	976 (80.9)
I take less than instructed						
Non-compliant	41 (4.9)	30 (7.3)	71 (5.6)	59 (7.3)	41 (10.3)	100 (8.3)
Compliant	50 (5.9)	41 (9.9)	91 (7.2)	58 (7.2)	37 (9.3)	95 (7.9)
Missing	754 (89.2)	342 (82.8)	1096 (87.1)	691 (85.5)	320 (80.4)	1011 (83.8)
I take more than instructed						
Non-compliant	41 (4.9)	29 (7.0)	70 (5.6)	62 (7.7)	39 (9.8)	101 (8.4)
Compliant	21 (2.5)	16 (3.9)	37 (2.9)	38 (4.7)	22 (5.5)	60 (5.0)
Missing	783 (92.7)	368 (89.1)	1151 (91.5)	708 (87.6)	337 (84.7)	1045 (86.7)
MARS-5 Total Score: median (IQ range)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)
MARS-5 plus additional question Total Score: median (IQ range)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)

**Table 160: MARS responses for remote patients by treatment group and questionnaire**

Characteristic	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention N=933	Control N=626	Total N=1559	Intervention N=838	Control N=606	Total N=1444
I forget to take them						
Non-compliant	39 (4.2)	20 (3.2)	59 (3.8)	28 (3.3)	27 (4.5)	55 (3.8)
Compliant	496 (53.2)	338 (54.0)	834 (53.5)	493 (58.8)	335 (55.3)	828 (57.3)
Missing	398 (42.7)	268 (42.8)	666 (42.7)	317 (37.8)	244 (40.3)	561 (38.9)
I alter the dose)						
Non-compliant	85 (9.1)	46 (7.3)	131 (8.4)	60 (7.2)	50 (8.3)	110 (7.6)
Compliant	95 (10.2)	77 (12.3)	172 (11.0)	102 (12.2)	81 (13.4)	183 (12.7)
Missing	753 (80.7)	503 (80.4)	1256 (80.6)	676 (80.7)	475 (78.4)	1151 (79.7)
I stop taking them for a while						
Non-compliant	78 (8.4)	45 (7.2)	123 (7.9)	65 (7.8)	49 (8.1)	114 (7.9)
Compliant	103 (11.0)	75 (12.0)	178 (11.4)	91 (10.9)	74 (12.2)	165 (11.4)
Missing	752 (80.6)	506 (80.8)	1258 (80.7)	682 (81.4)	483 (79.7)	1165 (80.7)
I decide to miss out a dose						
Non-compliant	82 (8.8)	47 (7.5)	129 (8.3)	59 (7.0)	49 (8.1)	108 (7.5)
Compliant	107 (11.5)	72 (11.5)	179 (11.5)	106 (12.6)	78 (12.9)	184 (12.7)
Missing	744 (79.7)	507 (81.0)	1251 (80.2)	673 (80.3)	479 (79.0)	1152 (79.8)
I take less than instructed						
Non-compliant	79 (8.5)	44 (7.0)	123 (7.9)	60 (7.2)	48 (7.9)	108 (7.5)
Compliant	76 (8.1)	60 (9.6)	136 (8.7)	62 (7.4)	56 (9.2)	118 (8.2)
Missing	778 (83.4)	522 (83.4)	1300 (83.4)	716 (85.4)	502 (82.8)	1218 (84.3)
I take more than instructed						
Non-compliant	82 (8.8)	44 (7.0)	126 (8.1)	61 (7.3)	47 (7.8)	108 (7.5)
Compliant	40 (4.3)	40 (6.4)	80 (5.1)	40 (4.8)	42 (6.9)	82 (5.7)
Missing	811 (86.9)	542 (86.6)	1353 (86.8)	737 (87.9)	517 (85.3)	1254 (86.8)
MARS-5 Total Score: median (IQ range)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)	24.0 (23.0-25.0)
MARS-5 plus additional question Total Score: median (IQ range)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)	29.0 (28.0-30.0)

9.4.3.3. Descriptive results regarding patients' views about medicines in general

The responses to questions relating to patients' views about medicines in general were similar between treatment groups. In the first questionnaire, 78% of patients disagreed with the statement that people who take medicines should stop treatment for a while every now and again, 14% were uncertain, while a small proportion (7%) agreed with the statement. The results were similar in the second questionnaire. A total of 92% of patients in the first questionnaire and 93% in the second questionnaire agreed with the statement that most medicines only work if they are taken as

prescribed. Approximately 50% of all patients in the first and second questionnaire disagreed with the statement that doctors prescribe too many medicines, 31% were uncertain and 17% agreed. In both questionnaires, more intervention patients agreed with the statement that doctors prescribe too many medicines compared to control patients (15.2% vs. 12.6% in the first questionnaire and 16.0% vs. 13.7% in the second questionnaire). Most patients agreed with the statement that most medicines are safe (57% in the first questionnaire and 60% in the second questionnaire), approximately 25% were uncertain and 15% disagreed. Again, in both questionnaires, more intervention patients disagreed with the statement that most medicines are safe compared to the control patients (Table 161).

**Table 161: General views about medicines by treatment group and questionnaire**

Characteristic	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=2626	N=1828	N=4454	N=2469	N=1772	N=4241
Should stop treatment for a while						
Agree	167 (6.4)	126 (6.9)	293 (6.6)	167 (6.8)	124 (7.0)	291 (6.9)
Uncertain	408 (15.5)	224 (12.3)	632 (14.2)	339 (13.7)	216 (12.2)	555 (13.1)
Disagree	2019 (76.9)	1453 (79.5)	3472 (78.0)	1928 (78.1)	1394 (78.7)	3322 (78.3)
Missing	32 (1.2)	25 (1.4)	57 (1.3)	35 (1.4)	38 (2.1)	73 (1.7)
Medicines only work if taken as prescribed						
Agree	2428 (92.5)	1680 (91.9)	4108 (92.2)	2286 (92.6)	1654 (93.3)	3940 (92.9)
Uncertain	120 (4.6)	94 (5.1)	214 (4.8)	99 (4.0)	70 (4.0)	169 (4.0)
Disagree	69 (2.6)	51 (2.8)	120 (2.7)	64 (2.6)	34 (1.9)	98 (2.3)
Missing	9 (0.3)	3 (0.2)	12 (0.3)	20 (0.8)	14 (0.8)	34 (0.8)
Doctors prescribe too many medicines						
Agree	468 (17.8)	283 (15.5)	751 (16.9)	463 (18.8)	285 (16.1)	748 (17.6)
Uncertain	841 (32.0)	557 (30.5)	1398 (31.4)	782 (31.7)	548 (30.9)	1330 (31.4)
Disagree	1297 (49.4)	972 (53.2)	2269 (50.9)	1196 (48.4)	914 (51.6)	2110 (49.8)
Missing	20 (0.8)	16 (0.9)	36 (0.8)	28 (1.1)	25 (1.4)	53 (1.2)
Most medicines are safe						
Agree	1450 (55.2)	1082 (59.2)	2532 (56.8)	1443 (58.4)	1113 (62.8)	2556 (60.3)
Uncertain	743 (28.3)	471 (25.8)	1214 (27.3)	653 (26.4)	413 (23.3)	1066 (25.1)
Disagree	412 (15.7)	263 (14.4)	675 (15.2)	343 (13.9)	228 (12.9)	571 (13.5)
Missing	21 (0.8)	12 (0.7)	33 (0.7)	30 (1.2)	18 (1.0)	48 (1.1)

Urban patients regardless of treatment group had similar responses in both questionnaires (Table 162). Eight percent of rural control patients in the first questionnaire compared to 6% of rural intervention patients agreed with the statement that treatment should be stopped for a while. In the second questionnaire this proportion did not change in the rural control group but increased in the rural intervention group to 8% (Table 163). In the first questionnaire, 19% of both intervention and control group patients agreed that doctors prescribe too many medicines which increased in both groups in the second questionnaire. A similar proportion of both treatment groups located in a remote area agreed with the statement that treatment should be stopped for a while (Table 164). Still in the remote group, 20% of intervention patients agreed that doctors prescribe too many medicines compared to 18% of control patients and this decreased to 17% in the second questionnaire for the control group and increased to 22% in the intervention group. Seventeen

percent of intervention patients disagreed with the statement that most medicines are safe compared to 14% of control patients which decreased in both groups in the second questionnaire (15% intervention vs. 13% control).

**Table 162: General views about medicines for urban patients by treatment group and questionnaire**

Views about medicines	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=848	N=789	N=1637	N=823	N=768	N=1591
Should stop treatment for a while						
Agree	58 (6.8)	46 (5.8)	104 (6.4)	52 (6.3)	49 (6.4)	101 (6.3)
Uncertain	127 (15.0)	109 (13.8)	236 (14.4)	104 (12.6)	96 (12.5)	200 (12.6)
Disagree	656 (77.4)	626 (79.3)	1282 (78.3)	655 (79.6)	610 (79.4)	1265 (79.5)
Missing	7 (0.8)	8 (1.0)	15 (0.9)	12 (1.5)	13 (1.7)	25 (1.6)
Medicines only work if taken as prescribed						
Agree	789 (93.0)	714 (90.5)	1503 (91.8)	764 (92.8)	719 (93.6)	1483 (93.2)
Uncertain	39 (4.6)	50 (6.3)	89 (5.4)	34 (4.1)	30 (3.9)	64 (4.0)
Disagree	18 (2.1)	24 (3.0)	42 (2.6)	19 (2.3)	15 (2.0)	34 (2.1)
Missing	2 (0.2)	1 (0.1)	3 (0.2)	6 (0.7)	4 (0.5)	10 (0.6)
Doctors prescribe too many medicines						
Agree	111 (13.1)	93 (11.8)	204 (12.5)	117 (14.2)	99 (12.9)	216 (13.6)
Uncertain	261 (30.8)	234 (29.7)	495 (30.2)	260 (31.6)	219 (28.5)	479 (30.1)
Disagree	470 (55.4)	456 (57.8)	926 (56.6)	436 (53.0)	438 (57.0)	874 (54.9)
Missing	6 (0.7)	6 (0.8)	12 (0.7)	10 (1.2)	12 (1.6)	22 (1.4)
Most medicines are safe						
Agree	487 (57.4)	466 (59.1)	953 (58.2)	480 (58.3)	482 (62.8)	962 (60.5)
Uncertain	221 (26.1)	209 (26.5)	430 (26.3)	223 (27.1)	189 (24.6)	412 (25.9)
Disagree	135 (15.9)	106 (13.4)	241 (14.7)	111 (13.5)	92 (12.0)	203 (12.8)
Missing	5 (0.6)	8 (1.0)	13 (0.8)	9 (1.1)	5 (0.7)	14 (0.9)

**Table 163: General views about medicines for rural patients by treatment group and questionnaire**

Views about medicine	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=845	N=413	N=1258	N=808	N=398	N=1206
Should stop treatment for a while						
Agree	47 (5.6)	33 (8.0)	80 (6.4)	62 (7.7)	32 (8.0)	94 (7.8)
Uncertain	127 (15.0)	48 (11.6)	175 (13.9)	100 (12.4)	58 (14.6)	158 (13.1)
Disagree	661 (78.2)	328 (79.4)	989 (78.6)	636 (78.7)	301 (75.6)	937 (77.7)
Missing	10 (1.2)	4 (1.0)	14 (1.1)	10 (1.2)	7 (1.8)	17 (1.4)
Medicines only work if taken as prescribed						
Agree	798 (94.4)	381 (92.3)	1179 (93.7)	749 (92.7)	362 (91.0)	1111 (92.1)
Uncertain	26 (3.1)	19 (4.6)	45 (3.6)	35 (4.3)	19 (4.8)	54 (4.5)
Disagree	19 (2.2)	13 (3.1)	32 (2.5)	19 (2.4)	14 (3.5)	33 (2.7)
Missing	2 (0.2)	0 (0.0)	2 (0.2)	5 (0.6)	3 (0.8)	8 (0.7)
Doctors prescribe too many medicines						
Agree	163 (19.3)	80 (19.4)	243 (19.3)	161 (19.9)	86 (21.6)	247 (20.5)
Uncertain	287 (34.0)	135 (32.7)	422 (33.5)	264 (32.7)	131 (32.9)	395 (32.8)
Disagree	392 (46.4)	194 (47.0)	586 (46.6)	374 (46.3)	178 (44.7)	552 (45.8)
Missing	3 (0.4)	4 (1.0)	7 (0.6)	9 (1.1)	3 (0.8)	12 (1.0)
Most medicines are safe						
Agree	488 (57.8)	245 (59.3)	733 (58.3)	463 (57.3)	253 (63.6)	716 (59.4)
Uncertain	234 (27.7)	100 (24.2)	334 (26.6)	226 (28.0)	83 (20.9)	309 (25.6)
Disagree	118 (14.0)	67 (16.2)	185 (14.7)	106 (13.1)	59 (14.8)	165 (13.7)
Missing	5 (0.6)	1 (0.2)	6 (0.5)	13 (1.6)	3 (0.8)	16 (1.3)

**Table 164: General views about medicines for remote patients by treatment group and questionnaire**

Views about medicines	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=933	N=626	N=1559	N=838	N=606	N=1444
Should stop treatment for a while						
Agree	62 (6.6)	47 (7.5)	109 (7.0)	53 (6.3)	43 (7.1)	96 (6.6)
Uncertain	154 (16.5)	67 (10.7)	221 (14.2)	135 (16.1)	62 (10.2)	197 (13.6)
Disagree	702 (75.2)	499 (79.7)	1201 (77.0)	637 (76.0)	483 (79.7)	1120 (77.6)
Missing	15 (1.6)	13 (2.1)	28 (1.8)	13 (1.6)	18 (3.0)	31 (2.1)
Medicines only work if taken as prescribed						
Agree	841 (90.1)	585 (93.5)	1426 (91.5)	773 (92.2)	573 (94.6)	1346 (93.2)
Uncertain	55 (5.9)	25 (4.0)	80 (5.1)	30 (3.6)	21 (3.5)	51 (3.5)
Disagree	32 (3.4)	14 (2.2)	46 (3.0)	26 (3.1)	5 (0.8)	31 (2.1)
Missing	5 (0.5)	2 (0.3)	7 (0.4)	9 (1.1)	7 (1.2)	16 (1.1)
Doctors prescribe too many medicines						
Agree	194 (20.8)	110 (17.6)	304 (19.5)	185 (22.1)	100 (16.5)	285 (19.7)
Uncertain	293 (31.4)	188 (30.0)	481 (30.9)	258 (30.8)	198 (32.7)	456 (31.6)
Disagree	435 (46.6)	322 (51.4)	757 (48.6)	386 (46.1)	298 (49.2)	684 (47.4)
Missing	11 (1.2)	6 (1.0)	17 (1.1)	9 (1.1)	10 (1.7)	19 (1.3)
Most medicines are safe						
Agree	475 (50.9)	371 (59.3)	846 (54.3)	500 (59.7)	378 (62.4)	878 (60.8)
Uncertain	288 (30.9)	162 (25.9)	450 (28.9)	204 (24.3)	141 (23.3)	345 (23.9)
Disagree	159 (17.0)	90 (14.4)	249 (16.0)	126 (15.0)	77 (12.7)	203 (14.1)
Missing	11 (1.2)	3 (0.5)	14 (0.9)	8 (1.0)	10 (1.7)	18 (1.2)

9.4.3.4. *Descriptive results regarding patients' views about medicines prescribed for their condition*

The responses to questions about patients' attitudes towards medicines prescribed for their condition is reported in Table 165 and did not differ substantially between treatment groups. In the first questionnaire 88% of patients agreed that their health depends on taking their medicines, 90% agreed with the statement that their medicines keep them from becoming worse and 92% disagreed that it is difficult to take their medicines as prescribed. The results were similar in the second questionnaire. Little difference was seen in results by treatment group and geographic location.

**Table 165: Attitudes towards medicines prescribed for condition(s) by treatment group and questionnaire**

Attitudes towards medicines	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=2626	N=1828	N=4454	N=2469	N=1772	N=4241
My present health depends on my medicines						
Agree	2314 (88.1)	1614 (88.3)	3928 (88.2)	2153 (87.2)	1575 (88.9)	3728 (87.9)
Uncertain	141 (5.4)	120 (6.6)	261 (5.9)	160 (6.5)	113 (6.4)	273 (6.4)
Disagree	149 (5.7)	78 (4.3)	227 (5.1)	124 (5.0)	65 (3.7)	189 (4.5)
Missing	22 (0.8)	16 (0.9)	38 (0.9)	32 (1.3)	19 (1.1)	51 (1.2)
My medicines keep me from becoming worse						
Agree	2363 (90.0)	1638 (89.6)	4001 (89.8)	2203 (89.2)	1611 (90.9)	3814 (89.9)
Uncertain	175 (6.7)	140 (7.7)	315 (7.1)	185 (7.5)	108 (6.1)	293 (6.9)
Disagree	68 (2.6)	35 (1.9)	103 (2.3)	49 (2.0)	35 (2.0)	84 (2.0)
Missing	20 (0.8)	15 (0.8)	35 (0.8)	32 (1.3)	18 (1.0)	50 (1.2)
Difficult to take my medicines as prescribed						
Agree	137 (5.2)	85 (4.6)	222 (5.0)	134 (5.4)	76 (4.3)	210 (5.0)
Uncertain	54 (2.1)	38 (2.1)	92 (2.1)	53 (2.1)	32 (1.8)	85 (2.0)
Disagree	2399 (91.4)	1690 (92.5)	4089 (91.8)	2242 (90.8)	1634 (92.2)	3876 (91.4)
Missing	36 (1.4)	15 (0.8)	51 (1.1)	40 (1.6)	30 (1.7)	70 (1.7)

9.4.3.5. *Descriptive results regarding patients' lifestyle activities*

Patients were asked to report their diet and exercise regime during the last seven days (Table 166). In the first questionnaire 30% of intervention patients and 31% of control patients did not participate in any specific exercise session (such as swimming, walking, jogging) other than what they would do around the house or as part of their work. In the second questionnaire the number of patients reporting no specific activity increased slightly in the intervention group (31% of intervention patients and 31% of control patients). In the first questionnaire, 35% of both intervention and control patients reported participating in a specific exercise session on 1-3 days over the past 7 days, which increased in the second questionnaire for the intervention group to 36%, whereas in the control group it did not change (Table 166). The proportion of patients reporting a specific exercise session on 4-6 days was 23% in the first questionnaire for both groups and had decreased to 22% in the intervention group and 21% in the control group in the second questionnaire. Interestingly, in the first questionnaire, 11% of patients regardless of treatment group reported participating in a specific exercise session every day.

Patients were asked to report on how many of the last seven days they participated in at least 30 minutes of other physical activity such as cleaning the house, gardening, but not a specific exercise session (Table 166). In the first questionnaire 10% of the intervention group and 11% of the control group reported no physical activity. The second questionnaire identified an increase in other physical activity to 12% in the intervention group and 13% in the control group. Approximately 28% of all patients in the first questionnaire reported exercising on 1-3 days and this remained the same in the second questionnaire. Thirty two percent of patients reported exercising on 4-6 days which decreased slightly in the second questionnaire for both groups. In the first questionnaire, the proportion of intervention and control patients reporting participation in other physical activity every day was similar (29% intervention and 28% control) and did not change substantially in the second questionnaire.

**Table 166: Leisure activities in the last seven days by treatment group and questionnaire**

Leisure activities	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=2626	N=1828	N=4454	N=2469	N=1772	N=4241
Specific Exercise Sessions (Last 7 Days)						
None	793 (30.2)	559 (30.6)	1352 (30.4)	769 (31.1)	555 (31.3)	1324 (31.2)
1-3 Days	913 (34.8)	629 (34.4)	1542 (34.6)	887 (35.9)	622 (35.1)	1509 (35.6)
4-6 Days	590 (22.5)	419 (22.9)	1009 (22.7)	534 (21.6)	369 (20.8)	903 (21.3)
7 Days	300 (11.4)	202 (11.1)	502 (11.3)	233 (9.4)	197 (11.1)	430 (10.1)
Missing	30 (1.1)	19 (1.0)	49 (1.1)	46 (1.9)	29 (1.6)	75 (1.8)
Other Physical Activity (Last 7 Days)						
None	264 (10.1)	201 (11.0)	465 (10.4)	289 (11.7)	223 (12.6)	512 (12.1)
1-3 Days	745 (28.4)	504 (27.6)	1249 (28.0)	694 (28.1)	487 (27.5)	1181 (27.8)
4-6 Days	836 (31.8)	592 (32.4)	1428 (32.1)	745 (30.2)	562 (31.7)	1307 (30.8)
7 Days	761 (29.0)	513 (28.1)	1274 (28.6)	704 (28.5)	475 (26.8)	1179 (27.8)
Missing	20 (0.8)	18 (1.0)	38 (0.9)	37 (1.5)	25 (1.4)	62 (1.5)

Patients were asked to report the type of diet they adhered to in the last seven days and could tick more than one response. Results from the first questionnaire for patients on anticoagulant therapy identified that the majority of intervention and control patients did not follow a special diet (62% compared to 64%, respectively) which did not change in the second questionnaire (62% in both groups). In both questionnaires more intervention patients reported a low salt diet (29% in the first questionnaire and 27% in the second questionnaire for the intervention group compared to 26% in the first questionnaire and 23% in the second questionnaire for control patients) (Table 167).

**Table 167: Diet in the last seven days for patients on anticoagulant therapy by treatment group and questionnaire**

Diet in last seven days	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=505	N=343	N=848	N=474	N=328	N=802
Low Fat Diet						
No	307 (60.8)	211 (61.5)	518 (61.1)	294 (62.0)	217 (66.2)	511 (63.7)
Yes	198 (39.2)	132 (38.5)	330 (38.9)	180 (38.0)	111 (33.8)	291 (36.3)
Low Salt Diet						
No	361 (71.5)	255 (74.3)	616 (72.6)	345 (72.8)	252 (76.8)	597 (74.4)
Yes	144 (28.5)	88 (25.7)	232 (27.4)	129 (27.2)	76 (23.2)	205 (25.6)
Diabetic Diet						
No	426 (84.4)	308 (89.8)	734 (86.6)	413 (87.1)	294 (89.6)	707 (88.2)
Yes	79 (15.6)	35 (10.2)	114 (13.4)	61 (12.9)	34 (10.4)	95 (11.8)
Cholesterol Lowering Diet						
No	387 (76.6)	281 (81.9)	668 (78.8)	379 (80.0)	267 (81.4)	646 (80.5)
Yes	118 (23.4)	62 (18.1)	180 (21.2)	95 (20.0)	61 (18.6)	156 (19.5)
Low Carbohydrate Diet						
No	483 (95.6)	328 (95.6)	811 (95.6)	449 (94.7)	305 (93.0)	754 (94.0)
Yes	22 (4.4)	15 (4.4)	37 (4.4)	25 (5.3)	23 (7.0)	48 (6.0)
Other Weight Loss Diet						
No	493 (97.6)	335 (97.7)	828 (97.6)	464 (97.9)	318 (97.0)	782 (97.5)
Yes	12 (2.4)	8 (2.3)	20 (2.4)	10 (2.1)	10 (3.0)	20 (2.5)
Other Diet						
No	479 (94.9)	326 (95.0)	805 (94.9)	452 (95.4)	316 (96.3)	768 (95.8)
Yes	26 (5.1)	17 (5.0)	43 (5.1)	22 (4.6)	12 (3.7)	34 (4.2)
No Special Diet						
No	193 (38.2)	125 (36.4)	318 (37.5)	178 (37.6)	124 (37.8)	302 (37.7)
Yes	312 (61.8)	218 (63.6)	530 (62.5)	296 (62.4)	204 (62.2)	500 (62.3)

The majority of patients with diabetes regardless of treatment group were not following a low fat, low salt, cholesterol lowering, low carbohydrate or other diet. However, in the first questionnaire, 54% of intervention and 60% of control patients with diabetes reported following a diabetic diet in the last seven days. In the second questionnaire 54% of intervention patients and 56% of control patients reported following a diabetic diet. Results from both questionnaires showed that 36% of all patients with diabetes were not following a special diet in the last seven days (Table 168).

**Table 168: Diet in the last seven days for diabetes patients by treatment group and questionnaire**

Diet in last seven days	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Intervention	Control	Total
	N=1048	N=726	N=1774	N=984	N=705	N=1689
Low Fat Diet						
No	596 (56.9)	378 (52.1)	974 (54.9)	563 (57.2)	394 (55.9)	957 (56.7)
Yes	452 (43.1)	348 (47.9)	800 (45.1)	421 (42.8)	311 (44.1)	732 (43.3)
Low Salt Diet						
No	742 (70.8)	496 (68.3)	1238 (69.8)	710 (72.2)	499 (70.8)	1209 (71.6)
Yes	306 (29.2)	230 (31.7)	536 (30.2)	274 (27.8)	206 (29.2)	480 (28.4)
Diabetic Diet						
No	482 (46.0)	290 (39.9)	772 (43.5)	452 (45.9)	310 (44.0)	762 (45.1)
Yes	566 (54.0)	436 (60.1)	1002 (56.5)	532 (54.1)	395 (56.0)	927 (54.9)
Cholesterol Lowering Diet						
No	777 (74.1)	531 (73.1)	1308 (73.7)	719 (73.1)	513 (72.8)	1232 (72.9)
Yes	271 (25.9)	195 (26.9)	466 (26.3)	265 (26.9)	192 (27.2)	457 (27.1)
Low Carbohydrate Diet						
No	951 (90.7)	647 (89.1)	1598 (90.1)	887 (90.1)	642 (91.1)	1529 (90.5)
Yes	97 (9.3)	79 (10.9)	176 (9.9)	97 (9.9)	63 (8.9)	160 (9.5)
Other Weight Loss Diet						
No	1025 (97.8)	711 (97.9)	1736 (97.9)	963 (97.9)	685 (97.2)	1648 (97.6)
Yes	23 (2.2)	15 (2.1)	38 (2.1)	21 (2.1)	20 (2.8)	41 (2.4)
Other Diet						
No	1005 (95.9)	686 (94.5)	1691 (95.3)	955 (97.1)	691 (98.0)	1646 (97.5)
Yes	43 (4.1)	40 (5.5)	83 (4.7)	29 (2.9)	14 (2.0)	43 (2.5)
No Special Diet						
No	667 (63.6)	487 (67.1)	1154 (65.1)	627 (63.7)	457 (64.8)	1084 (64.2)
Yes	381 (36.4)	239 (32.9)	620 (34.9)	357 (36.3)	248 (35.2)	605 (35.8)

From the first questionnaire, a large proportion of patients with hyperlipidaemia reported not following a low fat diet (56%), 70% were not following a low salt diet and 66% were not on a cholesterol lowering diet. Only 36% of control patients compared to 32% of intervention patients were on a cholesterol lowering diet and in the second questionnaire this had remained the same for intervention patients (32%) and decreased to 34% for control patients (Table 169).

**Table 169: Diet in the last seven days for hyperlipidaemia patients by treatment group and questionnaire**

Diet in last seven days	First Questionnaire (%)			Second Questionnaire (%)		
	Intervention	Control	Total	Control	Intervention	Total
	N=2086	N=1376	N=3462	N=1332	N=1970	N=3302
Low Fat Diet:						
No	1198 (57.4)	732 (53.2)	1930 (55.7)	748 (56.2)	1146 (58.2)	1894 (57.4)
Yes	888 (42.6)	644 (46.8)	1532 (44.3)	584 (43.8)	824 (41.8)	1408 (42.6)
Low Salt Diet						
No	1481 (71.0)	950 (69.0)	2431 (70.2)	942 (70.7)	1415 (71.8)	2357 (71.4)
Yes	605 (29.0)	426 (31.0)	1031 (29.8)	390 (29.3)	555 (28.2)	945 (28.6)
Diabetic Diet						
No	1644 (78.8)	1068 (77.6)	2712 (78.3)	1044 (78.4)	1543 (78.3)	2587 (78.3)
Yes	442 (21.2)	308 (22.4)	750 (21.7)	288 (21.6)	427 (21.7)	715 (21.7)
Cholesterol Lowering Diet						
No	1418 (68.0)	877 (63.7)	2295 (66.3)	878 (65.9)	1335 (67.8)	2213 (67.0)
Yes	668 (32.0)	499 (36.3)	1167 (33.7)	454 (34.1)	635 (32.2)	1089 (33.0)
Low Carbohydrate Diet:						
No	1947 (93.3)	1257 (91.4)	3204 (92.5)	1229 (92.3)	1830 (92.9)	3059 (92.6)
Yes	139 (6.7)	119 (8.6)	258 (7.5)	103 (7.7)	140 (7.1)	243 (7.4)
Other Weight Loss Diet						
No	2043 (97.9)	1343 (97.6)	3386 (97.8)	1311 (98.4)	1938 (98.4)	3249 (98.4)
Yes	43 (2.1)	33 (2.4)	76 (2.2)	21 (1.6)	32 (1.6)	53 (1.6)
Other Diet						
No	2004 (96.1)	1300 (94.5)	3304 (95.4)	1285 (96.5)	1904 (96.6)	3189 (96.6)
Yes	82 (3.9)	76 (5.5)	158 (4.6)	47 (3.5)	66 (3.4)	113 (3.4)
No Special Diet						
No	1034 (49.6)	756 (54.9)	1790 (51.7)	692 (52.0)	984 (49.9)	1676 (50.8)
Yes	1052 (50.4)	620 (45.1)	1672 (48.3)	640 (48.0)	986 (50.1)	1626 (49.2)

## 9.5. DISCUSSION

To answer the research question: 'Is the effectiveness of PoCT the same or better than the same tests using pathology laboratory testing?' the Trial undertook analysis in four areas; therapeutic control; number of GP visits; impact on patient care and patient disease management compliance.

### *Therapeutic control*

To address hypotheses 1 and 2 two approaches were taken to measure therapeutic control. Firstly, the proportion of patients within target range (point prevalence) and secondly the proportion of tests within target range for each of the three condition groups, the first being the primary outcome measure for the Trial.

Based on the analysis of the proportion of patients within target range, using -7% as the clinically acceptable limit, the Trial concluded that PoCT is non-inferior compared to pathology laboratory testing for HbA1c, urine albumin, ACR, total cholesterol and triglyceride testing but not for INR testing. Based on the analysis of the proportion of tests within target range, again using -7% as the clinical acceptable limit, the Trial concluded that PoCT is non-inferior compared with pathology laboratory testing for INR, HbA1c, urine albumin, ACR, total cholesterol and triglyceride testing. The Trial was unable to conclude non-inferiority for HDL-C testing for either of the hypotheses.

This analysis also found a higher percentage of patients in the intervention group compared with the control group with a significant reduction in their test result from baseline for three out of the four tests analysed (HbA1c, total cholesterol and triglycerides). The percentage of patients with an increase in their HDL-C test from baseline was lower in the intervention group and the null hypothesis that PoCT is worse than pathology laboratory testing could not be rejected.

The primary outcome measure was the proportion of patients within target range and based on these results, the Trial could not conclude that PoCT is non-inferior to pathology laboratory testing in relation to the proportion of patients within target range for INR. However, there were 944 INR patients included in the analysis of the proportion of patients within target range. This is substantially lower than the patient recruitment target of 2524 for INR. As a result, the analysis has reduced power to show that PoCT is non-inferior to pathology laboratory testing. The percentage of patients within target range was found to be lower in the intervention group compared with the control group. The 90% confidence interval for the difference in the percentage of patients within target range between treatment groups is fairly wide, indicating that the difference could not be estimated very precisely using the data collected.

The proportion of INR tests within target range has provided evidence that PoCT is the same or better than pathology laboratory testing. By analysing the proportion of tests within target range, more data could be included in the analysis and the power increased. The percentage of tests within target range was again found to be lower in the intervention group compared with the control group, though the difference between groups was smaller. The 90% confidence interval for the difference in the percentage of tests within target range is also much narrower, indicating that the difference was estimated with greater precision. Based on these results, the Trial concluded that PoCT is non-inferior to pathology laboratory testing in relation to the proportion of tests within target range for INR.

Direct comparison of the Trial INR results with other studies is difficult as no other trial has explored non-inferiority; most have involved another intervention, such as computerised decision support<sup>8, 18, 34</sup> and there is no consistency in how outcome measures are reported.<sup>133</sup> However, the results of the PoCT Trial support Fitzmaurice et al.'s<sup>8</sup> findings, which is the only other RCT in general practice to have measured point prevalence. When using a patient's last test result to measure INR control they found no significant differences between study groups. Yet Fitzmaurice et al's<sup>61</sup> subsequent study which investigated the model of care outside trial conditions for 452 patients (235 original study participants), measured the proportion of tests in range, as the PoCT Trial did. The results using this method found a significantly higher proportion of tests in range in the intervention group

compared to the control group. The Trial found a lower proportion of tests in target range in the intervention group compared to the control group but was unable to conclude non-inferiority. Other studies which have used the percentage of time spent in range as the outcome measure have found no significant differences between treatment groups.<sup>8, 18, 34, 61</sup>

Warfarin therapy is subject to multiple interactions, such as diet, alcohol, illness and interaction with other drugs, therefore INR results can fluctuate spasmodically. Hence focusing on the last test result to measure therapeutic control for INR testing may not be the ideal method for measuring therapeutic control. Fitzmaurice et al.<sup>133</sup> in their systematic review on describing therapeutic INR reporting found an inconsistency in how INR data is being presented, a range of methods being used to measure control of anticoagulant therapy, and how different outcome measures can provide different results. Hobbs et al.<sup>134</sup> recommend that trials investigating control of anticoagulant therapy report on three outcome measures: the percentage of patients within range (point prevalence); the proportion of tests within range; and the percentage of time spent in range. The PoCT Trial used the first two of these measures and each provided a different outcome. For Hypothesis 1 non-inferiority could not be concluded; however, for Hypothesis 2 it could. While the proportion of patients within target range and the proportion of tests within target range are commonly used in measuring clinical effectiveness of anticoagulant therapy, measuring the percentage of time spent in range may have provided a different outcome. However, as patients in the Trial could have one or more of the three conditions, the outcome measures relating to therapeutic control needed to be suitable for all three conditions rather than the most appropriate method for one particular condition. A secondary analysis of the PoCT Trial data using percentage of time in range is recommended and it may help overcome the variation in results using the other outcome measure.

The Trial findings in relation to diabetes found for HbA1c, urine albumin and ACR testing that PoCT, when compared to laboratory testing, using either of the outcome measures resulted in a greater proportion of patients and a greater proportion of tests being within target range. In addition, the percentage of patients with a reduction in their HbA1c test from baseline was significantly higher in the intervention group compared with the control group. This provides evidence that PoCT for HbA1c, urine albumin and ACR testing is the same or better compared to pathology laboratory testing and can achieve improved therapeutic control for patients with diabetes.

Results of this Trial support other studies which also found that the immediate availability of an HbA1c result at the time of a consultation lowered HbA1c levels in patients with Type 2 diabetes.<sup>6, 45, 47, 58, 68, 70, 135</sup> Only two RCTs have investigated the utilisation of PoCT to improve glycaemic control in general practice.<sup>33, 58</sup> While neither study found any significant differences between study groups, Miller et al.<sup>58</sup> did find a significant decrease in HbA1c results for patients within the intervention group compared to the control group after a second follow-up visit. The outcomes of the two studies do not support our Trial findings; however, both had their limitations. Khunti et al's<sup>33</sup> RCT randomised at the patient level which could have introduced bias in the management of patients. These authors did conclude that further research is needed using an RCT, such as the PoCT Trial, which randomised at the practice level. Miller et al's<sup>58</sup> RCT had a follow-up period of six months which meant that a majority of patients had only one test result. In addition, the study population was from one general practice and consisted of only African Americans with a majority being female. Their study also involved another intervention and again randomisation occurred at a patient level.

It is difficult to make any inferences about the outcomes of the urine albumin and ACR tests as there are no studies in the general practice setting that have investigated the clinical effectiveness of using PoCT devices to measure these tests.

This Trial is the first RCT to investigate the effectiveness of using PoCT compared to laboratory for all three diabetes related tests (HbA1c, urine albumin and ACR) analysed in the Trial. The improved therapeutic control found within the intervention group supports other study findings; however, this is the first Trial in GP to investigate non-inferiority and show that PoCT is non-inferior to pathology laboratory testing using two outcome measures – proportion of patients and proportion of tests within target range.

Lipid level results are divided into four sub fractions: total cholesterol; high-density lipoprotein cholesterol (HDL-C); triglyceride and low-density lipoprotein cholesterol (LDL-C). This Trial focuses on the first three and each sub fraction of the lipid test was analysed and presented separately. The outcome measures used not only looked at the proportion of patients in target range and the proportion of tests in target range but also investigated the reduction/increase in target lipid levels. As recommended in the Lipid Management Guidelines (Appendix 4), any improvements in target lipid levels, even if targets are not reached, is highly beneficial.<sup>136</sup>

The results of the Trial in relation to lipid testing have had mixed outcomes. While the Trial provides evidence that PoCT is non-inferior compared to laboratory pathology testing in both hypotheses for total cholesterol and triglycerides it could not conclude non-inferiority for HDL-C. In testing Hypotheses 1 and 2 the Trial found that for HDL-C the percentage of patients within target range and the percentage of tests within target range were lower in the intervention group compared to the control group. In addition, the Trial found that the percentage of patients with a reduction in their total cholesterol and triglyceride tests from baseline was much higher in the intervention group compared to the control group. However, when investigating the percentage of patients with an increase in their HDL-C test from baseline, the Trial found that this was lower in the intervention group.

Very little research in general practice was found that looks at therapeutic control in relation to lipid testing using PoCT, and of those published studies, only total cholesterol results have been investigated and none have reported on the other sub fractions of the lipid test. While an RCT conducted by Ruffin and McKenney<sup>44</sup> investigated the processes-of-care in patients with hypercholesterolaemia they did not investigate the impact on therapeutic control. Two other non-randomised studies have investigated the use of PoCT in relation to cholesterol testing. Cohen et al.<sup>23</sup> conducted a descriptive survey to examine the appropriateness, costs and attitudes of GPs and patients towards the use of PoCT. Their study found that the mean cholesterol result for 161 (78%) patients showed a reduction in cholesterol levels over time. Franks and Engerman<sup>137</sup> through their effectiveness study explored the relationship between providing immediate feedback of a cholesterol result and motivating patients to lower their cholesterol levels. Adjusted analysis found no between-group differences.

While there is little published evidence that having a cholesterol result at the time of consultation will result in a reduction in total cholesterol there are no studies that have investigated the other two sub fractions in relation to therapeutic control in general practice. It is therefore difficult to understand or explain why the Trial found discrepancies in the outcomes for the HDL-C test. While the Trial findings were unable to conclude that PoCT is the same or better compared with laboratory testing in relation to HDL-C levels it did find that in analysing the increases in HDL-C, from baseline to follow up, there were no improvements for either group; in fact both groups showed a decrease. What can be concluded from the literature is that HDL-C is difficult to manage.<sup>138</sup> It relies more on the patient's self-management to modify lifestyle factors as opposed to medication control. While it has been shown that raising HDL-C levels provides significant therapeutic advantages<sup>139</sup>, Singh et al.<sup>138</sup>, in their systematic review, found that the impact of drug-induced therapies to increase HDL-C levels was relatively modest and promotes the use of strategies that target lifestyle modifications (exercise, diet, weight loss and smoking cessation). Through the Trial's case note audit process, a large percentage of the patients were found to be on a statin medication such as atorvastatin calcium and simvastatin. These drugs have greater impact on total cholesterol levels but not on HDL-C and so results could be influenced by GPs not addressing lifestyle modifications and relying more on medication management. In turn, patients may be relying more on medication use and not translating lifestyle recommendations into healthy behaviours. Additionally, the majority of the patients in the Trial who have two or three of the conditions (62.7% and 67.2% respectively) are in the intervention group and could potentially have poorer health compared to control patients. This too could help explain why there was no improvement in HDL-C levels found in the intervention patients.

For two of the three lipid tests analysed, the Trial strongly concludes that PoCT is the same or better compared to laboratory testing and that PoCT can lead to significant improvements to therapeutic

control for lipid testing. This is the first RCT in general practice that has comprehensively looked at therapeutic control for lipid management using PoCT.

### *Visits to the GP*

Management of chronic disease requires structured care and co-ordination of care between health care providers.<sup>90</sup> The GP plays a pivotal role in this process<sup>140</sup> and therefore to avoid complications regular visits to the GP for assessment and monitoring of conditions are essential. There is some suggestion in the literature that better management of diabetes is associated with increased visits to the GP.<sup>141</sup> For the conditions in the PoCT Trial, regular review of pathology results forms a key part of the guidelines for anticoagulant therapy, diabetes and lipid management (see Appendix 2 to Appendix 4). The results of the Trial show that patients in the intervention group had significantly more visits to the GP than patients in the control group, particularly for patients residing in more remote locations (see Chapter 12).

In addition to investigating GP visits, the number of tests undertaken during Phase II of the Trial was examined. During Phase I intervention practices were required to obtain a corresponding laboratory test result for every PoCT performed. Although every effort was made to match duplicates it is still possible that test frequency in Phase I is over-represented. Therefore, the analysis was performed on Phase II as this is a more accurate reflection of the testing frequency during the Trial. Results of the analysis indicate that intervention practices were undertaking more tests compared to the control practices for each test type. However, the number of tests is within the recommended guidelines for warfarin, diabetes and hyperlipidaemia management (see Appendix 2 to Appendix 4). The higher number of PoC tests also helps to explain the higher number of visits to the GP detected in the intervention group.

The Trial results show that patients in the intervention group were having their INR tested more compared to control patients. The protocol for testing in the Trial Design was based on the warfarin therapy guidelines<sup>28</sup> which recommend that once a patient's INR dose is stable most people can be well controlled with four to six weekly testing and dose adjustment (Appendix 2). The results indicate that intervention patients were having their INR tested every 4.3 weeks while control patients were having their INR tested every 5.6 weeks. The testing frequency in both treatment groups is consistent with recommended guidelines.

During Phase II HbA1c testing was slightly higher in the intervention group compared to control group testing (7 months to 8 months respectively). These results indicate that HbA1c testing in the intervention group is more in line with diabetes management guidelines<sup>142</sup> which recommend that patients with diabetes have their HbA1c tested at least six monthly (see Appendix 3). Microalbuminuria is both a marker for early nephropathy and a strong predictor of cardiovascular disease.<sup>142</sup> It is estimated that 30% to 50% of patients will develop microalbuminuria and urinary ACR in the initial screen. The Trial Design protocol for testing microalbumin recommended that patients with diabetes be tested for microalbuminuria (ACR and urine albumin) at the start of the Trial and then annually. The Trial results indicate that intervention patients were having their urine albumin and ACR tested every 12 months compared to control patients who were being tested about every 2 years. These results are similar to other studies which have reported low levels of testing for microalbuminuria.<sup>143</sup>

To be eligible for recruitment to the Trial patients with hyperlipidaemia needed to be eligible for pharmaceutical benefits for lipid lowering drugs. Therefore patients in the Trial are classed as high risk, and current recommendations advise that high risk patients have their lipid levels measured every six to twelve months. Patients in the intervention group were having their lipid levels tested every nine months whereas control group patients were having their levels tested every 13 to 14 months. The testing frequency in the intervention group indicates that patients with hyperlipidaemia are being managed in line with new recommendations developed by the National Health Foundation of Australia and the Cardiac Society of Australia and New Zealand in their Position Statement on Lipid Management – 2005.<sup>139</sup>

The Trial has found that patients in the intervention group were having more tests and more GP visits. However the results show that patients having PoCT were being managed more in line with

recommended guidelines for anticoagulant therapy, diabetes and hyperlipidaemia (see Appendix 2 to Appendix 4).

#### *Process of care actions and prescribing patterns*

The literature around PoCT general practice suggests that access to PoCT by the GP could lead to more rational prescribing,<sup>4, 11</sup> although there is little research that has assessed this. For patients on anticoagulant therapy, the immediacy of the results of an INR test allows the GP to make appropriate dosage adjustments immediately;<sup>28</sup> however, the impact on prescribing patterns for diabetes and lipid management is less clear. Miller et al.<sup>58</sup> showed greater intensification of therapy for patients with diabetes in the PoCT arm of their trial (baseline compared to end-of-study), but no differences between the control and intervention groups.

An examination of the process of care actions undertaken by a GP upon receipt of an INR test result indicated that the patients within the intervention group were receiving a higher proportion of actions across all categories by their GP and this was true whether the test result was within or outside therapeutic range. For the intervention group, more tests were associated with a GP consultation, review of all medication, change or cessation of anticoagulant medication, measurement of blood pressure, cholesterol review, requests for follow-up test results and other actions. This suggests that for patients with PoCT results, the GPs are providing more comprehensive management. Importantly, for INR results outside therapeutic range, GPs in the intervention group were more likely to make changes to medication or cease medication than GPs in the control group.

While the key management goal for patients on anticoagulant therapy is maintaining INR within therapeutic range, its management is made difficult because of the potential adverse events, interactions with other medications, other conditions and lifestyle behaviours.<sup>28</sup> Successful anticoagulant therapy management requires careful monitoring of INR, dose adjustments, ongoing patient education (e.g. diet and lifestyle) and good communication between patients and their caregivers.<sup>144-146</sup> While management of warfarin therapy mainly focuses on monitoring of INR and dose adjustments<sup>28, 144</sup>, the results of this Trial indicate that the provision of the INR test result immediately through PoCT allowed the GP to make more of these changes and also undertake other process of care actions such as review of other medications, the measurement of blood pressure and request follow-up testing.

This study is the first to investigate the process of care actions related to the management of warfarin therapy in Australia. Other studies indicate that processes of care for patients on anticoagulant therapy can vary between type of setting (general practice versus specialists' clinics) and between countries<sup>146</sup> and that these management differences include frequency of face-to-face consultations, methods of dosage adjustment and monitoring intervals.<sup>146, 147</sup>

The results of poorly managed anticoagulant medication are serious. In 2004, anticoagulants were the medicines most commonly reported as causes of death.<sup>148</sup> An analysis of hospital separations in 2004-05 found that anticoagulants were the most commonly recorded medicines with adverse effects, accounting for 32% of total separations.<sup>148</sup> A Western Australian study also found that for people aged 60 years and over, anticoagulants were the most common medicines implicated in drug adverse events causing hospitalisations in 2002.<sup>149</sup>

The results of the Trial show that changes in anticoagulant medication by the GPs occurred with 41.74% of tests outside target range and for 10.54% of tests within target range. The changes in medication found within the anticoagulant therapy patients reflect the complexity of managing warfarin and the narrow window between therapeutic use and toxicity, as well as many interactions with other medicines.<sup>148</sup> The high number of changes being made by the GPs in terms of strength or dosage, particularly when the INR test results are outside target range, suggests that GPs are monitoring these patients and ensuring the safe use of the anticoagulant medication. At the same time, when test results are within target range, it appears that the GPs in the intervention group are making more adjustments to the patient's dosage, suggesting the PoCT is influencing their management.

The majority of patients in the Trial with diabetes had Type 2 diabetes, with only 17% of diabetes patients being Type 1. This differentiation reflects that found nationally, where 85% of all diabetes in Australia is Type 2.<sup>148</sup> For this group of patients, diabetes can be managed with dietary and lifestyle modifications alone or combined with oral hypoglycaemic medication.<sup>148</sup> The GP has a central role in co-ordinating management of the patient and in education and counselling. Regular monitoring and follow-up is essential.

The analysis of the impact of PoCT on GPs' management of patients with diabetes focused on three areas – general process of care actions, actions related to the diabetes annual cycle of care and microalbuminuria monitoring. As with anticoagulant therapy discussed above, the process of care actions that were not associated with the diabetes annual cycle of care suggests that GPs in the intervention group are undertaking a larger number of processes of care actions around an HbA1c test result across all categories, regardless of whether the test result was within or outside therapeutic range. This suggests that the immediacy of the PoCT result allows the GP to undertake more management changes for the patient.

However, what is interesting is that for an HbA1c test result outside the target range, GPs in the control group were more likely to request a follow-up test than the intervention GPs even though they had access to a PoCT device, a pattern also seen with microalbuminuria.

In 2001, Australia introduced a Service Incentive Payment (SIP) for Practice Incentive Program (PIP) practices to complete an annual cycle of care for patients with diabetes.<sup>90</sup> The items included in the annual cycle of care are based on optimal care guidelines developed by the RACGP (Appendix 3).<sup>29</sup> The PoCT Trial compared the number of actions identified in the diabetes annual cycle of care between the intervention and control groups of GPs. The results obtained from the case note audit indicate that GPs were not meeting the management targets for diabetes patients in either treatment group. The only actions that were being done at least once per person-year were a review of all patient medications, review of HbA1c test results and lipid testing for GPs in the control group. This latter result is somewhat surprising as the intervention GPs had access to lipid testing with the PoCT devices and it would be expected that this would be easy to complete. While the intervention GPs did not meet the target of lipid testing, the rate of urine albumin or ACR testing was much higher in this group who also had access to a PoCT device for this test. Lipid testing requires a fasting measurement and so patients may find this more convenient when undertaken by the laboratory, which has more flexible times for specimen collection than a GP surgery.

The results obtained from the PoCT Trial could indicate that optimal care is not being provided to patients with diabetes by GPs. However, this finding is not unique. The National Divisions Diabetes program review of data from Divisions of General Practice in Australia, found that less than 60% of patients were receiving care consistent with best-practice guidelines in 1999.<sup>150</sup> The results of this study showed a similar pattern of adherence for specific management actions as those in the Trial, with none of the process of care items completed for all patients in a year. The most common actions completed as part of the cycle were checking of blood pressure, review of HbA1c results and measure of body mass index. This result is also similar to studies that analysed the audit data from general practices in the UK.<sup>151, 152</sup> These studies found a wide variation in compliance with process measures for diabetes, the most common being review of HbA1c results and measurement of blood pressure while the checking of lipids and microalbumin received less than 50% compliance. In comparing the rate of microalbumin testing, the PoCT Trial obtained a much higher rate compared with that found in Divisions of General Practice, where less than half the patients received this test in a 12 month period in 2002.<sup>143</sup> While direct comparison of the PoCT Trial results with other studies is not possible because of different data collection and analysis methods, it seems clear that uptake of the more common process of care actions for diabetes is similar to other studies, but for one of the least common measures of care, microalbumin testing, the GPs in the intervention group achieved much higher levels of compliance than found by Georgiou et al.<sup>143</sup> and Khunti et al.<sup>151</sup>

Microalbuminuria is an important indicator of renal damage and it is for this reason that annual review is part of the recommended annual cycle of care for diabetes patients. However, as shown

above, testing for urine albumin is low and management poor.<sup>153</sup> The management of patients with microalbuminuria includes monitoring of results, blood pressure measures, use of ACE inhibitors or ARA.<sup>30</sup> The PoCT Trial results indicate that the intervention GPs were undertaking a larger number of processes of care actions compared to the GPs in the control group.

In terms of medications prescribed, there was little difference found between the prescribing patterns of the intervention and control GPs. The most common medications used by GPs in the Trial were metformin hydrochloride and gliclazide, both reported to be the most frequently used oral hypoglycaemic agents in Australia.<sup>154</sup>

It is quite common for Type 2 diabetes patients to move from non-medical management approaches alone to monotherapy then to a combination of two and sometimes three medicines (e.g. combination therapy). This is because of the progressive nature of Type 2 diabetes and the potential of reduced effects of a single oral hypoglycaemic agent over time.<sup>155</sup> This is borne out by the Trial results that indicated that a quarter of patients with test results within target range were on multiple medications, while more than half of patients with tests results that were outside target range were on multiple medications.

The process of care action results for hyperlipidaemia are more mixed, with GPs in both treatment groups undertaking a similar number of actions upon receipt of a lipid test result. Where lipid tests were within target range (e.g. on all of the three tests), intervention GPs undertook more changes in statin medication, more lifestyle advice (SNAP) and other actions, while GPs in the control group undertook more actions related to follow-up test requests and review of all patient medications. For test results outside of therapeutic range, control GPs undertook more actions relating to changes in statin medication, lifestyle advice (SNAP) and follow-up test result requested. The only other study that investigated the impact of PoCT on process of care actions was undertaken in the USA on a group of patients with hypercholesterolaemia.<sup>44</sup> This study was unable to detect a statistical difference in therapeutic interventions between the control and intervention groups, but the data did suggest that the provision of a cholesterol test during a consultation positively affected the process of care actions by the physician. A study of Australian GPs using PoCT to measure cholesterol found that GPs broadly followed the recommended management guidelines and that dietary advice was provided in 70% of consultations, although there was no evidence that this resulted from PoCT.<sup>23</sup>

The most common management of hyperlipidaemia is by medication. Bettering the Evaluation and Care of Health (BEACH) data show that medications were used to treat lipid disorders in 66.1 per 100 problems. Other treatments provided for hyperlipidaemia were advice and education on lifestyle issues and medication.<sup>156</sup> GPs gave patients advice on nutrition and weight (22.5 per 100 problems), exercise (3.9 per 100), other lifestyle factors (1.1 per 100), medication use (2.1 per 100) and other treatment (0.8 per 100). GPs referred patients managed for lipid disorders to other health professionals and services only occasionally (0.2 per 100 problems). Referrals to dieticians/nutritionists occurred at a rate of only 0.7 per 100 problems.<sup>156</sup>

A study on the beliefs, knowledge and self-reported management of hyperlipidaemia by GPs in the USA showed management varies considerably between GPs and that not all the recommended guidelines are adhered to.<sup>157</sup> Changing statin dosage was the most common management action for patients with poorly controlled hyperlipidaemia and the use of other actions such as the prescription of fibrates and referrals to specialists were used less often.<sup>157</sup>

In the Trial, the most common medication for the management of hyperlipidaemia patients was statins (atorvastatin and simvastatin), with very few GPs prescribing other medications such as fibrates. This prescribing pattern is similar to that found across Australia.<sup>148</sup> Over the period 1995-2005, there was increased use of statins in Australia, with other lipid lowering medication such as fibrates reported to be used rarely compared with statins.<sup>148</sup> In general practice, cardiovascular medicines account for 19% of all GP prescriptions<sup>158</sup>, with lipid modifying agents accounting for 3.9% of these types of prescriptions at a rate of 3.3 per 100 encounters.

### *Patient compliance with disease management*

Results from this Trial provide evidence that PoCT is non-inferior to pathology testing in relation to the proportion of MARS-5 questionnaire responses indicating compliance with disease management (use of medicines) and could be up to 4.6% better.

The evidence that PoCT can improve patient health outcomes is limited.<sup>13</sup> To date, there has been no research investigating whether PoCT improves patient compliance with disease management, particularly in terms of effect on the use of medicines, diet and exercise compared to usual care (pathology laboratory testing). Research by Shephard et al.<sup>68</sup> investigating whether PoCT was an effective intervention in improving clinical outcomes for Aboriginal patients with diabetes did not investigate patient compliance to medication but showed that 93% of patients felt that regular PoCT encouraged them to look after their health better. A study investigating satisfaction with INR PoCT found that significantly more patients preferred PoCT compared to usual care and referred to the benefits of improved communication regarding medication dosage with their GP.<sup>74</sup>

Descriptive results indicate that most patients (regardless of treatment group) did not intentionally stop taking their medicines, alter the dose or take less or more than instructed. Over 50% of patients in the Trial reported that they forgot to take their medicines to some degree. Generally, for both treatment groups and in all geographic regions the proportion of patients reporting forgetting to take their medicines increased in the second questionnaire. Forgetting to take medicines is not uncommon, particularly in the older age groups. It has been reported that as age increases so does medication compliance until the seventh decade, when adherence to medication regimes begins to decline and can be linked to the aging process such as increased incidence of dementia.<sup>159</sup> The results in the Trial reflect this, as 42% of Trial patients were aged 70 years or more.

Regardless of treatment group only a small proportion of patients on anticoagulant therapy intentionally stopped taking their medicines. Approximately 15% of all patients with diabetes reported altering their medication dose, 10% decided to miss out a dose with an estimated 10% taking less than instructed. This was similar for hyperlipidaemia patients with approximately 12% deciding to miss a dose or stop taking their medication for a while. The differences in compliance rates reported by patients are likely to be related to health outcomes of missing the medication. For instance, the health outcomes for a patient on anticoagulant therapy missing medication are severe and can be life-threatening compared to patients with diabetes or hyperlipidaemia. Generally, studies show that the discontinuation rates with statins medication (hyperlipidaemia medication) are high particularly in the elderly.<sup>46</sup> A retrospective cohort study including 34,501 patients who were 65 years or older and initiated therapy with a statin showed that the proportion of patients who were compliant with statin therapy dramatically decreased over time (60%, 43%, 26% and 32% after 3, 6, 60, and 120 months).<sup>160</sup> A systematic review of adherence with medications for diabetes revealed that many patients take less medication (oral hypoglycaemic agents) than prescribed, with the overall rate of adherence between 36%-93% in retrospective and prospective studies. Persistence with oral hypoglycaemic agents has also been reported to range from 16% to 80% of patients remaining on treatment for 6-24 months.<sup>161</sup>

In both treatment groups, patients' beliefs about medicines in general showed that most believed that medicines only work if taken as prescribed and that most medicines are safe. Of interest is that 20% of remote and rural patients agreed with the statement that most doctors prescribe too many medicines compared to 13% of urban patients. Patients' responses about medicines prescribed for their condition were similar between groups with the majority agreeing that their health depends on taking their medicines and that they did not find it difficult to take their medicines as prescribed. This finding is interesting as over 50% of patients in the Trial reported forgetting to take their medication to some degree.

In terms of lifestyle activities, the Trial indicated that regardless of treatment group a large proportion of patients reported not being on any type of diet or specific exercise regime. This is interesting in that two of the conditions investigated in the Trial (diabetes and hyperlipidaemia) benefit from diet and exercise. In the first questionnaire, 35% of all patients with diabetes reported that they were not on any special diet in the last seven days. This did not change substantially in

the second questionnaire. In the first questionnaire 48% of all hyperlipidaemia patients reported that they were not on any special diet in the last seven days with little change in the second questionnaire. Overall only 30%-40% of hyperlipidaemia patients reported adhering to a low fat diet, cholesterol lowering diet or low salt diet. Adherence to dietary therapy for hypercholesterolemia and diabetes is known to be poor<sup>36,161,162</sup> but is an important lifestyle risk factor that when adequately managed can help reduce the likelihood of long-term complications. While 30% of patients did not participate in any specific exercise session in the previous seven days, most (approximately 90%) patients reported at least 30 minutes of other physical activity such as cleaning the house and gardening. There was little difference between treatment groups.

### *Limitations*

The analysis in this chapter has a number of limitations. The use of case note audits for documentation of the management process can be unreliable. Not all GPs record their actions during a consultation and the notes are likely to reflect under-reporting.<sup>143</sup> However, this method was the most practical for a Trial that involved such a large number of patients and GPs. The data collection was also reliant on the accuracy of recording by the auditors and the probability of differences between recordings increasing with the number of auditors used. The training program and assessment of reliability undertaken by the Trial would have reduced the level of differences between auditors.

In addition, the case note audit did not review all consultations with the GPs for the patients sampled. The focus of analysis was the process of care actions around the result of a pathology test. However, some process of care items relevant to the conditions examined may have occurred at other consultations. This is particularly relevant to the analysis of the annual cycle of care actions for patients with diabetes. The results found in the Trial may under-report the number of actions undertaken by the GP as actions relevant to the annual cycle of care could have occurred at consultations not associated with a test result. However, the results of adherence to diabetes guidelines found in other studies suggest that the PoCT results are comparable and accurate.<sup>143, 151, 152</sup> Additionally, for many practices, good diabetes management is achieved in partnership with other health professionals, such as a diabetes nurse educator or dietician and some of the process of care actions may have occurred outside the GP consultations and may not have been picked up in the data collection process.

Data relating to GP visits is also limited in its usefulness by use of the Medicare Australia data. It is not possible to distinguish the reason for the encounter using Medicare Australia data which limits the usefulness of the results in assessing the role of PoCT in the number of GP visits. It was expected that the number of GP visits would increase for the PoCT group as the Trial Design required a PoCT to be undertaken in conjunction with a consultation, while this was not necessary for the control group.

As the prescribing data was limited to a broad level analysis it was not possible to investigate in detail the changes to medication.

Patient self-report is susceptible to overestimates of compliance and although not all patients were included in the analysis due to missing outcome data, this was not expected to bias the results.

## **9.6. CONCLUSION**

The analysis undertaken in this section has focused on the impact PoCT may have on the management of chronic disease in general practice. From the results, a number of clear patterns emerge.

### *Anticoagulant Therapy*

As the proportion of patients within target range was the primary outcome measure the Trial cannot conclude overall that INR testing is the same or better than pathology laboratory testing.

While the Trial found that PoCT for patients on anticoagulant therapy is non-inferior to pathology testing at a test level it could not conclude non-inferiority at the patient level. This mixed outcome could be explained by the potential for INR levels to vary spasmodically and measuring the percentage of time spent in range may have been a better outcome measure. The number of GP visits for anticoagulant therapy patients in the intervention group was much higher than the control patients; however, the test frequency is still within recommended warfarin therapy guidelines. From the case note audit data the Trial found that for the management of patients on anticoagulant therapy, PoCT resulted in more management actions being undertaken by the GP beyond the minimal management of INR testing and dosage changes. However, the analysis of medication changes indicated that GPs in the control and intervention groups were changing medication only 40% of the time when an INR test was outside therapeutic range. Overall the Trial found that there were fewer intervention patients with a last test result within target range, patients were visiting the GP more, having more tests and GPs were providing more management changes. However, only 40% of GPs were making medication changes when the result was outside of target range. In contrast, control GPs were making fewer management changes and only 36% were changing medication requirements when the test was outside of target range. This again reflects the complexity of anticoagulant therapy and the possibility that patients may have been marginally outside of target range, therefore the GP could be taking a 'wait and see' approach, or the Trial results may suggest that intervention patients were more unstable therefore required more monitoring. From a patient level the results suggest that only a small proportion of patients on anticoagulant therapy alter the dose of their medicine, stop taking their medicines for a while or decide to miss out a dose. This is not surprising given the potential serious consequences that could result from not taking the medication correctly.

Although the Trial could not conclude that PoCT is the same or better than pathology testing for both therapeutic control outcome measures the results do suggest that the provision of a test result at the time of consultation allows GPs to provide a broader range of care actions and to monitor INR levels through medication changes.

### *Diabetes*

At both the patient and test level PoCT was found to be non-inferior to pathology laboratory testing for diabetes, therefore therapeutic control for PoCT patients is the same or better compared to control patients. The Trial also found a significantly higher percentage of patients in the intervention group with a reduction in their HbA1c test results from baseline. The results indicated that HbA1c testing in the intervention group was more in line with diabetes management guidelines which recommend that testing be at least six monthly (Appendix 3). More interestingly, the results found that patients in the intervention group were having urine microalbumin tests performed every 12 months compared to control patients, who were having the test every 2 years. Again, this indicates that intervention GPs were following diabetes management guidelines. From the case note audit data the Trial found that GPs using PoCT results, overall, provided a greater number of processes of care actions compared to GPs in the control group when managing their patients with diabetes. While there was little evidence that PoCT influenced GPs to undertake the actions related to the diabetes annual cycle of care, overall, GPs in both treatment groups showed poor adherence to these actions. However, PoCT GPs did provide a higher rate of testing of urine microalbumin, eye examinations and measurement of BMI. These findings could be an indication that the annual cycle of care actions are being performed either outside the consultation regarding the test result and/or by someone else in the practice, such as the practice nurse. From a patient perspective the Trial found that only a small percentage of people reported that they intentionally failed to take their medication. In addition, only a small percent indicated that they participated in any specific exercise session in the previous seven days.

### *Hyperlipidaemia*

The results of the Trial in relation to lipid testing have provided mixed outcomes. At both patient and test level PoCT was found to be non-inferior to pathology laboratory testing for total cholesterol and triglycerides but not for HDL-C, therefore therapeutic control for PoCT patients is the same or better compared to control patients for two out of three of the lipid measures. The Trial also found

a significantly higher percentage of patients in the intervention group with a reduction in their total cholesterol and triglyceride tests from baseline, but no evidence of an increase in HDL-C for this group. In fact, patients in both treatment groups showed a decrease in their HDL-C test result from baseline. Testing frequency in the intervention group was much higher than compared to the control group (9 months versus 13 months) again indicating that intervention GPs are testing in line with recommended management guidelines (Appendix 4). In looking at the case note audit data the Trial found that GPs in both treatment groups undertook a similar number of actions upon receipt of a lipid test. Overall, GPs were making more changes to statin medication, referred more, completed more SNAP actions and requested a follow up lipid test for patients whose lipid levels were outside of target range. However, control GPs were found to be making more changes (including dosage and strength) to medications for this group of patients whereas intervention GPs were making more medication changes for patients within target range. Of interest is that over 80% of patients who had their case notes audited had lipid levels outside the target range. Again, from a patient perspective, the Trial found that only a small percentage of people reported that they intentionally failed to take their medication. In addition, only a small percent indicated that they participated in any specific exercise session in the previous seven days. It was clear from the Trial results that GPs spend more time reviewing and changing medications than they do discussing lifestyle behaviour modifications. Given that there is evidence to suggest that HDL-C levels are more influenced by lifestyle modifications than medication, it is not surprising that the Trial found no evidence of any improvement in HDL-C levels for either treatment group.

### *Disease Management*

For patients, the null hypothesis was that the proportion of MARS-5 questionnaire responses indicating compliance with disease management (use of medicines) would be worse in the intervention group compared to the control group. The analysis shows that PoCT is no worse than pathology testing with the estimate suggesting that medication compliance could be up to 4.6% better in the intervention group. This is the first randomised controlled trial to have evaluated patient medication compliance for patients receiving PoCT compared to patients receiving usual care (pathology laboratory testing).

It is well known that low compliance to medication compromises the effectiveness of treatment at substantial costs to the patient (to the potential detriment of health), to the health professional (treating morbidity) and to society (economic impact) making it an important area to improve.<sup>38, 36, 37</sup> PoCT provides the opportunity for GPs and their patients to discuss the test result and disease management at a time when it is uppermost in their minds. The analysis suggests that having an immediate test result is beneficial for patients in terms of medication compliance.

While the results of the therapeutic control analysis are varied, for most of the outcome measures PoCT was found to be the same or better compared with pathology laboratory testing. The analysis of the impact of PoCT on the management of the three conditions examined in general practice provides an interesting picture. While PoCT was found to lead to more GP visits and more testing, the testing frequency is more in line with recommended guidelines. In addition, the process of care actions varied between GPs and with the condition being managed. Results from the patient compliance to disease management analysis also support that PoCT is no worse than pathology laboratory testing.

General practice is the first point of contact for many people with their health needs. Patients with chronic conditions are primarily managed by their GPs. Effective chronic disease management relates to six key components. These include (1) organisation of health care; (2) delivery system design; (3) clinical information systems; (4) decision support; (5) community resources and (6) patient self-management support.<sup>163, 164</sup> Implementing the chronic disease model in general practice, traditionally oriented towards acute care, is not easy and requires re-organisation of how health care is delivered. PoCT enables a test to be performed at the time of consultation and allows a clinical decision to be made immediately. PoCT provides an alternative way of delivering health care whereby the GP can act on an immediate result and engage the patient in their own management, which is crucial to good chronic disease management. A chronic disease model of

care incorporating PoCT has been shown in this Trial to positively influence therapeutic control (for most tests), process of care actions, patient follow-up and patient medication adherence.



## 10. COST-EFFECTIVENESS OF PoCT IN GENERAL PRACTICE

### SUMMARY OF THE CHAPTER

This chapter describes the methodology and results of comparative cost analysis and a cost-effectiveness analysis of PoCT in a general practice setting.

A societal perspective was applied to the calculation for comparative costs between PoCT and laboratory testing. An intermediate health outcome indicator which was the proportion of patients within the therapeutic range for each condition was used. In order to account for clustering at the patient and practice levels, Generalised Estimating Equations were used to model count and normal data and obtain estimated values for resource use. These values were then used to estimate total and mean costs and group differences. One-way sensitivity analysis was undertaken on all resource items for which the underlying variable had a distribution, using the upper and lower 95% confidence limits as comparative values. Cost-effectiveness was determined using the Incremental Cost Effectiveness Ratio (ICER). Joint probability distributions were also calculated.

The key findings of the chapter are:

- the INR strategy using PoCT was associated with a small reduction in the indirect costs per patient to the health care sector (95% CI -\$16 to -\$3)
- the other three PoCT strategies, HbA1c, ACR and lipids, did not generate a statistically significant difference in the direct costs per patient to the health care sector over the duration of the Trial
- for INR testing, PoCT was associated with significantly higher costs per patient for GP consultations (95% CI \$120 to \$367) and pharmaceuticals (95% CI \$6 to \$30)
- for HbA1c and ACR testing, PoCT was not associated with a statistically significant difference in any of the other measured categories of direct costs to the health care sector
- for lipids testing, PoCT was associated with significantly higher costs per patient for pharmaceuticals (95% CI \$143 to \$296)
- regarding the point estimates of the ICERs:
  - a. INR by PoCT was dominated by its comparator
  - b. for HbA1c, this was \$40 per additional patient within the therapeutic range
  - c. for lipids, this was \$10,082 per additional patient within the therapeutic range
  - d. for ACR by PoCT was dominant
- the one-way sensitivity analysis showed that the costs of all tests were particularly sensitive to hospital admissions
- all PoCT strategies led to a small reduction in patient travel costs and in indirect costs
- because most patients in this Trial were bulk-billed, the overall level of co-payments was low
- the comparative direct costs to the health care sector of the actual tests depend on whether or not the establishment costs, consumables and maintenance costs, and quality assurance and control costs, all of which were provided free during the Trial, should be included.

The key conclusion:

- providing ACR testing using a PoCT device appeared to be dominant to its comparator in a general practice setting. On the other hand, INR using PoCT was dominated. The other two tests (HbA1c and lipids) generated health gains but at an extra cost.

## 10.1. INTRODUCTION

While a large number of studies have been undertaken on PoCT use in a primary care setting, few of these have included an economic analysis of PoCT.<sup>5</sup> The review by Hobbs et al. of PoCT in primary care concluded that there was "insufficient data for conclusions to be drawn on the cost effectiveness of NPT in primary care."<sup>3</sup> Some studies indicate that PoCT is more expensive when compared to laboratory testing,<sup>45</sup> but this may be offset by long-term societal gains such as prolonged life or by reduced hospital stays.<sup>5</sup> However, it should be noted that the cost-effectiveness of PoCT is likely to vary according to the disease group and the test in question.<sup>45</sup>

This Trial investigated the cost-effectiveness of PoCT as it related to the three devices used and focused on the incremental costs and consequences for practices, patients and the Government, i.e. the perspective was that of Australian society overall. Since resources are inevitably limited it is important to ensure that the resources allocated to these pathology tests are optimised.

## 10.2. AIMS AND OBJECTIVES

The cost-effectiveness analysis was undertaken as part of the PoCT Trial. The primary objective of the analysis was to assess the relative cost-effectiveness of performing PoCT in general practice compared to the alternative of testing through a pathology laboratory.

## 10.3. METHODS

Applying a societal perspective, the costs of PoCT strategy were calculated by quantifying the resources used and assigning to them the relevant unit cost. Initial costs, induced costs and averted costs were considered. Fees and charges were used as proxies for opportunity costs. The actual PoC test costs were based on the Medicare Australia fees established for the Trial tests. Elsewhere in this report (Chapter 16) there is a consideration of whether the MBS fees set for the PoCT tests in the Trial were a good estimate of the likely MBS fees that should be set to cover PoCT in routine practice. The cost analysis was undertaken using 18 months of Trial data.

### 10.3.1. Resource use

Resource use data were collected prospectively during the Trial. Unit costs and the source of volume data collected for each type of test for the analysis are provided in Table 170 to Table 173. Some of the resource data were obtained from Medicare Australia, namely the number of GP consultations, the number of patient episode initiations (control only), the number of specialist referrals, the number of allied health visits and the number of prescriptions. The reason for using Medicare Australia data is outlined in Section 0. As there are a number of pathology requests that could include total cholesterol and triglycerides (e.g. full blood count), a lipid study was identified by a request for HDL-C which is a single MBS item. HDL-C is only ordered in conjunction with total cholesterol and triglycerides.

The numbers of pathology tests undertaken during the Trial (either by PoCT or laboratory method) were also obtained from Medicare Australia. However, the Trial Design for Phase I required the intervention group to undertake both a PoC test and a laboratory test for the same patient on the same day. Thus, the number of tests undertaken were more than would have occurred on a routine basis. For the base case analysis, where similar tests were performed on the same day, only the PoCT version was counted. Moreover, within the intervention practices, not all pathology tests were undertaken using the PoCT device and so the volume of tests included the number of tests undertaken using PoCT and the number of tests undertaken using laboratory testing as per intention to treat. To take into account wastage and duplicate testing for the intervention group, data were obtained from the log sheets maintained by the practices which recorded all PoC tests or attempts at testing.

**Table 170: Details of resource use data and unit costs – INR  
costs based on 2006 calendar year**

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
Establishment costs	PoCT equipment	Industry source, device acquisition value at commencement of Trial in 2005	\$1200	Equivalent annual cost over clinically useful life (3 years) and CPI adjusted	Number of devices
	Device training – initial and refresher	Trial payment for attendance	\$400 per Device Operator	Trial data	Number of Device Operators
	Accreditation	Accreditation unit price – PoCT Trial	\$561+	Trial data	One
Consumables and maintenance	Device consumables – reagents and other associated consumables (gloves, filter kits, lancets, wastage)	Industry source Type of item used in every test	\$6.02 per test	Medicare Australia data	Number of tests claimed
		Type of item used periodically (filters, cleaners etc)	\$0.00	Device Group# data	
Quality management	QC and QA consumables	Industry source & Device Group	\$10.69 per test	Device Group# data	Number of QC tests (18 over 18 months)
	Quality Assurance Program	RCPA QAP 2006 price	\$490	Annual fee	One
	Device Operator time for QA and QC	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$16.90 per QC \$19.71 per QA	Time and Motion study	Minutes taken per test Number of tests (18 QC tests & 25 QA tests)
GP consultations	Consultations	MBS fee*	<i>Relevant MBS item</i>	<i>Medicare Australia</i>	<i>Number of consultations</i>
	Co-payments	Actual charge minus MBS fee rebate*	<i>Calculated from MBS data</i>	<i>Medicare Australia</i>	<i>Number of consultations</i>
Pathology testing	Device Operator time (test, writing up notes etc)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$2.78 per test	<i>Time and Motion study</i>	<i>Time taken per test</i>
	Pathology tests (PoCT and laboratory)	MBS fee PoCT	\$14.05 per test	<i>Medicare Australia data</i>	<i>Number of tests</i>
		MBS fee* laboratory (85% schedule fee)	\$11.95 per test	<i>Medicare Australia data</i>	<i>Number of tests</i>
	Patient follow-up of test results (Practice nurse and	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$2.82 per test	<i>Time and Motion Study</i>	<i>Minutes taken per test by number of tests</i>

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
	GP	SADI Division GP claims policy 2005-2007	\$9.06 per test	Time and Motion Study	Minutes taken per test by number of tests
	Patient episode initiation	MBS fee (85% schedule fee)	\$8.35 (73915) \$14.80 (73907)	Medicare Australia data	Number of episodes
Downstream costs	Hospital admissions	National Hospital Data Collection – Public Section Estimated Round 9 (2004-05) – AR-DRG 5.0	Relevant AR,DRG item	Case note audit/SAEs CPI applied	Number of admissions
	Emergency department visits	National Hospital Data Collection Round 9 (2004-2005) AR-DRGv5.0 – Non-admitted Triage 3	\$397 per visit	Patient questionnaire previous 12 months CPI applied	Number of visits
	Specialist referrals	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Allied health visits	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Pharmaceutical costs	PBS dispensed price and co-payment**	Relevant PBS item	Medicare Australia	Number of prescriptions***
Patient costs	Motor vehicle travel	Australian Taxation Office	\$0.66	Patient questionnaire	Distance (Km)
	Other travel costs (bus, taxi etc)	Patient satisfaction questionnaire		Patient questionnaire	Mean cost
	Time seeking health care (travel time, waiting time in surgery etc)	ABS seasonally adjusted average weekly earnings		Patient questionnaire Time and Motion study	Travel time (minutes) Waiting time (minutes)

+ Total costs were shared between three devices

\* Based on actual costs under MBS for particular items

\*\* Based on dispensed price per maximum quantity under PBS for particular items

\*\*\* Based on number of prescriptions for the conditions associated with the test and not for all prescriptions

# PoCT Trial Device Group

**Table 171: Details of resource use data and unit costs – HbA1c costs based on 2006 calendar year**

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
Establishment costs	PoCT equipment	Industry source, device acquisition value at commencement of Trial in 2005	\$7,436	Equivalent annual cost over clinically useful life (3 years) and CPI adjusted	Number of devices
	Device training – initial and refresher	Trial payment for attendance	\$400 per Device Operator	Trial data	Number of Device Operators
	Accreditation	Accreditation unit price – PoCT Trial	\$561+	Trial data	One
Consumables and maintenance	Device consumables – reagents and other associated consumables (gloves, filter kits, lancets)	Industry source Type of item used in every test	\$10.12 per test	Medicare Australia data	Number of tests claimed
		Type of item used periodically (filters, cleaners etc)	\$160.16 per annum	Device Group# data	One
Quality management	QC and QA consumables	Industry source & Device Group	\$26.70 per test	Device Group# data	Number of QC tests (18 over 18 months)
	Quality Assurance Program	RCPA QAP 2006 price	\$900	Annual fee	One
	Device Operator time for QA and QC	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$16.90 per QC \$19.71 per QA	Time and Motion study	Minutes taken per test Number of tests (18 QC tests & 25 QA tests)
GP consultations	Consultations	MBS fee*	Relevant MBS item	Medicare Australia	Number of consultations
	Co-payments	Actual charge minus MBS fee rebate*	Calculated from MBS data	Medicare Australia	Number of consultations
Pathology testing	Device Operator time (test, writing up notes etc)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$6.53 per test	Time and Motion study	Time taken per test
	Pathology tests (PoCT and laboratory)	MBS fee PoCT	\$17.10 per test	Medicare Australia data	Number of tests
		MBS fee* laboratory (85% schedule fee)	\$14.55 per test	Medicare Australia data	Number of tests
	Patient follow-up of test results (Practice nurse and GP)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$2.82 per test	Time and Motion Study	Minutes taken per test by number of tests
		SADI Division GP claims policy 2005-2007	\$9.06 per test	Time and Motion Study	Minutes taken per test by number of tests
Patient episode initiation	MBS fee (85% schedule fee)	\$8.35 (73915) \$14.80 (73907)	Medicare Australia data	Number of episodes	
Downstream	Hospital admissions	National Hospital Data	Relevant AR-DRG item	Case note audit/SAEs	Number of admissions

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
costs		Collection – Public Section Estimated Round 9 (2004-05) – AR-DRG 5.0		CPI applied	
	Emergency department visits	National Hospital Data Collection Round 9 (2004-2005) AR-DRGv5.0 – Non-admitted Triage 3	\$397 per visit	Patient questionnaire previous 12 months CPI applied	Number of visits
	Specialist referrals	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Allied health visits	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Pharmaceutical costs	PBS dispensed price and co- payment**	Relevant PBS item	Medicare Australia	Number of prescriptions***
Patient costs	Motor vehicle travel	Australian Taxation Office	\$0.66	Patient questionnaire	Distance (Km)
	Other travel costs (bus, taxi etc)	Patient satisfaction questionnaire		Patient questionnaire	Mean cost
	Time seeking health care (travel time, waiting time in surgery etc)	ABS seasonally adjusted average weekly earnings		Patient questionnaire Time and Motion study	Travel time (minutes) Waiting time (minutes)

\* Total costs were shared between three devices

\* Based on actual costs under MBS for particular items (either bulkbilling, 100% of rebate etc.)

\*\* Based on dispensed price per maximum quantity under PBS for particular items

\*\*\* Based on number of prescriptions for the conditions associated with the test and not for all prescriptions

# PoCT Trial Device Group

**Table 172: Details of resource use data and unit costs – microalbumin costs based on 2006 calendar year**

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
Establishment costs	PoCT equipment	Industry source, device acquisition value at commencement of Trial in 2005	\$7,436	Equivalent annual cost over clinically useful life (3 years) and CPI adjusted	Number of devices
	Device training – initial and refresher	Trial payment for attendance	\$400 per Device Operator	Trial data	Number of Device Operators
	Accreditation	Accreditation unit price – PoCT Trial	\$561+	Trial data	One
Consumables and maintenance	Device consumables – reagents and other associated consumables (gloves, filter kits, lancets)	Industry source Type of item used in every test	\$10.46 per test	Medicare Australia data	Number of tests claimed
		Type of item used periodically (filters, cleaners etc)	\$160.16 per annum	Device Group# data	One
Quality management	QC & QA consumables	Industry source & Device Group	\$26.70 per test	Device Group# data	Number of QC tests (18 over 18 months)
	Quality Assurance Program	RCPA QAP 2006 price	\$595	Annual fee	One
	Device Operator time for QA and QC	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$16.90 per QC \$19.71 per QA	Time and Motion study	Minutes taken per test Number of tests (18 QC tests & 25 QA tests)
GP consultations	Consultations	MBS fee*	Relevant MBS item	Medicare Australia	Number of consultations
	Co-payments	Actual charge minus MBS fee rebate*	Calculated from MBS data	Medicare Australia	Number of consultations
Pathology testing	Device Operator time (test, writing up notes etc)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$4.66 per test	Time and Motion study	Time taken per test
	Pathology tests (PoCT and laboratory)	MBS fee PoCT	\$20.50 per test	Medicare Australia data	Number of tests
		MBS fee* laboratory (85% schedule fee)	\$17.45 per test	Medicare Australia data	Number of tests
	Patient follow-up of test results (Practice nurse and GP)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$2.82 per test	Time and Motion Study	Minutes taken per test by number of tests
		SADI Division GP claims policy 2005-2007	\$9.06 per test	Time and Motion Study	Minutes taken per test by number of tests
Patient episode initiation	MBS fee (85% schedule fee)	\$8.35 (73915) \$14.80 (73907)	Medicare Australia data	Number of episodes	

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
			\$8.35 (73913)		
Downstream costs	Hospital admissions	National Hospital Data Collection – Public Section Estimated Round 9 (2004-05) – AR-DRG 5.0	Relevant AR-DRG item	Case note audit/SAEs CPI applied	Number of admissions
	Emergency department visits	National Hospital Data Collection Round 9 (2004-2005) AR-DRGv5.0 – Non-admitted Triage 3	\$397 per visit	Patient questionnaire previous 12 months CPI applied	Number of visits
	Specialist referrals	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Allied health visits	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Pharmaceutical costs	PBS dispensed price and co-payment**	Relevant PBS item	Medicare Australia	Number of prescriptions***
Patient costs	Motor vehicle travel	Australian Taxation Office	\$0.66	Patient questionnaire	Distance (Km)
	Other travel costs (bus, taxi etc)	Patient satisfaction questionnaire		Patient questionnaire	Mean cost
	Time seeking health care (travel time, waiting time in surgery etc)	ABS seasonally adjusted average weekly earnings		Patient questionnaire Time and Motion study	Travel time (minutes) Waiting time (minutes)

+ Total costs were shared between three devices

\* Based on actual costs under MBS for particular items (either bulkbilling, 100% of rebate etc.)

\*\* Based on dispensed price per maximum quantity under PBS for particular items

\*\*\* Based on number of prescriptions for the conditions associated with the test and not for all prescriptions

# PoCT Trial Device Group

**Table 173: Details of resource use data and unit costs – lipids (total cholesterol, triglycerides and HDL-C)  
costs based on 2006 calendar year**

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
Establishment costs	PoCT equipment	Industry source, device acquisition value at commencement of Trial in 2005	\$4,500	Equivalent annual cost over clinically useful life (3 years) and CPI adjusted	Number of devices
	Device training – initial and refresher ,	Trial payment for attendance	\$400 per Device Operator	Trial data	Number of Device Operators
	Accreditation	Accreditation unit price – PoCT Trial	\$561+	Trial data	One
Consumables and maintenance	Device consumables – reagents and other associated consumables (gloves, filter kits, lancets)	Industry source Type of item used in every test	\$13.35 per test	Medicare Australia data	Number of tests claimed
		Type of item used periodically (filters, cleaners etc)	\$80.50 per annum	Device Group# data	One
Quality management	QC and QC consumables	Industry source & Device Group	\$88.57 per test	Device Group# data	Number of test (18 QC tests & 25 QA tests)
	Quality Assurance Program	RCPA QAP 2006 price	\$750	Annual fee	One
	Device Operator time for QA and QC	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$16.90 per QC \$19.71 per QA	Time and Motion study	Minutes taken per test Number of tests (18 QC tests & 25 QA tests)
GP consultations	Consultations	MBS fee*	Relevant MBS item	Medicare Australia	Number of consultations
	Co-payments	Actual charge minus MBS fee rebate*	Calculated from MBS data	Medicare Australia	Number of consultations
Pathology testing	Device Operator time (test, writing up notes etc)	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$6.53 per test	Time and Motion study	Time taken per test
	Pathology tests (PoCT and laboratory)	MBS fee PoCT	\$9.75 per test	Medicare Australia data	Number of tests
		MBS fee* laboratory (85% schedule fee)	\$10.00 (Total Cholesterol & Triglycerides) \$9.60 (HDL-C)	Medicare Australia data	Number of tests
	Patient follow-up of test results (Practice nurse and	SA Nurses Award – Registered nurse 3 <sup>rd</sup> year + oncosts	\$2.82 per test	Time and Motion Study	Minutes taken per test by number of tests

Category of resources	Resource item used	Source of unit cost data	Unit cost	Source of volume data (time hours)	Volume
	GP	SADI Division GP claims policy 2005-2007	\$9.06 per test	Time and Motion Study	Minutes taken per test by number of tests
	Patient episode initiation	MBS fee (85% schedule fee)	\$8.35 (73915) \$14.80 (73907)	Medicare Australia data	Number of episodes
Downstream costs	Hospital admissions	National Hospital Data Collection – Public Section Estimated Round 9 (2004-05) – ARDRG 5.0	Relevant AR-DRG item	Case note audit/SAEs CPI applied	Number of admissions
	Emergency department visits	National Hospital Data Collection Round 9 (2004-2005) AR-DRGv5.0 – Non-admitted Triage 3	\$397 per visit	Patient questionnaire previous 12 months CPI applied	Number of visits
	Specialist referrals	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Allied health visits	MBS fee*	Relevant MBS item	Medicare Australia	Number of referrals
	Pharmaceutical costs	PBS dispensed price and co-payment**	Relevant PBS item	Medicare Australia	Number of prescriptions
Patient costs	Motor vehicle travel	Australian Taxation Office	\$0.66	Patient questionnaire	Distance (Km)
	Other travel costs (bus, taxi etc)	Patient satisfaction questionnaire		Patient questionnaire	Mean cost
	Time seeking health care (travel time, waiting time in surgery etc)	ABS seasonally adjusted average weekly earnings		Patient questionnaire Time and Motion study	Travel time (minutes) Waiting time (minutes)

+ Total costs were shared between three devices

\* Based on actual costs under MBS for particular items (either bulkbilling, 100% of rebate etc.)

\*\* Based on dispensed price per maximum quantity under PBS for particular items

\*\*\* Based on number of prescriptions for the conditions associated with the test and not for all prescriptions

# PoCT Trial Device Group

The effect of coning out of pathology tests arising from the use of Medicare data was taken into account. Pathology providers can charge through the MBS only for the three most expensive tests ordered on the one occasion even when more tests are actually done. This is known as 'coning' and means that the tests recorded in the MBS data include only those charged for and not all that were done. As some of the tests in the Trial were less expensive, they would have been coned out and the data from Medicare Australia would underestimate the volume of tests undertaken. Therefore, the number of laboratory based pathology tests was adjusted based on data obtained from experts in the pathology industry. Test numbers were adjusted to take account of the following coning percentages – 1% for INR, 34% for HbA1c, 8% for microalbumin, 52% for HDL-C and 6% for total cholesterol and triglycerides. For example, assuming that 34% of HbA1c tests were coned, then the adjusted figure was obtained by dividing the raw volume data by 0.66. This adjustment was also applied to patient waiting time and, for control practices, to the time spent following up test results.

Information on the number of emergency department visits over the previous 12 months was obtained from the Patient Satisfaction Questionnaire completed at the end of the Trial. The number of hospital visits was obtained from data collected as part of the SAE reporting through the case note audit. This audit was undertaken on a sample of patients in a sample of practices and these were then weighted to apply to the whole patient group (see Section 1.13 for a full description of the sampling frame used).

It is noteworthy that 91% of patients in the Trial held health care cards or were pensioners. At the same time, two-thirds of the practices were based in rural and remote areas and a majority of the urban practices were in lower socio-economic status areas. This meant that most Medicare items used in the Trial were bulked-billed so that patients did not make a co-payment. The actual PoCT was provided at no charge to patients, there was no co-payment for the PoC test. For hospital admissions, emergency department visits and allied health visits, the method of data collection did not allow for co-payments to be identified. Hence, the only direct cost to patients and their families that were measured in the study were their travel costs and the co-payments associated with GP consultations and pharmaceuticals.

Items related to the quality assurance activities carried out in the Trial (QC and QA) were obtained from the Device Group and RCPA QAP Pty Ltd. Throughout the Trial, QC and QA were undertaken every four weeks. Device Operator training occurred twice, at the commencement of the Trial and 12 months later. The latter course was deemed a refresher course and was for a shorter period. In routine practice, it would be expected that refresher courses would occur every 12 months. The number of Device Operators attending this training was obtained from the attendance records of the Trial Manager and the Device Group. For Pathology Providers, it was assumed that the cost of accreditation and QA program were incorporated into the relevant MBS fee.

### 10.3.2. Unit costs

Where possible unit costs were reported in 2006 Australian dollars (\$) as this covered the bulk of the Trial period. Since the total duration of the Trial was only 18 months, it was thought that adjusting for inflation by the consumer price index (CPI) would be trivial and lead to little change in resource costs. However, where costs were only obtainable for a period before the Trial, costs were adjusted using the CPI. As the Trial only covered an 18 month period, costs were not discounted. The costs were allocated as being borne either by the patient and family or the health care sector.<sup>165</sup> Costs were grouped into direct and indirect costs. Indirect costs comprised the time patients spent seeking health care and with all other costs being classified as direct costs.

The costs of the three PoCT devices used in the Trial were obtained from industry sources and the acquisition value adjusted by the CPI to 2006. The clinically useful life of each device was assumed to be three years as stated in the Trial Design.<sup>25</sup>

The accreditation costs were based on the cost of providing the Accreditation Program developed and implemented as part of the PoCT Trial. Costs associated with accreditation were shared equally between the three devices.

The training costs were based on those used for training practice staff in the Trial. This consisted of 1.5 days at the beginning of the Trial and a half day refresher 12 months later. The costs of the training were allocated equally between the three devices.

The annual cost of the QA program was obtained from the RCPA QAP Pty Ltd. The cost for QC consumables was obtained from industry source. A per test cost for consumables used for QC and QA was obtained by combining the cost of items required to undertake the QA and QC. This included QC control kits, gloves, pipette tips and mini pet pipettes.

The unit cost of a GP consultation for both the control and intervention groups was derived from the Schedule of Medicare Benefits at 100% of the scheduled fee for 1 November 2006. Any co-payment charged by the GP was calculated from the difference between the schedule fee and the charged fee from the Medicare dataset. The unit cost for specialist referrals (Group A3) and allied health referrals Group M3 (diabetes education, dietetics and chiropody) were dealt with in the same way.

For patients in the control group, the Patient Episode Initiation (PEI) fee was obtained from the Medicare Australia dataset. The PEI covers the cost of the collection of a specimen from a patient on the same day and could cover more than one test. Data provided by the pathology industry indicated that the average GP requested episode included more than two items per episode. This varied between the tests and to account for this the PEI was adjusted by a factor of .95 for INR and 2.6 for HbA1c, microalbumin and lipids. For example for HbA1c, the adjusted figure was obtained by dividing the raw volume data by 2.6.

The cost of pathology testing was derived from the Medicare Benefits Schedule. For the intervention group, the unit costs of the PoC tests were 100% of the MBS fee set for the PoCT Trial. The cost of pathology tests and the PEI was taken as 85% of the scheduled fee because across Australia 87% of GP requested pathology tests are bulk billed.<sup>166</sup>

A per test consumables cost for each of the PoC tests in the Trial was obtained by combining the cost of the items required to undertake each test. This included the testing strip/cassette, lancet, capillary tubes, plungers, urine pots, dipsticks and gloves. Periodically used items such as dust filters and cleaning kits were costed on an annual basis. The costs of these consumables were obtained from industry sources. There was no annual maintenance fees associated with the devices as the manufacturers were willing to replace defective devices at no cost.

The unit cost estimated for the GP staff to undertake PoCT was obtained through a Time and Motion study undertaken on a sample of practices. This measured the time taken for the Device Operator to undertake each pathology test, including the time required to bring the patient into the treatment room, collect specimens and record notes. The time taken by the Device Operators to undertake the QC and QA requirements was based on an estimate provided by those Device Operators participating in the Time and Motion study. The average time taken to undertake each PoC test and also the QA and QC tests was derived from this data and the cost per minute was calculated based on the award rate in South Australia for nurses working in a medical practitioner's rooms (2005-2007) – 3<sup>rd</sup> year of service. The South Australian award was similar to awards in New South Wales and Victoria. Where a test was undertaken using a pathology laboratory in the intervention practice, the cost for this test was included, consisting of the 85% of the PEI MBS fee for the pathology test.

The value of a patient's time was estimated as the cost of foregone activities. A patient's time included travel time and waiting time. Time costs for patients were equivalent to the value of foregone production approximated by the seasonally adjusted average weekly earnings.<sup>167</sup> This method was applied to patients who were employed, unemployed or retired. Transport costs were calculated on mean return distance (kilometres) to the GP or pathology laboratory based on an

average size car (1601 to 2600 cc engine capacity) and at the Australian Taxation Office rate of 66.0 cents (2005-2006). The mean costs for other travel expenses such as bus fare or taxi fares were based on data obtained from the Patient Satisfaction Questionnaire.

The cost of an emergency department visit was obtained from the National Hospital Cost Data Collection Cost Report Round 9 (2004-2005)<sup>168</sup> for the public sector. These costs were adjusted to 2006 using the CPI for the eight capital cities in Australia.<sup>169</sup> As we were not able to determine from the data the type of emergency department visit, the non-admitted Triage 3 level was selected as a mid-range cost. This method of data collection did not allow for co-payments to be calculated.

The cost of hospital admissions were derived from National Hospital Data Collection 2004-05 using AR-DRG 5.0,<sup>170</sup> adjusted by the CPI.<sup>169</sup> These were costed on the basis of public hospital weights in the absence of information in the GP's records on whether particular patients were managed in a public or private hospital. This seemed a reasonable approach as to the large percentage of health care card holders and pensioners in the Trial. Hospitalisation rates were applied to a sample of patients obtained through the case note audit and weighted estimates generated for the Trial population. The hospitalisations were then assigned an AR-DRG code by a researcher blinded to the patient identification and their allocation to intervention or control under guidance from an expert AR-DRG coder. This method of data collection did not allow for co-payments to be calculated.

For the Trial GPs in the intervention group were provided free of charge with devices, accreditation and training (establishment costs), QAP, and consumables and maintenance. In addition the GPs were provided with access to the PoCT MBS fee.

The calculation of testing costs incorporated for the intervention group: the Device Operator time in undertaking the test and the laboratory MBS fee (85%) and the PEI (85%) where applicable under intention to treat (ITT). For the control group this included: the pathology MBS fee (85%), the PEI (85%) and the time for practice staff to follow-up tests which was based on estimations provided by a sample of control practices. The Device Operator time was included in the cost comparisons because, although the GPs received 100% of the MBS item for PoCT, this was insufficient to cover all GP fixed costs because of the low volume of tests and the provision of certain costs for free.

### 10.3.3. Health outcome indicator

The Trial Design determined the intermediate outcome indicator to be used in the cost-effectiveness analysis. This indicator was the proportion of patients within the therapeutic range for each condition at the end of the Trial. These ranges are provided in Table 4.

Clinical trials investigating the benefits of lowering blood glucose on the incidence of complications in diabetes patients provide robust evidence that good glycaemic control (HbA1c <7%) reduces serious long-term complications<sup>118, 119, 171</sup> and lower health care costs.<sup>120</sup> The results from the UKPDS also provide evidence that improving therapeutic control even slightly in patients with either Type 1 or Type 2 diabetes will prevent or delay the onset of complications.<sup>118</sup> The PoCT device used in the Trial provided two methods of assessing microalbuminuria – urine albumin and ACR. ACR is the preferred indicator for early renal disease and so this was the test used in cost-effectiveness analysis for microalbumin.

The National Heart Foundation's Lipid Management Guidelines recommend that any improvement in cholesterol target ranges, even if target levels are not reached, is highly beneficial.<sup>31</sup> The Multiple Risk Factor Intervention Trial (MRFIT),<sup>172</sup> in a sample of 360,000 men, found that every 1mmol/L lowering of blood total cholesterol was associated with an approximately 50% lower risk of mortality from coronary heart disease. The results from the Framingham Study indicate that the risk of coronary heart disease increases by 2% for each 1% increase in total cholesterol.<sup>173</sup> For the cost-effectiveness analysis of the lipid PoCT, a single health outcome indicator was calculated based on the three tests available in a Lipid Study – total cholesterol, triglycerides and HDL-C. Only if all three tests were within their target range was the lipids indicator then taken to be within its target range. This was required as the PoCT device performed all three tests at every use.

The benefit of anticoagulant therapy in preventing cardiovascular events such as stroke has been demonstrated<sup>174</sup> yet anticoagulation control can be difficult with the most serious side effect of this treatment being bleeding which at times can require hospital admission.<sup>175</sup> Therefore to prevent such episodes, therapeutic control needs to be regularly monitored and maintained. A primary prevention trial in atrial fibrillation showed that when the INR was out of its therapeutic range there were more thromboembolic and bleeding events and that the safety and efficacy of warfarin was increased by maintaining good anticoagulant control.<sup>176</sup>

#### 10.3.4. Statistical analysis

In general, the strategy was to calculate the actual total cost for all practices and participants over the Trial period. However, problems with missing data necessitated using complex statistical procedures for the costing calculation. Data were missing due to inability to match participants adequately with Medicare records (see Section 0) and also to attrition. Data were presumed to be missing at random.<sup>177</sup>

It is a common strategy to impute data for missing values.<sup>178</sup> When possible, continuous variables with missing observations and a monotone missing pattern were imputed using the regression method.<sup>179, 180</sup> Categorical variables with missing data were imputed using a logistic or discriminant function method. If the data did not show monotone missingness, the Markov Chain Monte Carlo Method<sup>181</sup> was used to produce monotone missingness, and then the imputation was completed as above.

In the imputations, information about the participants that was used to generate the value for the missing observations included:

- gender
- age at the time of consent
- duration of time in the study
- disease status (Diabetes, Hyperlipidaemia, Anticoagulant Therapy)
- treatment group
- urban, rural and remote locations
- practice.

Medicare data were used to estimate the average usage of a particular service by a participant in the Trial over 18 months. Generalised Estimating Equations (GEE) were used to estimate the predicted number of health care item usages for a participant in the intervention and control arms, controlling for gender and age at consent, and allowing for correlation among those participants from the same practice site. As an individual's costs may be dependent on the length of time involved in the study, the number of days from consent to withdrawal or the end of the study was included as an offset in the model.

Count data were modelled as a Poisson distribution with log link. Variables estimated in such a manner were:

- GP consultations
- specialist health referrals
- allied health visits
- pathology tests
- emergency department visits
- prescriptions
- laboratory testing episodes.

GEEs were also used to estimate mean travel costs and distances. These values were assumed to be normally distributed. Variable estimates in such a manner were:

- distance travelled to GP and laboratory (if applicable)
- cost
- time of travel.

Once the mean value for a person over 18 months was obtained, the cost associated with that resource item was calculated. The total cost for any particular item was determined from the estimated mean from the GEE analysis, the sample size, and the unit cost of the item:

$$\text{Total cost} = \text{mean} \times \text{sample size} \times \text{unit cost}$$

Items within each general category (for example, consumables and maintenance or GP consultations) were totalled. An overall total for the intervention and control groups was calculated.

Bootstrapped CIs were obtained for unit, total and mean costs, and total and mean group differences. From the original sample, 500 bootstrap samples were obtained, sampling at the practice level. This resulted in each bootstrap sample having different numbers of subjects (due to different numbers of subjects attending each practice), but over all bootstrap samples, the correlation due to clustering at the practice level was controlled. The 2.5th and 97.5th percentile values were taken as the limits of the 95% CI.

All imputations and subsequent analyses were performed with SAS 9.1 (Cary, NC, USA).

#### *Impact of Phase I versus Phase II of Trial*

An assessment was made of the impact on cost of the design of Phase I of the Trial, where the intervention group was required to have both a PoC test and a laboratory test. While this was meant to occur on the same day, some laboratory tests were performed up to seven days later. The cost differences were assessed based on each: same day test, one day difference, three days difference and seven days difference. Differences in the cost between these different windows were small. Therefore, all subsequent analysis used the base case (same day results).

#### 10.3.5. Cost-effectiveness analysis

Cost-effectiveness was determined using the Incremental Cost Effectiveness Ratio (ICER) between PoCT and laboratory testing for each of the tests according to the formula:

$$\frac{\text{COST}_{\text{PoCT}} - \text{COST}_{\text{laboratory}}}{\text{outcome}_{\text{PoCT}} - \text{outcome}_{\text{laboratory}}}$$

The outcome measure used was the number of patients whose therapeutic range was within the normal clinical range for their condition at the end of the Trial. The ICER was calculated using total cost per patient.

#### 10.3.6. Sensitivity analysis

To examine the influence of uncertainty in the variables, one-way sensitivity analysis was undertaken on each resource item for which the underlying variable had a distribution. Using this approach, the impact of each such variable in the study was examined across a plausible range of values, while holding all other variables constant. Where applicable, the upper and lower 95% CIs were used as the range for the sensitivity analysis.

### 10.3.7. Joint probability distribution

To represent uncertainty around cost and effect data, a distribution of these estimates was generated using non-parametric bootstrapping<sup>182</sup>. The total cost difference and the effectiveness difference was estimated from each 500 bootstrap samples. As described previously, costs were estimated using a Poisson model with log link, allowing for clustering at the practice level. Effectiveness was defined as the proportion of patients who were within the target range for a particular test. This was estimated using an identity binomial model, also with allowance for clustering at the practice level. However, for three of the outcomes (HbA1c, microalbumin and lipids), the identity binomial model would not converge in the bootstrap samples, as it did not in the primary analysis of the sample data. Therefore, for those three outcomes, a logistic regression model with clustering was used.

The resulting bootstrapped distributions of incremental cost and incremental effectiveness were plotted, along with the actually observed base case. In the scatterplots, cost and effectiveness increments for each bootstrap sample can lie in one of four quadrants compared to the comparator which is located at the origin:

1. NE: In this quadrant, the incremental effectiveness is positive, indicating that the intervention is more effective. However, the incremental cost is also positive, indicating that the intervention is more expensive as well. Thus there is a trade-off between extra effectiveness and extra cost.
2. NW: Here, the incremental effectiveness is negative, and the incremental cost is positive. Therefore, the comparator dominates in this quadrant. On these grounds, the intervention would not be recommended.
3. SW: In this quadrant, the intervention is less effective, and also less expensive than the comparator. Despite the reduction in cost, it is uncommon in Australian health policy to accept new interventions that are less effective than the existing intervention.
4. SE: In this quadrant, the intervention dominates the comparator. It is both more effective and less expensive.

## 10.4. RESULTS

### 10.4.1. Cost comparisons

#### 10.4.1.1. INR tests

All costs associated with INR testing are shown in Table 174. The total direct cost to the health care sector for an INR testing strategy by PoCT was \$3,175 per person over the Trial period compared to \$3,023 per person by pathology laboratory, although this difference was not statistically significant. This included a difference of \$36 for the costs of the actual tests.

Regarding these direct costs to the health care sector, the intervention group generated \$229 greater costs for GP consultations and \$18 greater costs for pharmaceuticals, both of which were statistically significant. This was offset by \$126 greater hospital costs for the control group although this difference was not significant.

For the intervention group, the overall direct cost of travel for patients and their families for INR tests was \$20 per patient. For the control group, the equivalent amount was \$24 per patient (Table 174). The difference of \$4 was statistically significant. Co-payments were low reflecting the large proportion of health care card holders amongst the patients. For the indirect costs for patients and families of their time seeking health care, the intervention group experienced \$97 per patient with \$99 per patient for the control group.

**Table 174: Comparison of direct and indirect costs at 18 months for INR tests – costs per patient**

<b>Resources</b>	<b>Intervention N=572</b>	<b>Control N=372</b>	<b>Difference intervention - control</b>
<b>Direct costs to the health care sector</b>	<b>(95% CI)</b>	<b>(95% CI)</b>	<b>(95% CI)</b>
Establishment costs in GP	\$121	\$0	\$121
Consumables & maintenance in GP	\$107 (\$77, \$137)	\$0	\$107 (\$77, \$137)
Quality assurance & control in GP	\$47	\$0	\$47
INR tests (100% MBS fee in GP, 85% MBS fee in pathology laboratory)	\$326 (\$221, \$359)	\$565 (\$383, \$621)	-\$239 (-\$310, -\$165)
<b>Sub total cost of actual test</b>	<b>\$606 (\$416, \$634)</b>	<b>\$565 (\$383, \$621)</b>	<b>\$36 (-\$54, \$120)</b>
GP consultations	\$938 (\$848, \$1,049)	\$708 (\$632, \$772)	\$229 (\$120, \$367)
Hospital admissions	\$1,048 (\$214, \$2,060)	\$1,174 (-\$37, \$2,019)	-\$126 (-\$1,343, \$1,568)
Emergency Dept visits	\$19 (\$4, \$34)	\$14 (\$5, \$22)	\$4 (-\$12, \$24)
Specialist consultations	\$188 (\$171, \$204)	\$198 (\$183, \$212)	-\$10 (-\$31, \$11)
Allied health visits	\$251 (\$220, \$285)	\$250 (\$203, \$301)	\$1 (-\$61, \$66)
Pharmaceuticals	\$131 (\$124, \$138)	\$113 (\$101, \$124)	\$18 (\$6, \$30)
Subtotal direct costs to healthcare sector	\$3,175 (\$2,163, \$4,092)	\$3,023 (\$1,669, \$3,730)	\$153 (-\$1,097, \$1,828)
Sector direct cost per 1000 patients	\$3,175,431	\$3,022,913	\$152,518
<b>Direct costs to the patients and families</b>			
Co-payment for GP consultations and pharmaceuticals	\$4 (\$4, \$5)	\$4 (\$2, \$7)	\$0 (-\$2, \$3)
Patient travel costs	\$20 (\$10, \$24)	\$24 (\$18, \$26)	-\$4 (-\$15, -\$2)
Subtotal direct costs to patients and families	\$24 (\$14, \$38)	\$28 (\$23, \$31)	-\$4 (-\$16, -\$3)
Sector direct cost per 1000 patients	\$24,173	\$28,232	-\$4,059
<b>Indirect costs</b>			
Time seeking health care	\$97 (\$86, \$100)	\$99 (\$89, \$107)	-\$2 (-\$16, \$5)
<b>Total costs (both sectors)</b>			
Total	\$3,297 (\$2,262, \$4,197)	\$3,150 (\$1,786, \$3,853)	\$147 (-\$1114, \$1816)

Note: totals not exact due to rounding

If the establishment costs in GP, the consumables and maintenance costs in GP and the quality assurance costs in GP, which were all provided free in the Trial, were regarded as research protocol costs and removed from Table 174, the total cost for the INR PoCT strategy per patient would be \$3,022, a reduction of \$275. However, elsewhere in this report (Chapter 16) it has been demonstrated that the volume of tests in this Trial was insufficient to cover these kinds of fixed costs at an MBS fee in parity with pathology laboratory testing. It is also a moot point whether the Device Operator time should be excluded from the INR PoC test cost, but it is unclear whether or not the Government would replace this with a PEI for testing actually conducted in general practice.

#### 10.4.1.2. *HbA1c tests*

All the costs associated with HbA1c testing are shown in Table 175. The total direct cost to the health care sector for an HbA1c testing strategy by PoCT was \$3,636 per person over the Trial period compared to \$3,606 per person by pathology laboratory, although this was not statistically significant. This included a difference of \$137 for the costs of the actual tests.

Regarding these direct costs to the health care sector, neither the costs of GP consultations nor the downstream costs (hospital admissions, emergency department visits, specialist consultations, allied health visits and pharmaceuticals) showed a statistically significant difference between the two arms of the Trial. However, the cost of HbA1c tests was \$34 less for the intervention group, which was significant.

For the intervention group, the overall direct cost of travel for patients and their families for HbA1c tests were \$12 per patient. For the control group, the equivalent amount was \$28 per patient. The difference of \$16 was statistically significant. Co-payments were low reflecting the large proportion of health care card holders amongst the patients. For the indirect costs for patients and families of their time seeking health care, the intervention group experienced \$23 per patient with \$34 per patient for the control group. The difference of \$11 was statistically significant.

If the establishment costs in GP, the consumables and maintenance costs in GP and the quality assurance costs in GP, which were all provided free in the Trial, were regarded as research protocol costs and removed from Table 175, the total cost for the HbA1c PoCT strategy per patient would be \$3,505, a reduction of \$171. However, elsewhere in this report (Chapter 16) it has been demonstrated that the volume of tests in this Trial was insufficient to cover these kinds of fixed costs at an MBS fee in parity with pathology laboratory testing. It is also a moot point whether the Device Operator time should be excluded from the HbA1c PoC test cost, but it is unclear whether or not the Government would replace this with a PEI for testing actually conducted in general practice.

#### 10.4.1.3. *Microalbumin tests*

All the costs associated with microalbumin testing are shown in Table 176. The total direct cost to the health care sector for a microalbumin testing strategy by PoCT was \$1,692 per person over the Trial period compared to \$1,895 per person by pathology laboratory, although this was not statistically significant. This included a difference of \$111 for the costs of the actual tests.

Regarding these direct costs to the health care sector, neither the costs of GP consultations nor the downstream costs (hospital admissions, emergency department visits, specialist consultations, allied health visits and pharmaceuticals) showed a statistically significant difference between the two arms of the Trial. However, the cost of HbA1c tests was \$14 less for the intervention group, which was significant.

For the intervention group, the overall direct cost of travel for patients and their families for microalbumin tests were \$12 per patient. For the control group, the equivalent amount was \$28 per patient. The difference of \$16 was statistically significant. Co-payments were low reflecting the large proportion of health care card holders amongst the patients. For the indirect costs for patients and families of their time seeking health care, the intervention group experienced \$18 per patient with \$26 per patient for the control group. The difference of \$8 was statistically significant.

**Table 175: Comparison of direct and indirect costs at 18 months for HbA1c tests - costs per patient**

<b>Resources</b>	<b>Intervention N=1182</b>	<b>Control N=785</b>	<b>Difference intervention - control</b>
<b>Direct costs to the health care sector</b>	<b>(95% CI)</b>	<b>(95% CI)</b>	<b>(95% CI)</b>
Establishment costs in GP	\$114	\$0	\$114
Consumables & maintenance in GP	\$28 (\$22, \$31)	\$0	\$28 (\$22, \$31)
Quality assurance & control in GP	\$29	\$0	\$29
HbA1c tests (100% MBS fee in GP, 85% MBS fee in pathology laboratory)	\$64 (\$49, \$65)	\$98 (\$88, \$107)	-\$34 (-\$54, -\$28)
<b>Sub total cost of actual test</b>	<b>\$235 (\$184, \$290)</b>	<b>\$98 (\$88, \$107)</b>	<b>\$137 (\$84, \$194)</b>
GP consultations	\$579 (\$515, \$659)	\$560 (\$502, \$618)	\$18 (-\$69, \$112)
Hospital admissions	\$171 (-\$181, \$662)	\$506 (-\$137, \$1,241)	-\$334 (-\$1,131, \$460)
Emergency Dept visits	\$8 (\$3, \$13)	\$8 (\$2, \$13)	-\$1 (-\$8, \$7)
Specialist consultations	\$173 (\$163, \$183)	\$169 (\$157, \$180)	\$4 (-\$11, \$20)
Allied health visits	\$221 (\$195, \$253)	\$232 (\$188, \$282)	-\$11 (-\$72, \$47)
Pharmaceuticals	\$2,249 (\$1,889, \$2,555)	\$2,032 (\$1,859, \$2,586)	\$217 (-\$280, \$253)
Subtotal direct costs to healthcare sector	\$3,636 (\$3,019, \$4,149)	\$3,606 (\$2,902, \$4,563)	\$30 (-\$988, \$673)
Sector direct cost per 1000 patients	\$3,636,420	\$3,605,958	\$30,462
<b>Direct costs to the patients and families</b>			
Co-payment for GP consultations and pharmaceuticals	\$4 (\$4, \$6)	\$4 (\$2, \$6)	\$0 (-\$2, \$4)
Patient travel costs	\$12 (\$10, \$14)	\$28 (\$23, \$33)	-\$16 (-\$22, -\$11)
Subtotal direct costs to patients and families	\$16 (\$15, \$19)	\$32 (\$28, \$39)	-\$16 (-\$22, -\$10)
Sector direct cost per 1000 patients	\$16,101	\$32,139	-\$16,038
<b>Indirect costs</b>			
Time seeking health-care	\$23 (\$22, \$25)	\$34 (\$32, \$37)	-\$11 (-\$14, -\$8)
<b>Total costs (both sectors)</b>			
Total	\$3,676 (\$3,062, \$4,191)	\$3,672 (\$2,972, \$4,628)	\$4 (-\$1,103, \$642)

Note: totals not exact due to rounding

**Table 176: Comparison of direct and indirect costs at 18 months for microalbumin tests - costs per patient**

<b>Resources</b>	<b>Intervention N=1182</b>	<b>Control N=785</b>	<b>Difference intervention - control</b>
<b>Direct costs to the health care sector</b>	(95% CI)	(95% CI)	(95% CI)
Establishment costs in GP	\$87	\$0	\$87
Consumables & maintenance in GP	\$20 (\$14, \$22)	\$0	\$20 (\$14, \$22)
Quality assurance & control in GP	\$18	\$0	\$18
Microalbumin tests (100% MBS fee in GP, 85% MBS fee in pathology laboratory)	\$43 (\$35, \$47)	\$57 (\$48, \$63)	-\$14 (-\$24, -\$5)
<b>Sub total cost of actual test</b>	<b>\$168 (\$132, \$214)</b>	<b>\$57 (\$48, \$63)</b>	<b>\$111 (\$76, \$157)</b>
GP consultations	\$579 (\$515, \$659)	\$560 (\$502, \$618)	\$18 (-\$69, \$112)
Hospital admissions	\$171 (-\$181, \$662)	\$506 (-\$137, \$1,241)	-\$334 (-\$1,131, \$460)
Emergency Dept visits	\$8 (\$3, \$13)	\$8 (\$2, \$13)	-\$1 (-\$8, \$7)
Specialist consultations	\$173 (\$163, \$183)	\$169 (\$157, \$180)	\$4 (-\$11, \$20)
Allied health visits	\$221 (\$195, \$253)	\$232 (\$188, \$282)	-\$11 (-\$72, \$47)
Pharmaceuticals	\$371 (\$361, \$462)	\$363 (\$351, \$418)	\$8 (-\$9, \$66)
Subtotal direct costs to healthcare sector	\$1,692 (\$1,348, \$2,265)	\$1,895 (\$1,268, \$2,659)	-\$204 (-\$1,030, \$641)
Sector direct cost per 1000 patients	\$1,691,632	\$1,895,224	-\$203,592
<b>Direct costs to the patients and families</b>			
Co-payment for GP consultations and pharmaceuticals	\$5 (\$5, \$8)	\$5 (\$2, \$8)	\$0 (-\$2, \$5)
Patient travel costs	\$12 (\$10, \$14)	\$28 (\$23, \$33)	-\$16 (-\$22, -\$11)
Subtotal direct costs to patients and families	\$17 (\$16, \$21)	\$33 (\$29, \$40)	-\$16 (-\$22, -\$10)
Sector direct cost per 1000 patients	\$17,543	\$33,235	-\$15,783
<b>Indirect costs</b>			
Time seeking health care	\$18 (\$16, \$19)	\$26 (\$24, \$28)	-\$8 (-\$14, -\$8)
<b>Total costs (both sectors)</b>			
Total	\$1,727 (\$1,387, \$2,309)	\$1,954 (\$1,319, \$2,712)	-\$228 (-\$1041, \$625)

Note: totals not exact due to rounding

If the establishment costs in GP, the consumables and maintenance costs in GP and the quality assurance costs in GP, which were all provided free in the Trial, were regarded as research protocol costs and removed from Table 176, the total cost for the microalbumin PoCT strategy per patient would be \$1,602, a reduction of \$125. However, elsewhere in this report (Chapter 15) it has been demonstrated that the volume of tests in this Trial was insufficient to cover these kinds of fixed costs at an MBS fee in parity with pathology laboratory testing. It is also a moot point whether the Device Operator time should be excluded from the Microalbumin PoC test cost, but it is unclear whether or not the Government would replace this with a PEI for testing actually conducted in general practice.

#### 10.4.1.4. *Lipid tests*

All the costs associated with lipid testing are shown in Table 177. The total direct cost to the health care sector for a lipid testing strategy by PoCT was \$2,686 per person over the Trial period compared to \$2,139 per person by pathology laboratory, although this was not statistically significant. This included a difference of \$63 for the costs of the actual tests.

Regarding these direct costs to the health care sector, neither GP consultations nor the majority of downstream costs (hospital admissions, emergency department visits, specialist consultations and allied health visits) showed a statistically significant difference between the two arms of the Trial. The intervention group generated \$252 greater costs for pharmaceutical costs which was statistically significant. However, the cost of HbA1c tests was \$24 less for the intervention group, which was significant.

For the intervention group, the overall direct cost of travel for patients and their families for lipid tests were \$17 per patient. For the control group, the equivalent amount was \$24 per patient. The difference of \$7 was statistically significant. Co-payments were low reflecting the large proportion of health care card holders amongst the patients. For the indirect costs for patients and families of their time seeking health care, the intervention group experienced \$24 per patient with \$33 per patient for the control group. The difference of \$9 was statistically significant.

If the establishment costs in GP, the consumables and maintenance costs in GP and the quality assurance costs in GP, which were all provided free in the Trial, were regarded as research protocol costs and removed from Table 177, the total cost for the lipid PoCT strategy per patient would be \$2,645 a reduction of \$87. However, elsewhere in this report (Chapter 16) it has been demonstrated that the volume of tests in this Trial was insufficient to cover these kinds of fixed costs at an MBS fee in parity with pathology laboratory testing. It is also a moot point whether the Device Operator time should be excluded from the lipid PoC test cost, but it is unclear whether or not the Government would replace this with a PEI for testing actually conducted in general practice.

**Table 177: Comparison of direct and indirect costs at 18 months for lipid tests – costs per patient**

<b>Resources</b>	<b>Intervention N=2536 (95% CI)</b>	<b>Control N=1463 (95% CI)</b>	<b>Difference intervention - control (95% CI)</b>
<b>Direct costs to the health care sector</b>			
Establishment costs in GP	\$23	\$0	\$23
Consumables & maintenance in GP	\$38 (\$21, \$43)	\$0	\$38 (\$21, \$43)
Quality assurance & control in GP	\$26	\$0	\$26
Lipid tests (100% MBS fee in GP, 85% MBS fee in pathology laboratory)	\$54 (\$36, \$59)	\$78 (\$63, \$78)	-\$24 (-\$37, -\$18)
<b>Sub total cost of actual test</b>	<b>\$141 (\$103, \$143)</b>	<b>\$78 (\$63, \$78)</b>	<b>\$63 (\$32, \$71)</b>
GP consultations	\$573 (\$509, \$651)	\$503 (\$457, \$544)	\$70 (-\$7, \$155)
Hospital admissions	\$417 (-\$178, \$1,098)	\$276 (-\$139, \$692)	\$142 (-\$554, \$985)
Emergency Dept visits	\$2 (\$0, \$10)	\$0 (\$0, \$12)	\$1 (-\$6, \$5)
Specialist consultations	\$166 (\$157, \$176)	\$168 (\$158, \$179)	-\$2 (-\$16, \$13)
Allied health visits	\$196 (\$166, \$227)	\$175 (\$169, \$249)	\$20 (-\$63, \$40)
Pharmaceuticals	\$1190 (\$987, \$1,268)	\$938 (\$905, \$1,108)	\$252 (\$143, \$296)
Subtotal direct costs to healthcare sector	\$2,686 (\$1,953, \$3,199)	\$2,139 (\$1,814, \$2,702)	\$547 (-\$468, \$1096)
Sector direct cost per 1000 patients	\$2,685,532	\$2,138,968	\$546,564
<b>Direct costs to the patients and families</b>			
Co-payment for GP consultations and pharmaceuticals	\$7 (\$6, \$9)	\$7 (\$2, \$8)	\$0 (-\$1, \$6)
Patient travel costs	\$17 (\$11, \$18)	\$24 (\$20, \$28)	-\$7 (-\$15, -\$7)
Subtotal direct costs to patients and families	\$23 (\$18, \$24)	\$30 (\$27, \$36)	-\$7 (-\$16, -\$6)
Sector direct cost per 1000 patients	\$23,141	\$30,066	-\$6,924
<b>Indirect costs</b>			
Time seeking health care	\$24 (\$20, \$26)	\$33 (\$31, \$35)	-\$9 (-\$14, -\$9)
<b>Total costs (both sectors)</b>			
Total	\$2,732 (\$1,994, \$3,241)	\$2,202 (\$1,875, \$2,765)	\$530 (-\$489, \$1,078)

Note: totals not exact due to rounding

### 10.4.2. Incremental cost-effectiveness ratio

The incremental cost-effectiveness ratio (ICER) for PoCT compared to laboratory testing was calculated for each of the tests. The results reported in this section rely on point estimates, which are shown in Table 178. ACR testing through PoCT dominates its comparator in that it was both less costly and more effective. Conversely, INR by PoCT was dominated by its comparator. That is, INR by PoCT was more expensive and less effective than laboratory testing.

The ICER for PoCT HbA1c was \$40 per additional patient in the target range and for lipids the ICER was \$10,082 per additional patient in the target range. These tests fell in the north-east quadrant of the incremental cost-effectiveness plane, having higher costs and being more effective. Therefore trade-offs between costs and effects need to be considered.

**Table 178: Point estimates of the ICERs for the PoC tests per patient maintained in the target range\* compared with laboratory tests**

Test	Treatment group	Costs per patient (\$)	Effects per patient	ICER (\$)
INR	Intervention	3,297.84	0.5701	Dominated
	Control	3,150.01	0.6147	
	Difference	147.82	-0.0446	
HbA1c	Intervention	3,676.01	0.6548	40.16
	Control	3672.28	0.5618	
	Difference	3.73	0.0930	
ACR	Intervention	1,726.63	0.7739	Dominant
	Control	1,954.27	0.7418	
	Difference	-227.64	0.0321	
Lipids	Intervention	2,732.33	0.1592	10,081.65
	Control	2,202.04	0.1066	
	Difference	530.29	0.0526	

\*Effect is proportion of patients in target range as determined at the end of the Trial (18 months mean observation time)

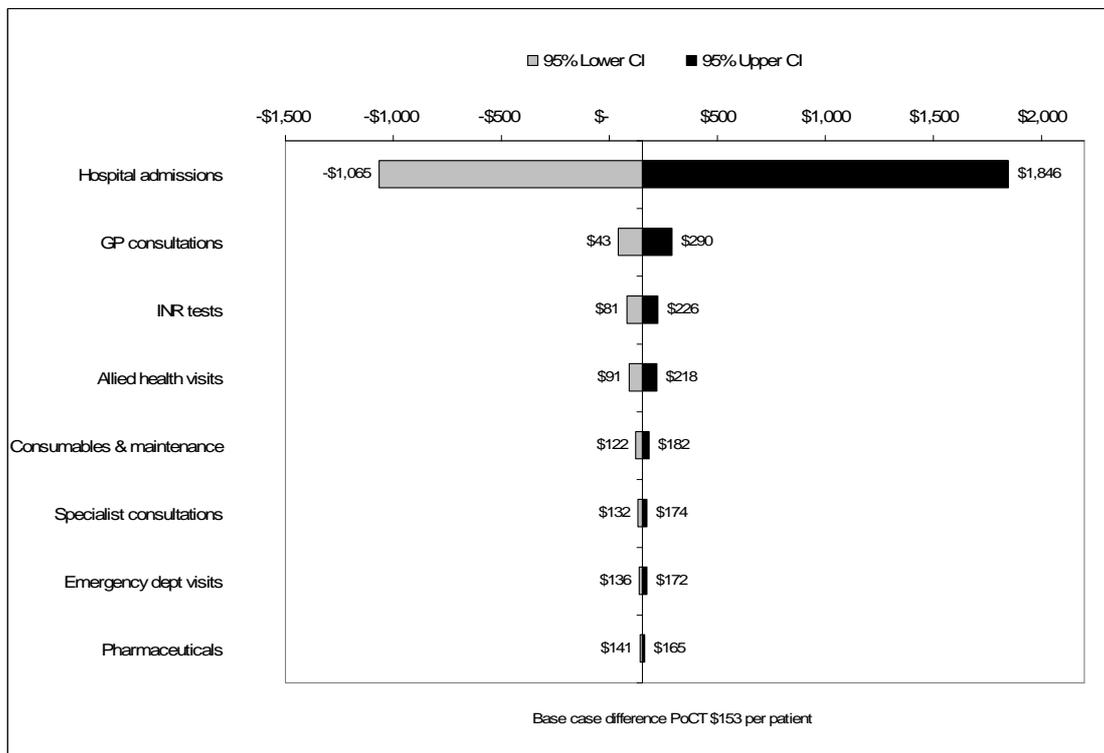
### 10.4.3. Sensitivity analysis on the incremental direct costs

To explore the impact of uncertainty in the variables measured, one-way sensitivity analyses were undertaken for each testing strategy by applying the relevant upper and lower 95% confidence limits. First, these were conducted on the incremental direct costs associated with the healthcare sector as the patient and family costs were not of sufficient magnitude to have much influence on the overall results. Tornado diagrams based on the point estimates are used to present the results (Figure 31 to Figure 35). Then, the impact on the ICERs was analysed (Table 179)

#### 10.4.3.1. INR

The results of the one-way sensitivity analysis for the cost difference in direct health care sector costs per patient between PoC INR testing and laboratory INR testing are shown in Figure 31. The base case incremental cost for INR using PoCT was \$153 per patient. This difference was particularly sensitive to the cost of hospital admissions and somewhat sensitive to the costs of GP consultations, tests and allied health visits.

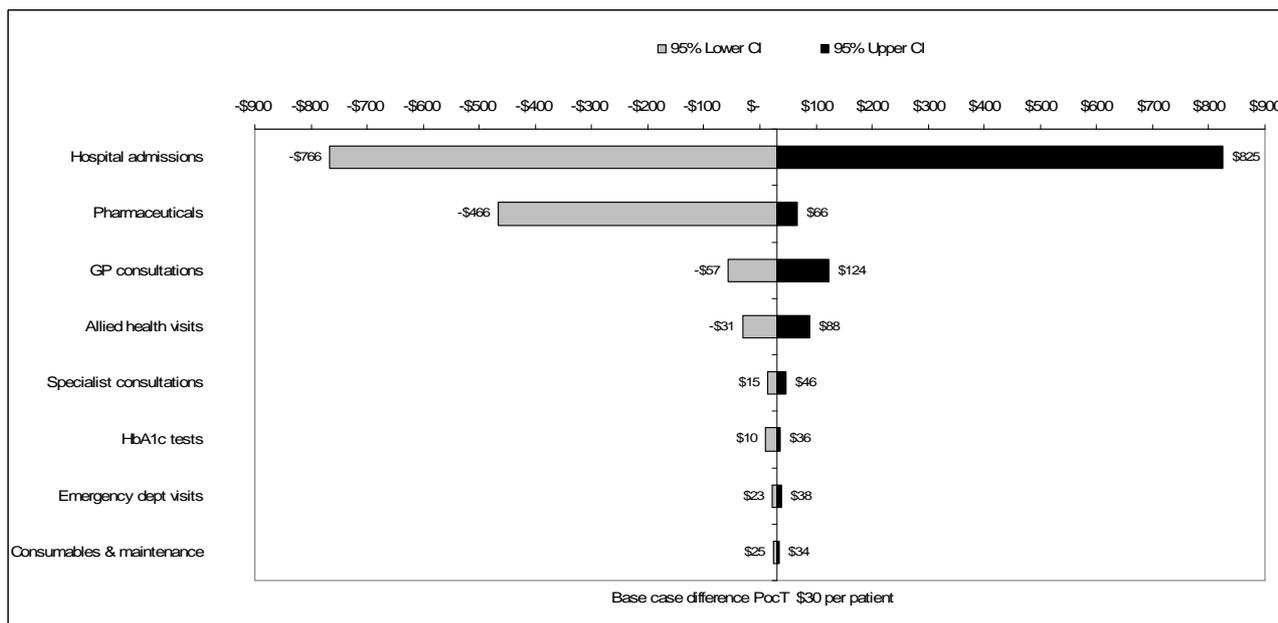
**Figure 31: One way sensitivity analysis for the difference in direct health care sector costs per patient for PoC INR testing compared to a laboratory INR testing**



10.4.3.2. HbA1c

The results of the one-way sensitivity analysis for the difference in direct health care sector costs per patient between PoC HbA1c testing and laboratory HbA1c testing are shown in Figure 32. The base case incremental cost for HbA1c using PoCT was \$30 per person. This cost difference per patient was sensitive to hospital admissions and pharmaceuticals and somewhat sensitive to GP consultations and allied health visits.

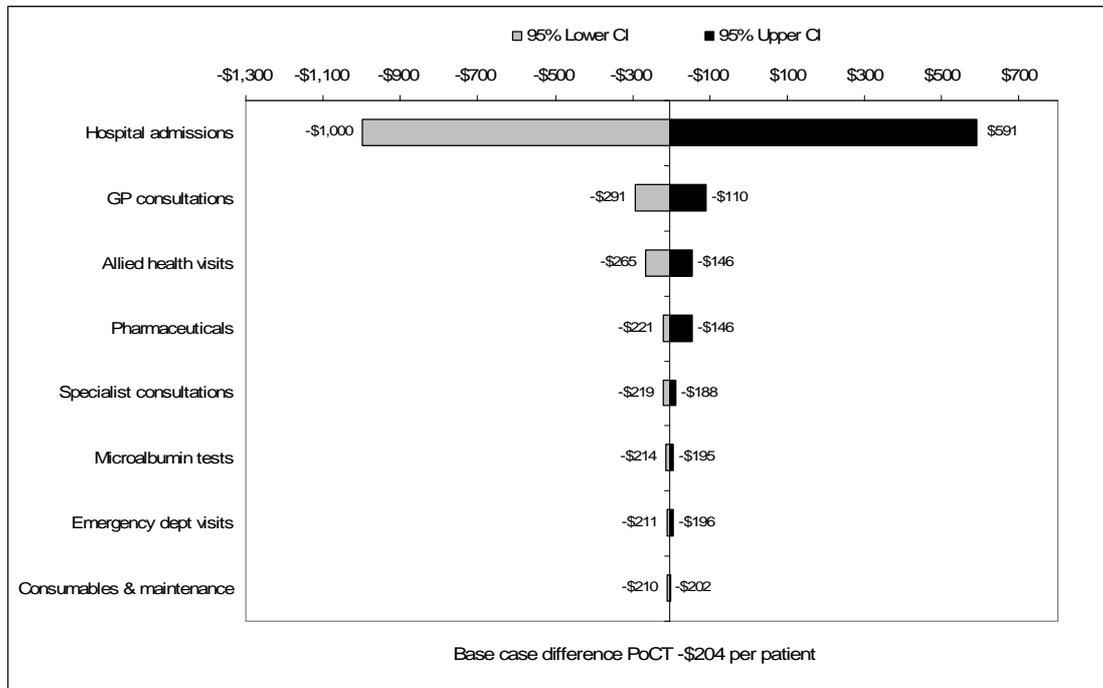
**Figure 32: One way sensitivity analysis for the difference in direct health care sector costs per patient for PoC HbA1c testing compared to a laboratory HbA1c testing**



### 10.4.3.3. ACR

The results of the one-way sensitivity analysis for the difference in direct health care sector costs per patient between PoC ACR testing and laboratory ACR testing are shown in Figure 33. The base case incremental cost for ACR testing was -\$204. The cost difference was particularly sensitive to hospital admissions and somewhat sensitive to GP consultations and allied health visits.

**Figure 33: One way sensitivity analysis for the difference in direct health care sector costs per patient for PoC ACR testing compared to a laboratory ACR testing**

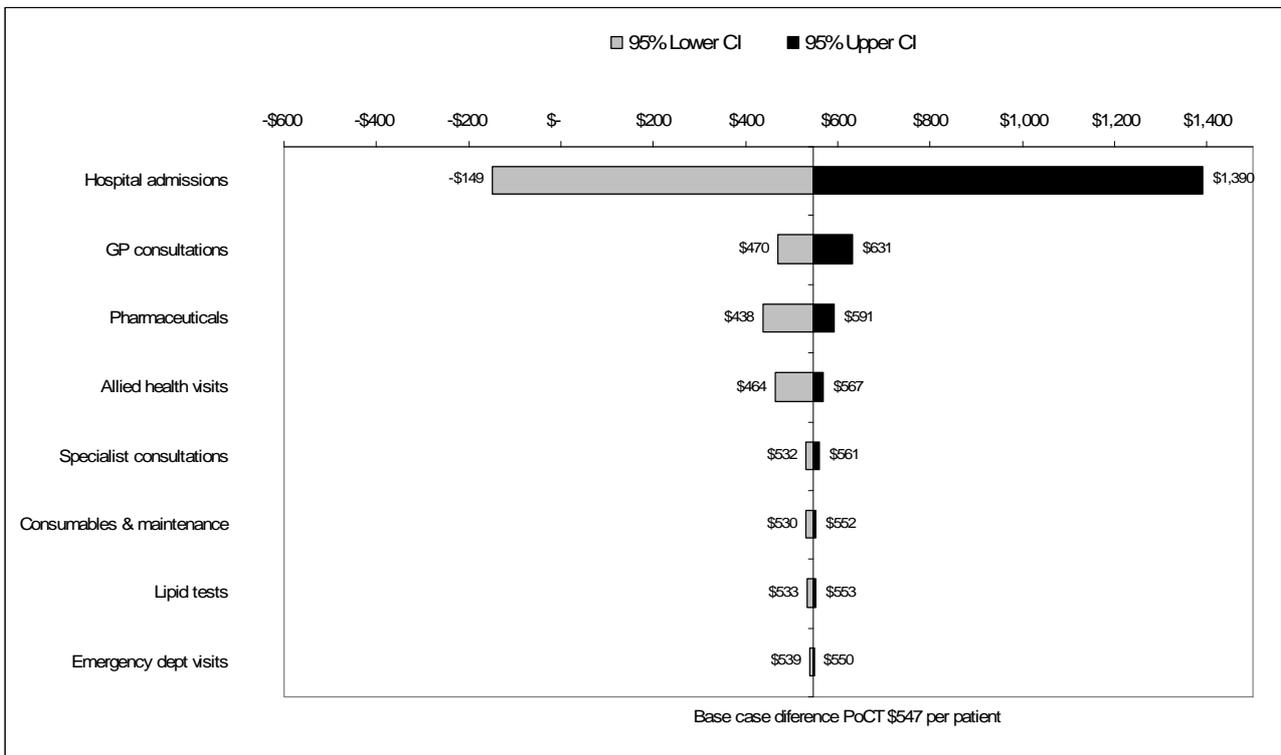


### 10.4.3.4. Lipids

The results of the one-way sensitivity analysis for the difference in direct health care sector costs per patient between PoC lipid testing and laboratory lipid testing are shown in Figure 34. The base case incremental cost for a lipid test was \$547. The cost difference somewhat sensitive to GP consultations and pharmaceuticals; however, it was particularly sensitive to hospital admission, with the cost more than doubling over the base case difference when the upper CIs was used.

Overall, these incremental costs per patient were most sensitive to differences in the costs of hospitalisation and somewhat sensitive to differences in the costs of GP consultations, pharmaceuticals and allied health visits. The impact on the hospital costs on the ICERs was explored by removing hospital costs and recalculating the ICERs. The results are shown in Appendix 32.

**Figure 34: One way sensitivity analysis for the difference in direct health care sector costs per patient for PoC lipid testing compared to a laboratory Lipid testing**



#### 10.4.4. Exploration of the impact of uncertainty on the ICERs

##### 10.4.4.1. One-way sensitivity analyses of the ICERs

The sensitivity of the base case ICER to changes in hospitalisations and GP consultations for each type of test is shown in Table 179. The results for all variables tested are provided in Appendix 33.

These one-way sensitivity analyses (Table 179) indicate that the ICER for each PoC test is quite sensitive to variation in hospitalisation costs. Variations in GP costs have less influence, although the point estimate of the ICER for HbA1c is shifted into a different quadrant.

**Table 179: One way sensitivity analysis on the ICERs as expressed in \$ per one patient maintained in target range compared to the base case ICER for PoCT**

Test	Selected variables	Costs per patient maintained in target range (\$)
INR	Base ICER	Dominated*
	GP consultations – Upper 95% CI	Dominated*
	GP consultations – Lower 95% CI	Dominated*
	Hospital admissions – Upper 95% CI	Dominated*
	Hospital admissions – Lower 95% CI	SW Quadrant**
HbA1c	Base ICER	40
	GP consultations – Upper 95% CI	1,049
	GP consultations – Lower 95% CI	Dominant***
	Hospital admissions – Upper 95% CI	8,579
	Hospital admissions – Lower 95% CI	Dominant***
ACR	Base ICER	Dominant***
	GP consultations – Upper 95% CI	Dominant***
	GP consultations – Lower 95% CI	Dominant***
	Hospital admissions – Upper 95% CI	17,647
	Hospital admissions – Lower 95% CI	Dominant***
Lipids	Base ICER	10,082
	GP consultations – Upper 95% CI	11,691
	GP consultations – Lower 95% CI	8,618
	Hospital admissions – Upper 95% CI	26,120
	Hospital admissions – Lower 95% CI	Dominant***

\* Dominated: PoCT was more costly and less effective than laboratory testing

\*\* SW Quadrant: PoCT was less costly and less effective than laboratory testing

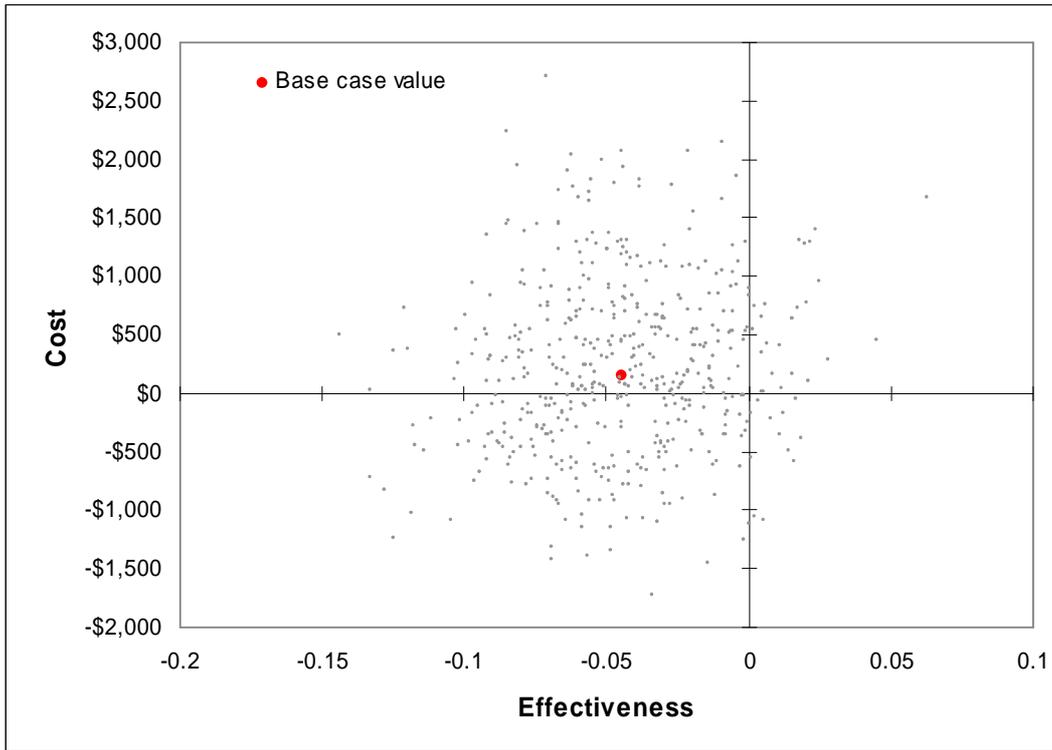
\*\*\*Dominant: PoCT was less costly and more effective than laboratory testing

#### 10.4.4.2. Joint probability distribution of the incremental cost and incremental effectiveness

The joint probability distribution for the incremental costs and incremental effectiveness was modelled for each PoC test. It should be noted that these probability distributions cover all variables considered in the base case ICERs, including hospitalisation costs. The results are shown in Figure 35 to Figure 38.

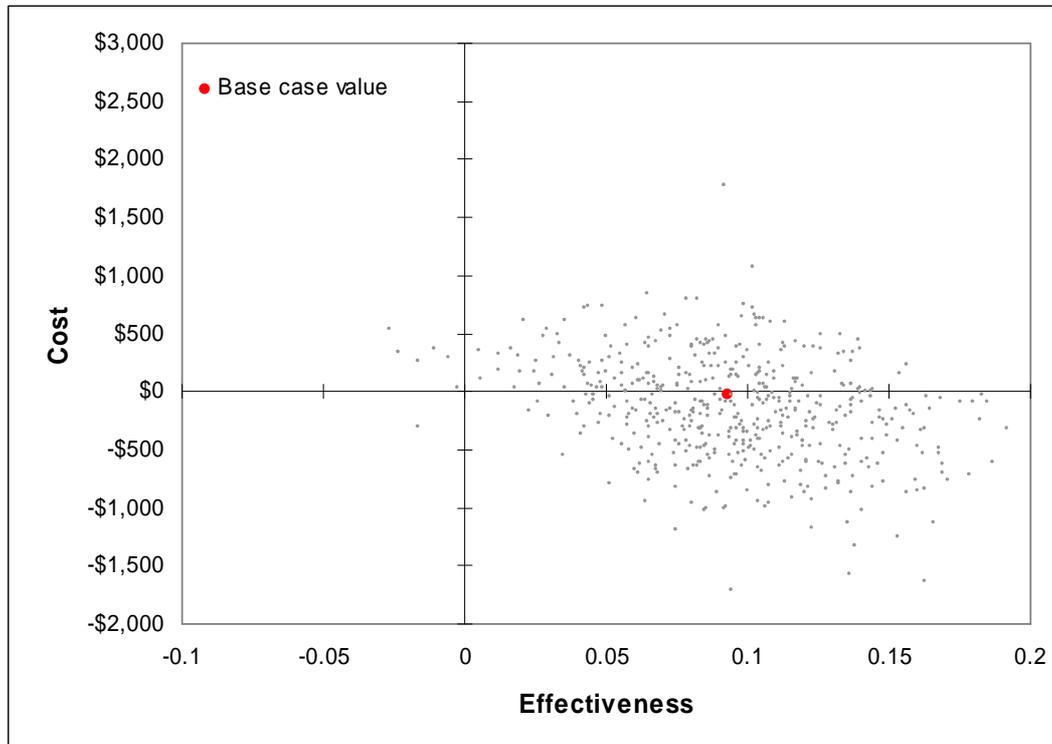
The joint probability distribution for INR is rather diffuse with all but a small proportion lying either within the north-west (55.2%) or south-west (37.4%) quadrants of the ICER plane (Figure 35).

**Figure 35: Joint probability distribution for INR**



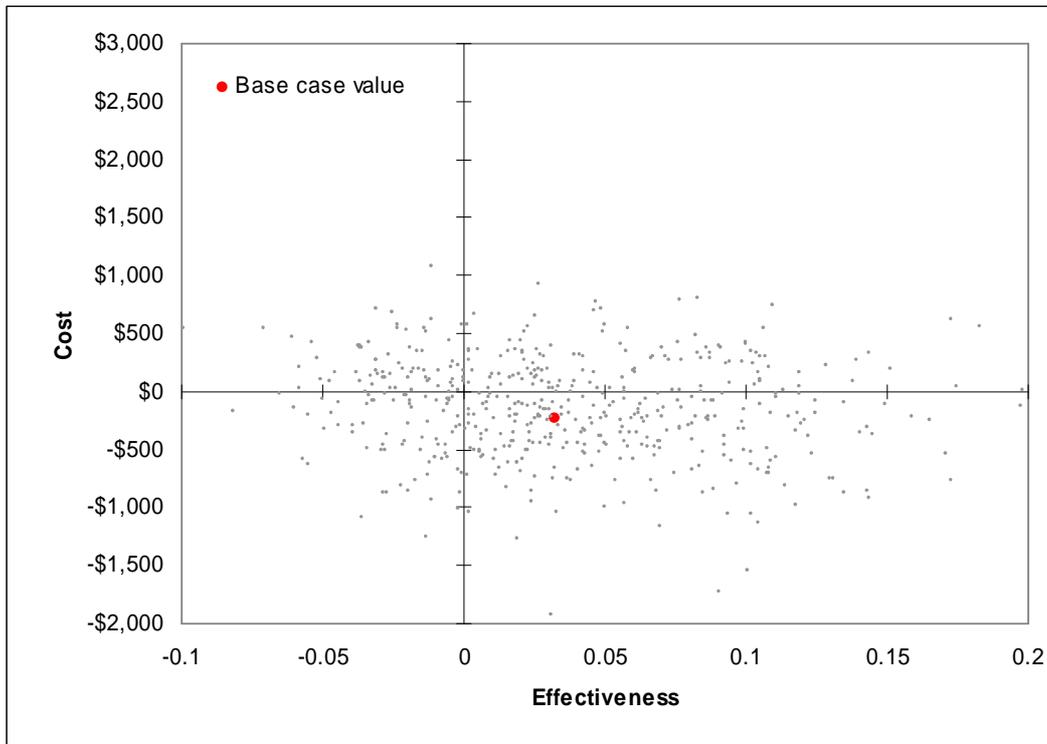
For HbA1c, virtually all the joint probability distribution lies within the north-east (36.4%) or south-east (62.2%) quadrants (Figure 36). Estimates in the south-east quadrant dominate their comparator.

**Figure 36: Joint probability distribution for HbA1c**



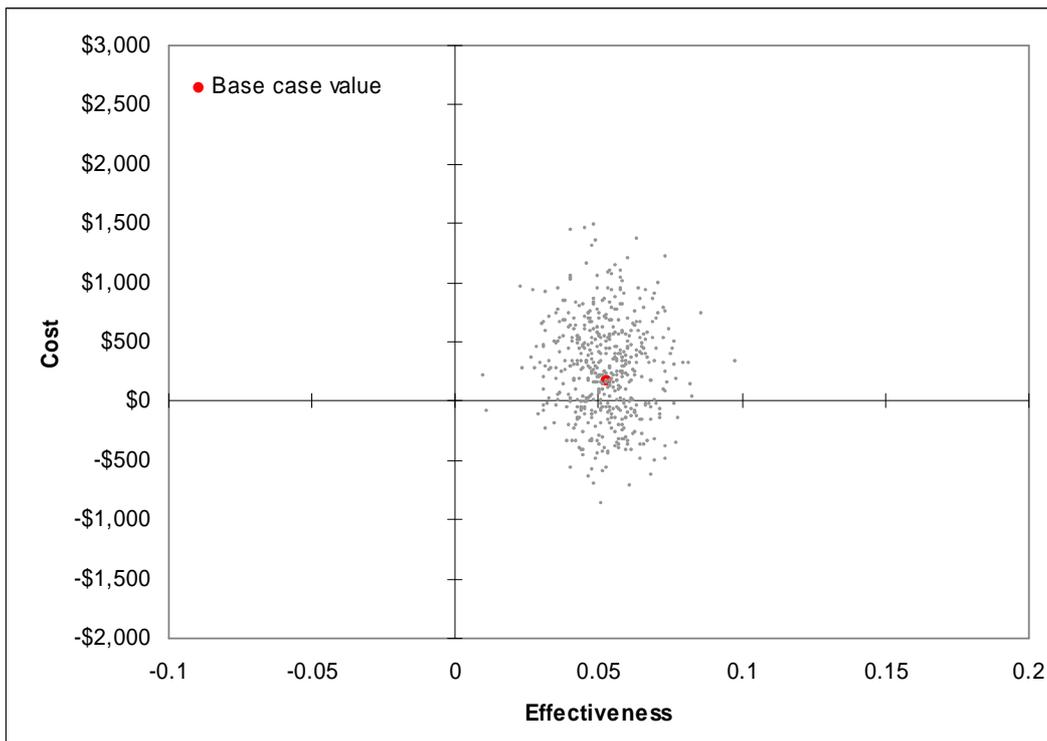
For ACR testing, the joint probability distribution is somewhat diffuse (Figure 37). Although 47.4% of the bootstrapped results lie in the quadrant that dominates, 27.6% of the distribution lies in the north-west or south-west quadrants.

**Figure 37: Joint probability estimate for Albumin creatinine ratio**



For lipid testing, 28.2% of the joint probability distribution lies in the dominant quadrant (Figure 38). All the remaining distribution lies in the north-east quadrant (71.8%) indicating a trade-off between incremental costs and incremental effectiveness.

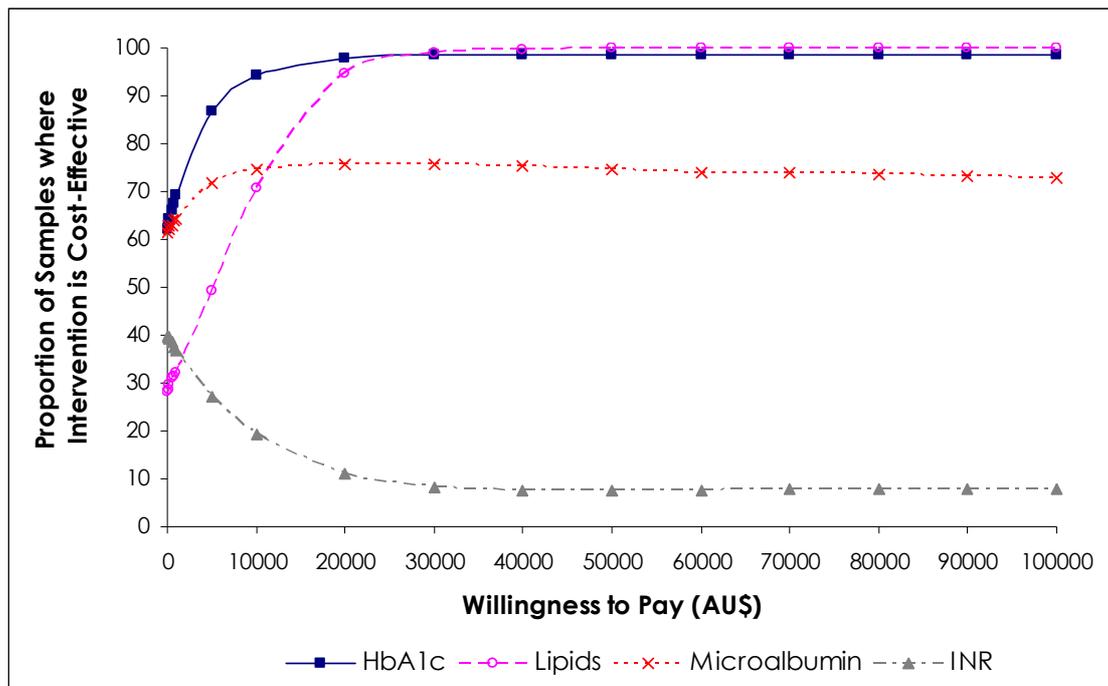
**Figure 38: Joint probability distribution for lipids**



### 10.4.4.3. Cost-effectiveness acceptability curves

The cost-effectiveness acceptability curve (CEAC) represents the proportion of the joint probability density of incremental costs and incremental effects that would be considered cost-effective for differing values of the decision-maker's incremental cost-effectiveness threshold. The CEACs for each PoC test is shown in Figure 39.

**Figure 39: Cost-effectiveness acceptability curves for PoCT compared with laboratory testing for INR, HbA1c, ACR and Lipids**



Bearing in mind that the incremental effectiveness indicator used in this study is not the usual life-year gained or QALY gained, it does appear that the HbA1c and lipids testing would be considered cost-effective if the decision-maker had an incremental cost-effectiveness threshold of \$20,000 or more per patient whose therapeutic range was within the normal clinical range at the end of the Trial, but that the result for microalbumin is more equivocal and the result for INR testing is discouraging.

## 10.5. DISCUSSION

This aspect of the Trial focused on evaluating the costs per patient and the incremental cost-effectiveness of implementing PoCT in general practice compared to laboratory testing for INR, HbA1c, ACR and lipids (total cholesterol, triglycerides and HDL-C) within a time horizon of 18 months. In terms of point estimates of the costs per patient, ACR testing using PoCT was less costly compared to laboratory testing both overall and to the health care sector. For the remaining tests, INR, HbA1c and lipids, PoCT was more costly per patient than laboratory testing, both overall and to the health care sector. All four PoC tests led to savings for patients and their families and reductions in indirect costs, though of a small magnitude.

These incremental costs per patient were most sensitive to differences in the costs of hospitalisations and somewhat sensitive to differences in the costs of GP consultations, pharmaceuticals and allied health visits.

The patient and family costs were not of sufficient magnitude to have much influence on the overall results. It is noteworthy that 91% of patients in the Trial held health care cards or were pensioners. At the same time, two-thirds of the practices were based in rural and remote areas

and a majority of the urban practices were in lower socio-economic status areas. This meant that most Medicare items used in the Trial were bulk-billed so that patients did not make a co-payment.

### *INR*

The results of the base case analysis found INR to be both less effective and more costly. In sensitivity analyses using 95% CIs for the two variables found to be most sensitive (GP consultations and hospital admissions) the ICER was in the north-west or the south-west quadrants. Most of the joint probability distribution for INR was in the north-west or south-west quadrants. This indicates that this test is unlikely to be recommended on cost-effectiveness grounds. The circumstances under which the test was used need to be re-examined to ensure its use is optimised.

### *HbA1c*

The results of the cost-effectiveness analysis for HbA1c placed virtually all of the joint probability distribution within the north-east (trade-off) or south-east (dominant) quadrants. Although this result is somewhat favourable, any recommendation to implement this test using PoCT would depend on the value society would place on maintaining a patient within the target range. Estimates in the north-east quadrant indicate a trade-off between incremental cost and incremental effectiveness. It may be worthwhile modelling the results using a longer time horizon and a final health outcome indicator such as the quality adjusted life year (QALY) if this is feasible.

### *ACR*

Although the point estimate of the ICER for ACR was in the dominant quadrant, the joint probability distribution was somewhat diffuse suggesting that before a positive policy recommendation can be made, more precision in the estimate of incremental cost-effectiveness is required.

### *Lipids*

For lipid testing, the point estimate of the ICER lies within the NE quadrant as does most of its joint distribution, indicating a trade-off between incremental costs and incremental effectiveness. As the incremental effectiveness is not expressed in life-years gained or QALYs, it is uncertain whether the trade-off involved would be acceptable to the policy maker.

The results of the cost-effectiveness analysis for Lipids indicated that the variability of these tests lay mainly in the NE quadrant where PoCT was both more costly and more effective. Thus, the implementation of these tests using PoCT would depend on the value society would place on maintaining a patient within the target range. It may be worthwhile modelling the results using a longer time horizon and a final health outcome indicator such as the QALY.

### *Comparing the Trial results with other literature*

Comparing the results of the cost and the cost-effectiveness analyses for this Trial with other studies is difficult because of the lack of research into the cost-effectiveness associated with PoCT in a general practice setting.<sup>21, 33, 59, 62, 64, 67, 183</sup> The studies that do exist are also limited in their scope and design. The most common analyses were cost comparisons of PoCT used in GP clinics as part of a wider intervention and comparing this with care provided in a hospital clinic. Only one study directly compared PoCT in general practice with usual care using laboratory testing.<sup>33</sup> Few studies looked at cost-effectiveness.<sup>21, 59, 67</sup> and only one reported the incremental cost effectiveness ratio.<sup>59</sup>

The Trial showed the INR PoCT strategy to be dominated by laboratory testing. This result differed from a Belgian study which found that the use of a PoCT device for anticoagulant management combined with a multifaceted education intervention was dominant to usual care in general practice.<sup>59</sup> However, the inclusion of an education program in the Belgian intervention makes direct comparison with the Australian PoCT Trial results difficult. The ICER for the intervention using PoCT was also dominant to the other interventions in the study which did not use PoCT, suggesting the importance of PoCT in this result.

Anticoagulant management in general practice, using PoCT, was also found to be more costly by Parry et al.<sup>21</sup> This UK study investigated the cost-effectiveness of PoCT, using data obtained through an RCT of PoCT and a computerised decision support to manage anticoagulation therapy in general practice. It found that the costs per patient per year were significantly higher in primary care than in hospital based clinics because of the less efficient use of fixed costs. While sensitivity analysis showed that costs to primary care could be reduced, they still remained higher than secondary care. The cost drivers were clinic sizes and the number of visits. The reduced cost to patients and their families using PoCT for anticoagulant management found in this study confirmed a previous study by Parry et al.<sup>67</sup> In contrast, another study which investigated HbA1c PoCT in a GP setting found no differences in patient borne costs between the intervention and control group (laboratory testing).<sup>33</sup>

The results for HbA1c from this Trial are congruent with work undertaken in the UK by Khunti et al.<sup>33</sup> This small study assessed the effect and cost of using PoCT for HbA1c testing in the management of Type 2 diabetes in general practice. They found no difference in the total cost for diabetes care using PoCT compared with laboratory testing. While Khunti et al. could not conclude that PoCT led to cost savings in managing people with Type 2 diabetes, the data did show a trend to cost savings that has been confirmed by the much larger PoCT Trial. There are no studies about the comparative costs and cost-effectiveness of PoCT for ACR or lipids in a general practice setting.

### *Limitations*

As would be expected, this cost-effectiveness analysis had a number of limitations. Firstly, the Trial used an intermediate outcome indicator in the ICER, namely the proportion of patients maintained within the target range. This indicator is specific to this particular trial and not immediately generalisable. As the incremental effectiveness is not expressed in life-years gained or QALYs gained, it is uncertain how to interpret whether the trade-offs involved would be acceptable to the policy maker.

Additionally, the short duration of the Trial may have limited the identification of any clear health gains which in turn would influence the ICER. These issues could be addressed by using modelled data to extend the length of the analysis<sup>184</sup> and applying other health outcome measures, but this was beyond the scope of the Trial specification. However, there may well be considerable uncertainty in extrapolating what occurred in the short-term over a life span.

Secondly, a number of limitations arose from using Medicare data to estimate costs and volumes. Medicare data were used to determine the volume of tests used in the costing analysis because analysis of the data provided directly from the practices and Pathology Providers indicated under-reporting of results, particularly for the control group (see Section 0). However, with Medicare data the number of tests claimed is not identifiable by type of medical practitioner and so the proportion of tests requested by GPs versus other specialists could not be identified.

Thirdly, the wide range of confidence intervals suggests that the Trial may have been underpowered for measuring costs. The point estimates derived are not necessarily generalisable to another sample.

Fourthly, PBS data has a number of drawbacks.<sup>185</sup> The data from the PBS provides incomplete drug utilisation history as only scripts priced over the co-payment threshold are recorded. However, as the PBS was used for both arms of the Trial, these limitations would apply to both groups.

## **10.6. CONCLUSION**

This is the first study to undertake a cost-effectiveness analysis into PoCT in general practice alongside a RCT comparing four types of tests. The results add to the small body of work in this area. Cost-effectiveness is useful in comparing a range of options and in this Trial it clearly showed that providing microalbumin testing using a PoCT device was cost-effective, thereby providing evidence to support its implementation in general practice in Australia. On the other hand, INR was not cost-effective. While the results provide valuable information about the benefits and costs

for PoCT in general practice, other factors need to be considered when determining whether PoCT should be implemented in Australian general practice.<sup>184</sup> For example, GP, Device Operator and patient satisfaction with PoCT, its impact on GP management and improved adherence to medications by intervention patients, which have been demonstrated in other parts of the Trial may influence the decision to support PoCT.



## 11. PARTICIPANT SATISFACTION WITH PoCT

### SUMMARY OF CHAPTER

This chapter describes the methodology and results of the analysis focused on participants' attitudes and satisfaction with PoCT.

The method of analysis for participants' attitudes used statements from the Baseline and Satisfaction Questionnaires, as measured by the Visual Analogue Score (VAS). Between and within-group analysis of attitudes was undertaken for GPs and patients. The analysis for participants' satisfaction used statements from the Satisfaction Questionnaire, as measured by the VAS. For all statements analysis was performed using a mixed model analysis of variance (ANOVA).

The key findings are:

- from baseline, intervention GPs reported a greater change in attitudes to all statements compared to the control GPs, with a majority of the statements (5 out of 9) reaching statistical significance ( $p < 0.05$ ). In particular, intervention GPs agreed more strongly than control GPs that PoCT would help with disease management, would not interrupt patient flow or add time to the consultation
- for all attitude statements, intervention patients showed a higher level of agreement compared to control patients, although for only one statement did the difference reach statistical significance ( $p < 0.0001$ )
- for Device Operators, there was no significant change in attitudes to PoCT from the commencement to the end of the Trial, except in the area of quality control, which they found more time-consuming at the completion of the Trial ( $p = 0.0012$ )
- Pathology Providers' attitudes did not alter by the end of the Trial and they were non-committal in their views about the analytical quality of PoCT or having PoCT in general practice
- intervention GPs on average were more satisfied with PoCT compared to control GPs, particularly for the usefulness of clinical practice ( $p = 0.0097$ ) and confidence in PoCT results ( $p = 0.0022$ )
- for all statements measuring patient satisfaction, the intervention group showed a greater level of satisfaction compared to the control group, with all but one statement reaching statistical significance ( $p < 0.05$ )
- Device Operators indicated high levels of satisfaction with PoCT
- Pathology Providers indicated low levels of satisfaction with PoCT.

The key conclusion:

- results supported patient, GP and Device Operator acceptability of PoCT in a general practice setting.

### 11.1. INTRODUCTION

The attitudes of the key stakeholders and their satisfaction with PoCT form an important part of the assessment of introducing PoCT in general practice. These stakeholders include patients, GPs, practice staff and pathology laboratories. PoCT may lead to greater convenience for GPs and patients, but result in greater costs and require organisational changes that may reduce stakeholder satisfaction.

Patient satisfaction and acceptability of PoCT in a general practice setting has not been widely studied. From the available evidence, the findings are mixed with some studies suggesting

patients' preference for PoCT<sup>23, 65</sup> and improved satisfaction with their health care after the introduction of PoCT,<sup>68,70, 74</sup> while other studies have found no significant difference.<sup>45, 60</sup> There have been two randomised trials that have examined patient acceptability and satisfaction with PoCT in a general practice setting.<sup>60,18</sup>

General practitioner and nurse satisfaction with PoCT is also important but there are mixed findings regarding the acceptability and satisfaction of PoCT. Thus GP and practice staff acceptability of PoCT is unclear.

Overall, most studies have found that patients and health professionals find PoCT useful and acceptable with health professional concerns related to the cost and the time of undertaking such a service.

## 11.2. AIMS AND OBJECTIVES

The aim of this section of the Trial was to address the research question: 'Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?' To answer this question the Trial evaluated the satisfaction and attitudes of the key stakeholders (patients, GPs, Device Operators and Pathology Providers) with PoCT in a number of areas including convenience, quality of process, role in consultation and patient disease management.

The hypotheses being investigated for attitudes to and satisfaction with PoCT are as follows:

### Attitude Hypotheses

- |                    |   |
|--------------------|---|
| GP                 | The average change in attitudes in GPs from PoCT practices is different to the average change in attitudes in GPs from control practices.           |
| Patient            | The average change in attitudes in patients from PoCT practices is different to the average change in attitudes in patients from control practices. |
| Device Operator    | Device Operators report a change in average attitudes.  |
| Pathology Provider | Pathology Providers report a change in average attitudes.   |

### Satisfaction Hypotheses

- |                    |  |
|--------------------|--|
| GP                 | The average level of satisfaction with PoCT of GPs from PoCT practices is different to the average level of satisfaction with PoCT of GPs from control practices.  |
| Patient            | <p>The average level of satisfaction with regard to the collection process in intervention patients is different to the average level of satisfaction with regard to the collection process in control patients.</p> <p>The average level of confidence in the process in intervention patients is different to the average level of confidence in the process in control practices.</p> <p>The average level of confidence in the results in intervention patients is different to the average level of confidence in the results in control patients.</p> <p>The average level of satisfaction with regard to convenience in intervention patients is different to the average level of satisfaction with regard to convenience in control patients.</p> <p>The average level of satisfaction with regard to cost in intervention patients is different to the average level of satisfaction with regard to cost in control patients.</p> <p>The average level of satisfaction with regard to disease management in intervention patients is different to the average level of satisfaction with regard to disease management in control patients.</p> |
| Device Operator    | Device Operators are satisfied with PoCT.  |
| Pathology Provider | Pathology Providers are satisfied with PoCT.   |

### 11.3. METHODS

Two questionnaires were developed to answer the research question. Baseline and Satisfaction Questionnaires were designed for the following participants in the Trial:

- Patients
- General Practitioners
- Device Operators
- Pathology Providers associated with the Trial

The Baseline Questionnaire asked participants to indicate how strongly they agreed/disagreed with various statements concerning their satisfaction, acceptability and attitudes towards PoCT with questions tailored for each participant group. The Satisfaction Questionnaire included questions from the Baseline Questionnaire to determine the change in attitudes and specific questions regarding satisfaction with PoCT for the intervention group.

Participants were asked to indicate how strongly they agreed/disagreed with various statements concerning their satisfaction and attitudes towards PoCT using a Visual Analogue Scale (VAS). A VAS is a horizontal line, 10 centimetres in length with the left end labelled as 'strongly disagree' and the right end labelled as 'strongly agree'. Participants mark on the line the point they feel represents their attitude or level of satisfaction.

The methods, results and response rates for the Baseline Questionnaire are presented in Chapter 4 under Baseline Characteristics.

#### 11.3.1. Satisfaction Questionnaire pilot

Two practices participated in piloting the Satisfaction Questionnaire. Both practices were located on the Yorke Peninsula, South Australia. Practice personnel and patients were invited to complete the questionnaires and provide feedback regarding any item that was either unclear or confusing, or that could be improved on.

- The results of the Satisfaction Questionnaire pilot are as follows:
- three GPs completed the GP Satisfaction Questionnaire and feedback sheet
- one practice nurse completed the Device Operator Satisfaction Questionnaire and feedback sheet; and
- one patient completed the Patient Satisfaction Questionnaire and feedback sheet.

Members of the Trial Management Committee were also invited to provide feedback regarding the questionnaires and any modifications were made prior to mail out.

The questionnaires were also approved by the University of Adelaide, RACGP, Monash University, University of Sydney and the Department of Health and Ageing Ethics Committees.

#### 11.3.2. Survey mail out

All patients, practice personnel and Pathology Providers were sent the Satisfaction Questionnaire at the end of the Trial (30th April 2007).

To maximise the response rate, the Dillman Method<sup>87</sup> was used which included:

- initial mail out of the questionnaire to all participant groups

- follow-up reminder using a flyer to all non-responders
- final reminder to non-responders with a copy of the questionnaire
- Node Support Officers assisted in following up outstanding GP and Device Operator questionnaires.

### 11.3.3. Response rate

The response rates for each stakeholder group are outlined in Table 180. The response rate is calculated on all participants who were sent the questionnaire and excludes participants who withdrew or died prior to dissemination.

The lowest response rate was from the Pathology Providers (64%). Sixty one certified Device Operators were sent a questionnaire; however, six did not complete it as they had not participated in operating any of the PoCT devices.

**Table 180: Response rate for satisfaction questionnaires**

Participant Group	No. of Satisfaction Questionnaires Disseminated	No. of Satisfaction Questionnaires Received	Response Rate Based on Number of Questionnaires Disseminated (%)
Patients (excludes ineligible)	4573	4022	87.95%
General Practitioners	189	167	88.36%
Device Operators	61	55	90.16%
Pathology Providers	22	14	63.64%

### 11.3.4. Statistical analysis of the change in participants' attitudes and satisfaction (patients, GPs, Device Operators and Pathology Providers)

To answer each hypothesis relating to the change in participant attitudes, a number of questions from the Baseline and Satisfaction Questionnaires were used. The outcomes of interest were scored relating to each of the questions, as measured by the VAS, and each participant could have up to two outcomes for each question corresponding to the two questionnaires disseminated. To answer each hypothesis relating to participant satisfaction, a number of questions from the Satisfaction Questionnaires were used. The outcomes of interest were scored relating to each of the questions, as measured by the VAS.

Since the data were not normally distributed, a Box-Cox or log transformation was applied. For some questions, the data were negatively skewed and hence needed to be reflected before the transformation was applied. Details of data reflections and transformations are given in Appendix 34. In the raw data, a larger value indicates a *higher* level of agreement with the statement of interest. In the transformed data, if the data were not reflected then a larger value also indicates a *higher* level of agreement. However, if the data were reflected then a larger value indicates a *lower* level of agreement.

For change in participants' attitude the analysis was performed for each question separately using a mixed model ANOVA. For patients, GPs and Device Operators, allowance was made for clustering at both the practice and participant level. For Pathology Providers, allowance was made for clustering at the participant level only. For participant satisfaction the analysis was performed for each question separately using a mixed model ANOVA with allowance for clustering at the practice level. Treatment group was included in the model to allow the mean to be compared between treatment groups. For GP, Device Operator and Pathology Provider attitudes, only unadjusted analyses were performed. For GP satisfaction, only unadjusted analyses were

performed. For patients' attitudes and satisfaction both unadjusted and adjusted analyses (with adjustment for age at consent and gender) were performed; however, only the adjusted results are presented.

The Hawthorne effect describes a change to behaviour, usually the response being an improvement, simply by participating in a study or trial. Intervention and control GPs were asked a range of questions relating to satisfaction at both baseline and follow-up to investigate the effect of the availability of PoCT devices for patient care on GP satisfaction. Statistical analysis was performed to determine whether the change in satisfaction from baseline differed between intervention and control GPs. Since control GPs were not given PoCT devices, changes in satisfaction from baseline in this group represent changes due to being involved in the study (and possibly changes in knowledge etc.). Interest is therefore in determining whether the change in satisfaction in the intervention group differs from the change in the control group, since this would suggest that satisfaction in the intervention group is being influenced by factors other than the Hawthorne effect. Any differences in the change in satisfaction from baseline between intervention and control GPs is then assumed to be attributable to the availability of the PoCT devices for patient care.

#### *Patient and GP attitudes*

Treatment group, time (baseline or follow-up) and an interaction between treatment group and time were included in the model to allow the difference in means (follow-up – baseline) to be compared between treatment groups and the mean at each time point to be compared within each treatment group.

In order to conclude that PoCT is different to pathology laboratory testing in relation to the change in mean transformed VAS score, the 95% confidence interval for the difference (intervention-control) must not contain 0. Alternatively, the p-value must be <0.05.

#### *Patient and GP satisfaction*

In order to conclude that PoCT is different to pathology laboratory testing in relation to the mean transformed VAS score, the 95% confidence interval for the difference (intervention-control) must not contain 0. Alternatively, the p-value must be <0.05.

#### *Device Operator and Pathology Provider attitudes*

Time (baseline or follow-up) was included in the model to allow the mean at each time point to be compared.

In order to conclude that there has been a change compared to baseline in relation to the mean transformed VAS score, the 95% confidence interval for the difference (follow-up - baseline) must not contain 0. Alternatively, the p-value must be <0.05.

#### *Device Operator and Pathology Provider satisfaction*

Descriptive statistics (medians and inter-quartile ranges) were calculated for each question. No analysis was performed as there was no comparison group.

## **11.4. RESULTS**

The following sections report the results of the four groups of participants. The data are presented by treatment group and geographic area. VAS scores indicate the level of agreement with the statement. Agreement relates to either satisfaction or attitudes to various statements.

## 11.4.1. Change in participants' attitudes

### 11.4.1.1. Patients

The change in patient attitude analysis investigated differences in the change in average attitudes towards PoCT between the two treatment groups (between-group comparisons) and differences within the treatment groups between baseline and follow-up (within-group comparisons). Three statements from the Patient Baseline and Satisfaction Questionnaires were used for the analysis.

Not all patients were included in the analysis due to missing outcome data. There were a slightly higher percentage of patients excluded from the analysis in the intervention group compared to the control group (approximately 4% and 6% respectively, depending on the statement of interest); however, this was largely due to patients from intervention practices that withdrew from the Trial and hence these patients were not sent questionnaires. The nature of the missingness was investigated and the missing outcomes are not expected to bias the results.

#### *Between-group comparisons*

Based on the adjusted analysis, the change in mean transformed VAS score from baseline for the statement 'I would prefer to have my test done at the time of consultation' was similar in the intervention and control groups, with no significant difference between-groups detected ( $p=0.6619$ ) (Table 181). The change in mean transformed VAS score from baseline for the statement 'Not having to wait for test results would ease my anxiety' was similar in the intervention and control groups with no significant difference between-groups detected ( $p=0.5843$ ). The change in the mean transformed VAS score from baseline was significantly different in the intervention group compared to the control group for the statement 'I would prefer tests to be done by/on behalf of my own GP at his/her practice' ( $p<0.0001$ ). The unadjusted analysis confirms these results.

**Table 181: Between-group comparisons for a change in patient attitude by treatment group**

Statement	Change in mean transformed VAS score from baseline (intervention)	Change in mean transformed VAS score from baseline (control)	Difference (intervention - control)	95% confidence interval for difference	P-value
I would prefer to have my tests done at the time of consultation	-0.27	-0.25	-0.02	-0.11, 0.07	0.6619
Not having to wait for test results would ease my anxiety	-0.61	-0.58	-0.03	-0.12, 0.07	0.5843
I would prefer tests to be done by/on behalf of my own GP at his/her practice	-0.01	0.19	-0.20	-0.29, -0.12	<0.0001

*Note: A lower score indicates a higher level of agreement*

#### *Within-group comparisons*

There was very strong evidence of a decrease in the mean transformed VAS score between baseline and follow-up within each treatment group for the statement 'I would prefer to have my tests done at the time of consultation' ( $p<0.0001$  in both cases) (Table 182).

There was evidence of a decrease in the mean transformed VAS score (e.g. increased level of satisfaction) between baseline and follow-up within each treatment group for the statement 'Not having to wait for test results would ease my anxiety' ( $p < 0.0001$  in both cases) (Table 182).

There was no evidence of a change in the mean transformed VAS score from baseline within the intervention group for the statement 'I would prefer tests to be done by/on behalf of my own GP at his/her practice' ( $p = 0.6159$ ) but there was a significant increase in the mean transformed VAS score in the control group corresponding to a reduction in the level of agreement with the statement compared to baseline ( $p < 0.0001$ ) (Table 182).

**Table 182: Within-group comparisons for a change in patient attitude by treatment group**

Attitude statements	Treatment group	Mean transformed VAS score at baseline	Mean transformed VAS score at follow-up	Difference (follow-up - baseline)	95% confidence interval for difference	P-value
I would prefer to have my tests done at the time of consultation	Intervention	0.44	0.17	-0.27	-0.32, -0.21	<0.0001
	Control	0.71	0.46	-0.25	-0.31, -0.18	<0.0001
Not having to wait for test results would ease my anxiety	Intervention	0.79	0.18	-0.61	-0.67, -0.55	<0.0001
	Control	1.15	0.57	-0.58	-0.65, -0.51	<0.0001
I would prefer tests to be done by/on behalf of my own GP at his/her practice	Intervention	0.26	0.24	-0.01	-0.07, 0.04	0.6159
	Control	0.36	0.55	0.19	0.12, 0.26	<0.0001

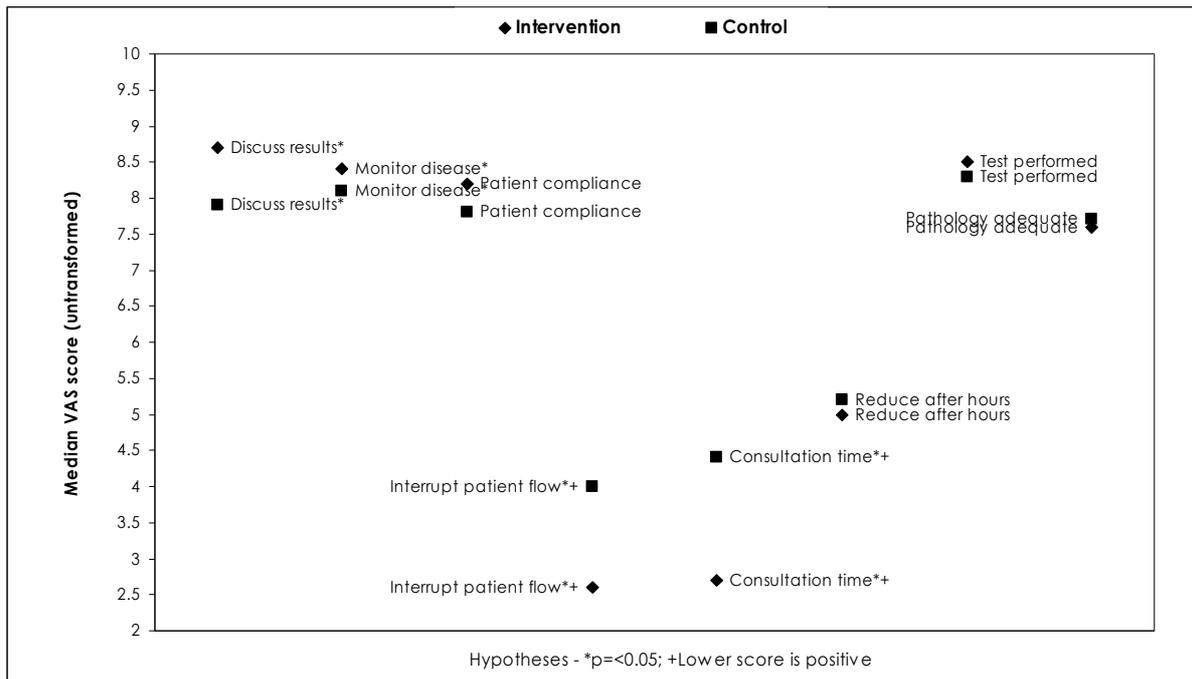
*Note: A lower score indicates a higher level of agreement*

#### 11.4.1.2. General Practitioners

The change in GP attitudes analysis investigated differences in the change in attitudes to PoCT between the two treatment groups (between-group comparisons) and differences within the treatment groups between baseline and follow-up (within-group comparisons). Nine statements from the GP Baseline and Satisfaction Questionnaires were used for the analysis which have been grouped into three categories; disease management, work flow and testing.

There was missing outcome data at baseline and/or follow-up for approximately 33%-36% of GPs (depending on the statement of interest). There was a higher percentage of GPs with complete data in the control group (approximately 69%) compared to the intervention group (approximately 62%) for all statements of interest. This was largely due to GPs from intervention practices that withdrew from the Trial and hence were not sent a questionnaire. The nature of the missingness was investigated and there was evidence to suggest that the missing data were not missing completely at random. Multiple imputation was used to impute the missing (transformed) values using firstly the MCMC method to produce a monotone missing data pattern and secondly the regression method. Analysis was performed on each of 10 completed datasets and the results were combined. A summary of results for GP attitude statements is presented in Figure 40.

**Figure 40: Mean VAS score by treatment group for GP attitude statements**



*Between-group comparisons*

The category 'disease management' consists of four statements: 'It is helpful to have pathology results at the time of consultation'; 'PoCT would allow me to discuss with the patient the implications of the result when it is foremost in both our minds'; 'PoCT would help me monitor disease' and 'PoCT would contribute to patient compliance'. For each of the first three statements there was strong evidence to suggest that the change in mean transformed VAS satisfaction score from baseline was different between the intervention and control groups ( $p=0.0076$ ;  $p=0.0314$  and  $p=0.0154$  respectively) (Table 183). While there was some evidence of a difference in the change in mean transformed VAS score from baseline between treatment groups for the fourth statement this did not reach statistical significance ( $p=0.0636$ ) (Table 183).

The second category 'work flow' consists of three statements: 'PoCT would interrupt patient flow through my practice'; 'PoCT would add too much time to the consultation' and 'PoCT would reduce my after hours workload'. For each of the first two statements strong evidence was found to suggest that a change in mean transformed VAS score from baseline was different between the intervention and control groups ( $p<0.0001$  in both cases) (Table 183). For the third statement there was no evidence that the change in the mean transformed VAS score from baseline was different between the intervention and control groups ( $p=0.9735$ ) (Table 183). The final category relates to 'testing' and consists of two statements: 'PoCT would ensure that the test I request is done' and 'current external pathology arrangements are adequate'. For both statements there was no evidence to suggest that the change in the mean transformed VAS score from baseline was different between the intervention and control groups ( $p=0.3449$  and  $p=0.1537$  respectively) (Table 183).

Where there is evidence of a difference in the change in mean transformed VAS score from baseline between treatment groups, the nature of this difference can be explained by examining the within-group comparisons.

**Table 183: Between-group comparisons for a change in GP attitude by treatment group**

Category	Attitude statements	Change in mean transformed VAS score from baseline (intervention)	Change in mean transformed VAS score from baseline (control)	Difference (intervention - control)	95% confidence interval for difference	P-value
Disease Management	It is helpful to have pathology results at the time of consultation	-0.37	0.25	-0.62	-1.07, -0.17	0.0076
	PoCT would allow me to discuss with the patient the implications of the result when it is foremost in both our minds	-0.29	0.19	-0.48	-0.91, -0.04	0.0314
	PoCT would help me monitor disease	-0.16	0.34	-0.50	-0.90, -0.10	0.0154
	PoCT would contribute to patient compliance	-0.32	0.09	-0.41	-0.85, -0.02	0.0636
Work Flow	PoCT would interrupt patient flow through my practice	-0.49	0.59	-1.08	-1.57, -0.59	<0.0001
	PoCT would add too much time to the consultation	1.64	-1.07	2.71	1.76, 3.66	<0.0001
	PoCT would reduce my after hours workload	-0.35	-0.36	0.01	-0.71, 0.73	0.9735
Testing	PoCT would ensure that the test I request is done	-0.25	-0.03	-0.22	-0.69, 0.25	0.3449
	Current external pathology arrangements are adequate	-0.22	0.12	-0.34	-0.81, 0.13	0.1537

Note: A lower score indicates a higher level of agreement except for the statement 'PoCT would interrupt patient flow through my practice', where a higher score indicates a higher level of agreement

### *Within-group comparisons*

As shown in Table 184 for three of the statements relating to disease management: 'It is helpful to have pathology results at the time of consultation'; 'PoCT would allow me to discuss with the patient the implications of the result when it is foremost in both our minds' and 'PoCT would contribute to patient compliance' there was strong evidence of a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs, indicating that these GPs agreed more strongly with these statements at follow-up compared to baseline ( $p=0.0210$ ;  $p=0.0473$  and  $p=0.0425$  respectively). In contrast, the mean transformed VAS score increased from baseline for control GPs for each of these statements, although they did not reach statistical significance ( $p=0.1198$ ;  $p=0.2561$  and  $p=0.5525$  respectively). While there was a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs for the other statement relating to disease management; 'PoCT would help me monitor disease', this did not reach statistical significance ( $p=0.2325$ ). In contrast, there was strong evidence of an increase in the mean transformed VAS score from baseline for control GPs, indicating that these GPs disagreed more strongly with the statement at follow-up compared to baseline ( $p=0.0301$ ) (Table 184).

As shown in Table 184 for the first statement relating to work flow 'PoCT would interrupt patient flow through my practice' there was strong evidence of a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs, indicating that these GPs disagreed more strongly with the statement at follow-up compared to baseline ( $p=0.0024$ ). In contrast, there was strong evidence of an increase in the mean transformed VAS score between baseline and follow-up among the control GPs, indicating that these GPs more strongly agreed with the statement at follow-up ( $p=0.0025$ ). For the second statement 'PoCT would add too much time to the consultation' there was strong evidence of an increase in the mean transformed VAS score between baseline and follow-up among the intervention GPs, indicating that these GPs disagreed more strongly with the statement at follow-up compared to baseline ( $p<0.0001$ ). In contrast, there was strong evidence of a decrease in the mean transformed VAS score between baseline and follow-up among the control GPs, indicating that these GPs agreed more strongly with the statement ( $p=0.0099$ ) (Table 184). While there was evidence of a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs and control GPs for the last statement 'PoCT would reduce my after hours workload', these did not reach statistical significance ( $p=0.1306$  and  $p=0.1942$  respectively).

There was a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs and control GPs for the first statement relating to testing 'PoCT would ensure that the test I request is done'; however, these did not reach statistical significance ( $p=0.0918$  and  $p=0.8731$  respectively) (Table 184). For the statement 'Current external pathology arrangements are adequate' there was some evidence of a decrease in the mean transformed VAS score between baseline and follow-up among the intervention GPs, suggesting that these GPs agreed more with the statement at follow-up compared to baseline ( $p=0.0554$ ). In contrast, there was no evidence of a change in the mean transformed VAS score between baseline and follow-up among the control GPs ( $p=0.5617$ ) (Table 184).

**Table 184: Within-group comparisons for a change in GP attitude by treatment group**

Category	Attitude statements	Treatment group	Mean transformed VAS score at baseline	Mean transformed VAS score at follow-up	Difference (follow-up – baseline)	95% confidence interval for difference	P-value	
Disease Management	It is helpful to have pathology results at the time of consultation	Intervention	0.05	-0.31	-0.37	-0.68, -0.06	0.0210	
		Control	0.15	0.40	0.25	-0.07, 0.57	0.1198	
	PoCT would allow me to discuss with the patient the implications of the result when it is foremost in both our minds	Intervention	0.53	0.24	-0.29	-0.57, -0.00	0.0473	
		Control	0.43	0.62	0.19	-0.14, 0.52	0.2561	
	PoCT would help me monitor disease	Intervention	0.50	0.34	-0.16	-0.42, 0.10	0.2325	
		Control	0.47	0.81	0.34	0.03, 0.65	0.0301	
	PoCT would contribute to patient compliance	Intervention	0.80	0.48	-0.32	-0.63, -0.01	0.0425	
		Control	0.78	0.87	0.09	-0.22, 0.40	0.5525	
	Work Flow	PoCT would interrupt patient flow through my practice	Intervention	1.63	1.14	-0.49	-0.81, -0.18	0.0024
			Control	1.55	2.13	0.59	0.21, 0.96	0.0025
PoCT would add too much time to the consultation		Intervention	5.83	7.48	1.64	0.99, 2.29	<0.0001	
		Control	6.14	5.07	-1.07	-1.87, -0.26	0.0099	
PoCT would reduce my after hours workload		Intervention	2.85	2.50	-0.35	-0.80, 0.11	0.1306	
		Control	2.87	2.51	-0.36	-0.90, 0.19	0.1942	
Testing	PoCT would ensure that the test I request is done	Intervention	0.62	0.36	-0.25	-0.55, -0.04	0.0918	
		Control	0.67	0.64	-0.03	-0.39, 0.33	0.8731	
	Current external pathology arrangements are adequate	Intervention	1.31	1.09	-0.22	-0.45, -0.01	0.0554	
		Control	1.13	1.24	0.12	-0.30, 0.54	0.5617	

Note: A lower score indicates a higher level of agreement except for the statement 'PoCT would interrupt patient flow through my practice', where a higher score indicates a higher level of agreement

### 11.4.1.3. Device Operators

The analysis to determine the average change in Device Operators' attitudes from baseline to follow-up used three statements from the Device Operator Baseline and Satisfaction Questionnaires.

There was no evidence of a change in the mean transformed VAS score from baseline for the statement 'PoCT is technically difficult to use' ( $p=0.6371$ ). There was some evidence of a change for the statement 'QA requirements for PoCT are time consuming' ( $p=0.0868$ ) and strong evidence of a change for the statement 'QC requirements for PoCT are time consuming' ( $p=0.0012$ ), suggesting that Device Operators agreed more strongly with the statement that QC requirements for PoCT are time consuming at follow-up compared to baseline (Table 185).

**Table 185: Device operators' change in attitudes (unadjusted analysis)**

Attitude statements	Mean transformed VAS score (baseline)	Mean transformed VAS score (follow-up)	Difference (follow-up - baseline)	95% confidence interval for difference	P-value
PoCT is technically difficult to use	0.45	0.37	-0.09	-0.45, 0.27	0.6371
QA requirements for PoCT are time consuming	1.23	0.86	-0.37	-0.80, 0.05	0.0868
QC requirements for PoCT are time consuming	1.50	0.77	-0.73	-1.17, -0.30	0.0012

*Note: a higher score indicates a lower level of agreement except for the statement 'PoCT is technically difficult to use', where a higher score indicates a higher level of agreement.*

### 11.4.1.4. Pathology Providers

The analysis to determine the average change in Pathology Providers' attitudes from baseline to follow-up used three statements from the Pathology Provider Baseline and Satisfaction Questionnaires.

Not all Pathology Providers were included in the analysis due to missing outcome data (approximately 63%). Questionnaires were sent to a selection of pathology organisations (25 at baseline and 22 at follow up) deemed to be representative of the total (33) involved in the Trial and hence not all Pathology Providers were given the opportunity to respond to both questionnaires. During the Trial a number of Pathology Providers either amalgamated or closed down. Of those Pathology Providers included in the analysis, approximately 35%-40% responded to the statement of interest on both the Baseline and the Satisfaction Questionnaires, while approximately 30%-35% provided a response to only one questionnaire (these percentages varied slightly depending on the statement of interest).

There was no evidence of a change in the mean transformed VAS score from baseline for the statements; 'PoCT requires less quality monitoring than testing performed by pathology laboratories', 'PoCT performance should be assisted and monitored by pathology laboratories' and 'PoCT will result in less laboratory testing' ( $p=0.4800$ ,  $p=0.5845$  and  $p=0.1235$  respectively) (Table 186).

Note that due to the relatively low response rates for the two Pathology Provider questionnaires, the available data may not reflect the views of all Pathology Providers involved in the Trial and hence the results of the analysis should be interpreted with caution.

**Table 186: Pathology provider change in attitudes (unadjusted analysis)**

<b>Attitude statements</b>	<b>Mean transformed VAS score (baseline)</b>	<b>Mean transformed VAS score (follow-up)</b>	<b>Difference (follow-up - baseline)</b>	<b>95% confidence interval for difference</b>	<b>P-value</b>
PoCT requires less quality monitoring than testing performed by pathology laboratories	-0.41	-0.12	0.29	-0.64, 1.22	0.4800
PoCT performance should be assisted and monitored by pathology laboratories	-0.01	-0.25	-0.24	-1.25, 0.78	0.5845
PoCT will result in less laboratory testing	1.33	0.80	-0.53	-1.24, 0.19	0.1235

*Note: a higher score indicates a lower level of agreement except for the statement 'PoCT requires less quality monitoring than testing performed by pathology laboratories', where a higher score indicates a higher level of agreement.*

#### 11.4.2. Participant satisfaction analysis

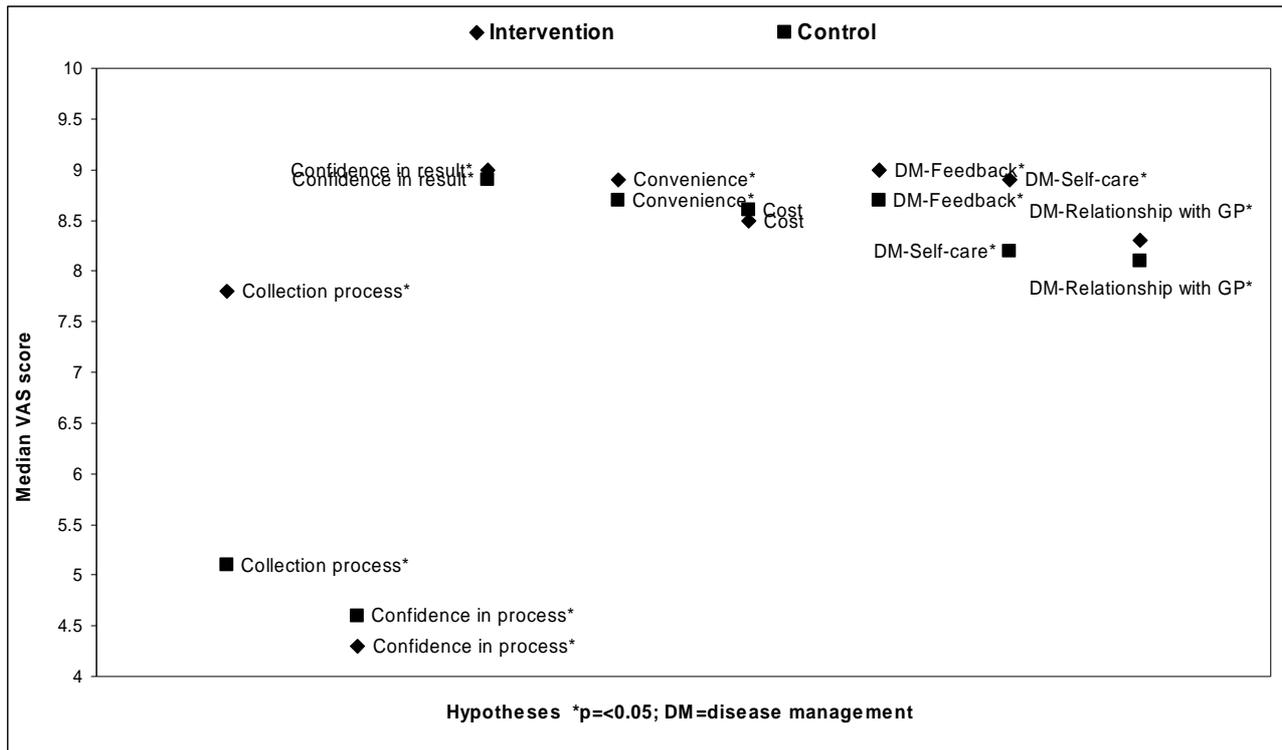
##### 11.4.2.1. Patients

The patient satisfaction analysis investigated differences in the level of agreement with a variety of statements taken from the end of study Patient Satisfaction Questionnaire, between the intervention and control groups. Eight statements from the questionnaire were used for the analyses which address the six hypotheses: collection process, confidence in process, confidence in result, convenience, cost and disease management (Table 187).

There was missing outcome data for approximately 22%-25% of patients (depending on the statement of interest). The percentage of patients with missing data was higher in the intervention group compared to the control group for all statements of interest; however, this was largely due to patients from intervention practices that withdrew from the Trial and hence these patients were not sent a questionnaire. The nature of the missingness was investigated and there was evidence to suggest that the missing data were not missing completely at random. Multiple imputation was used to impute the missing (transformed) values using firstly the MCMC method to produce a monotone missing data pattern and secondly the regression method to fill in the remaining missing values. Analysis was performed on each of 10 completed datasets and the results were combined.

A summary of results for each patient statement is presented in Figure 41. Overall, all statements (except for 'Outside pathology laboratories involves extra time and transport costs') were statistically significant. The three key statements which demonstrated large significant differences between treatment groups in satisfaction were around testing 'I would rather have blood taken by a finger prick than by needle in my arm', and disease management 'Having immediate feedback of the test result for my condition was important as it allowed me to discuss the management of my condition with my GP' and 'I am more motivated to look after my condition because of regular Point of Care Testing'.

**Figure 41: Median VAS satisfaction scores by treatment group for patient satisfaction statements**



For the hypothesis that relates to satisfaction with the collection process, the mean transformed VAS score for the statement 'I would rather have blood taken by a finger prick than by needle in my arm', was significantly lower in the intervention group compared to the control group ( $p < 0.0001$ ). That is, the intervention group agreed more strongly with this statement than the control group (Table 187). The unadjusted analysis confirms this finding.

For the hypothesis that relates to confidence in the process, the mean transformed VAS score for the statement 'Laboratories have better hygiene than point of care testing' was significantly higher in the control group compared to the intervention group ( $p < 0.0001$ ). That is the control patient agreed more strongly with this statement than intervention patients (Table 187). The unadjusted analysis confirms this finding.

For the hypothesis that relates to confidence in the results, the mean transformed VAS score for the statement 'I have confidence in the information given by my GP or practice regarding my pathology test result' was significantly lower (corresponding to a stronger level of agreement) in the intervention group compared to the control group ( $p = 0.0101$ ) (Table 187). The unadjusted analysis confirms this finding.

**Table 187: Between-group comparisons of patient satisfaction**

Hypothesis category	Statement	Mean transformed VAS score (intervention)	Mean transformed VAS score (control)	Difference (intervention - control)	95% confidence interval for difference	P-value
Collection process	I would rather have blood taken by a finger prick than by needle in my arm	0.92	1.64	-0.73	-0.89, -0.57	<0.0001
Confidence in the process	Laboratories have better hygiene than Point of Care Testing	1.65	2.07	-0.43	-0.62, -0.23	<0.0001
Confidence in the results	I have confidence in the information given by my GP or practice regarding my pathology test result	0.06	0.18	-0.12	-0.21, -0.03	0.0101
Convenience	Not having to travel to an outside laboratory would be convenient	0.17	0.36	-0.20	-0.34, -0.05	0.0089
Cost	Outside pathology laboratories involves extra time and transport costs	0.44	0.39	0.06	-0.11, 0.23	0.5108
Disease management	Having immediate feedback of the test result for my condition was important as it allowed me to discuss the management of my condition with my GP	0.12	0.30	-0.18	-0.30, -0.06	0.0027
	I am more motivated to look after my condition because of regular Point of Care Testing	0.29	0.64	-0.36	-0.49, -0.22	<0.0001
	Point of Care Testing strengthened by relationship with my GP	0.52	0.72	-0.20	-0.35, -0.05	0.0104

Note: A lower score indicates a higher level of agreement except for the hypothesis relating to confidence in the process, where a higher score indicates a higher level of agreement

For the hypothesis that relates to convenience, the mean transformed VAS score for the statement 'Not having to travel to an outside laboratory would be convenient' was significantly lower in the intervention group compared to the control group ( $p=0.0089$ ) providing evidence that intervention patients more strongly agreed with the statement on average than control patients (Table 187). The unadjusted analysis confirms this finding.

For the hypothesis that relates to cost, the mean transformed VAS score for the statement 'Outside pathology laboratories involves extra time and transport costs' was similar in both treatment groups ( $p=0.5108$ ) (Table 187). The unadjusted analysis confirms this finding.

For the hypothesis that relates to disease management, three statements from the Patient Satisfaction Questionnaire were analysed: 'Having immediate feedback of the test result for my condition was important as it allowed me to discuss the management of my condition with my GP', 'I am more motivated to look after my condition because of regular Point of Care Testing' and 'Point of Care Testing strengthened my relationship with my GP'. For all statements the mean transformed VAS satisfaction score was significantly lower in the intervention group compared to the control group providing strong evidence that intervention patients agreed more with the statements on average than control patients ( $p=0.0027$ ,  $p<0.0001$  and  $p=0.0104$ ) (Table 187). The unadjusted analysis confirms these findings.

#### 11.4.2.2. General Practitioners

The GP satisfaction analysis investigated differences in the level of agreement with a variety of statements taken from the end of study GP Satisfaction Questionnaire between the intervention and control groups. Five statements from the questionnaire were used for the analysis which have been grouped into three categories; disease management, work flow and testing.

Responses were missing for around 34% of GPs, depending on the statement of interest. There was a higher percentage of GPs with missing data in the intervention group compared to the control group; however, this was largely due to GPs from intervention practices that withdrew from the Trial and hence these GPs were not sent questionnaires. The nature of the missingness was investigated and there was evidence to suggest that the missing data were not missing completely at random. Multiple imputation was used to impute the missing (transformed) values using firstly the MCMC method to produce a monotone missing data pattern and secondly the regression method. Analysis was performed on each of 10 completed datasets and the results were combined.

The category 'disease management' consists of two statements: 'PoCT would assist in overall care' and 'The availability of the PoCT was/would be useful for clinical practice'. For the first statement the mean transformed VAS satisfaction score was smaller in the intervention group compared to the control group, indicating that the intervention GPs agreed more strongly with the statement, although this did not reach statistical significance ( $p=0.1068$ ). For the second statement the mean transformed VAS satisfaction score was significantly smaller in the intervention group compared to the control group. This corresponds with a high level of agreement in the intervention group compared to the control group ( $p=0.0097$ ) (Table 188).

For the statement relating to the category 'work flow' 'PoCT interrupted/would interrupt the flow of a particular consultation' the mean transformed VAS satisfaction score was smaller in the intervention group compared to the control group, suggesting the intervention GPs disagreed more strongly with the statement, although this did not reach statistical significance ( $p=0.0638$ ) (Table 188).

The category 'testing' consists of two statements: 'I am/would be confident of the accuracy of the results provided by the PoCT devices' and 'Currently it takes considerable time to receive a test from the laboratory'. For the first statement the mean transformed VAS satisfaction score was significantly smaller in the intervention group compared to the control group. This corresponds with a high level of agreement in the intervention group compared to the control group ( $p=0.0022$ ) (Table 188).

**Table 188: GP satisfaction**

Category	Statement	Mean transformed VAS satisfaction score (intervention)	Mean transformed VAS satisfaction score (control)	Difference (intervention - control)	95% confidence interval for difference	P-value
Disease Management	PoCT would assist in overall patient care	0.43	0.83	-0.40	-0.89, 0.09	0.1068
	The availability of the PoCT was/would be useful for clinical practice	0.28	0.96	-0.68	-1.19, -0.17	0.0097
Work Flow	PoCT interrupted/would interrupt the flow of a particular consultation	1.50	2.02	-0.51	-1.06, 0.03	0.0638
Testing	I am/would be confident of the accuracy of the results provided by the PoCT devices	1.23	2.19	-0.96	-1.56, -0.36	0.0022
	Currently it takes considerable time to receive a test from the laboratory	2.07	1.67	0.40	-0.10, 0.91	0.1156

Note: A lower score indicates a higher level of agreement except for the statements 'PoCT interrupted/would interrupt the flow of a particular consultation' and 'currently it takes considerable time to receive a test from the laboratory', where a higher score indicates a higher level of agreement

#### 11.4.2.3. Device Operators

The analysis to determine the Device Operators' satisfaction with PoCT used five statements from the Device Operators' Satisfaction Questionnaire. As shown in Table 189 in all statements Device Operators indicated a high level of satisfaction with PoCT. Highest levels of satisfaction were shown for the statements 'I am competent in use of PoCT devices' and 'PoCT devices were easy to maintain' (9 out of 10 for both). The lowest level of satisfaction was found in the statement 'Confident in accuracy of PoCT (8.3).

**Table 189: Device operator satisfaction (descriptive results)**

Statement	Total
I am competent in use of PoCT devices: median (IQ range)	9.0 (7.4-9.6)
PoCT devices were easy to use: median (IQ range)	8.8 (7.6-9.6)
PoCT devices were easy to maintain: median (IQ range)	9.0 (8.2-9.7)
Confident in accuracy of PoCT results: median (IQ range)	8.3 (7.1-9.0)
Prefer PoCT to conventional pathology testing: median (IQ range)	8.4 (7.3-9.4)

#### 11.4.2.4. Pathology Providers

The analysis to determine the Pathology Providers' satisfaction with PoCT used three statements from the Pathology Providers' Satisfaction Questionnaire.

As shown in Table 190, Pathology Providers strongly agreed with the statement 'PoCT equipment should be accredited' (9.5). Their response to the statements 'PoCT has sufficient analytical quality' and 'PoCT in general practice is generally worthwhile' was neutral (4.5 and 4.8 respectively).

**Table 190: Pathology provider satisfaction (descriptive results)**

Statement	Total
	N=14
PoCT has sufficient analytical quality: median (IQ range)	4.5 (1.8-4.8)
POCT equipment should be accredited: median (IQ range)	9.5 (9.0-9.8)
PoCT in general practice is generally worthwhile: median (IQ range)	4.8 (4.4-7.2)

## 11.5. DISCUSSION

In relation to change in attitudes the Trial found a significant difference between treatment groups for a majority of the GP attitude statements indicating that the intervention GPs' attitude towards PoCT had positively changed while the control group GPs' attitudes either stayed the same or showed a less favourable attitude towards PoCT. For Device Operators, there was no significant change in attitudes to PoCT from the commencement to the end of the Trial except in the area of quality control, which they found more time-consuming. For patients' attitudes the Trial found no consistent effect of treatment between-groups; however, intervention patients showed a positive attitude towards PoCT at baseline and at follow-up.

In relation to satisfaction, the Trial found that intervention patients on average were more satisfied than control patients with regard to the PoCT testing process, the convenience of not travelling to an outside laboratory and disease management. For GPs the Trial found evidence that intervention GPs on average were more satisfied with PoCT compared to control GPs. Device Operators indicated high levels of satisfaction with POCT. Lower levels of satisfaction with PoCT were found for Pathology Providers.

## Attitudes

The change in patients' attitudes compared to baseline for the statement relating to a preference to having tests done by or on behalf of their own GP at his/her practice showed no evidence of a change in the intervention group, with a significant reduction in the control group. The score at baseline for intervention patients was high and this did not alter at the end of the Trial making a significant change difficult to detect. The Trial finding supports other published literature regarding pathology testing arrangements. Stone et al.'s<sup>60</sup> sub-study of patient satisfaction for patients with Type 2 diabetes, finding no significant differences between treatment groups and arrangements for blood testing.

There were no statistically significant differences found between treatment groups in the changes in scores compared to baseline for statements relating to a preference for having the test done at the time of consultation and an ease in anxiety by not having to wait for test results. Interestingly, there was evidence of a decrease in the average transformed scores (corresponding to an increase in agreement) between baseline and follow-up within each treatment group for both statements.

It was hypothesised that intervention GP's attitudes would be different to control GPs' towards using PoCT. The Trial found that overall the attitudes of the intervention GPs changed significantly compared to the control GPs' attitudes from baseline to follow-up. Between-group comparisons found that intervention GPs more strongly agreed that PoCT would help with disease management, and they more strongly disagreed that PoCT would interrupt patient flow or add too much time to the consultation. There were no statistical differences found between the treatment groups for the statements 'PoCT would reduce my after hours workload', 'PoCT would ensure that the test I request is done' and 'current external pathology arrangements are adequate'.

Within-group comparisons found that intervention GPs' change in attitudes, from baseline to follow-up, reached statistical significance for six of the nine statements with the other three statements showing a positive change but not reaching statistical significance. Within the intervention GPs there were significant improvements for all statements relating to disease management except for the statement 'PoCT would help me monitor disease' where the change did not reach statistical significance. In contrast, at follow-up control GPs were in greater agreement with the same statement. The Trial also found significant within-group changes in attitudes for both the intervention and control GPs for two of the three statements relating to work flow. At follow-up intervention GPs disagreed more with the statements 'PoCT would interrupt patient flow through my practice' and 'PoCT would add too much time to the consultation'. In contrast, at follow-up control GPs agreed more with the statements. While there was a change in attitudes detected at follow-up for both treatment groups for the statement 'PoCT would reduce my after hours workload', meaning GPs agreed more with the statement, these did not reach statistical significance. For the statements relating to testing the Trial findings were mixed. GPs from both treatment groups agreed more with the statement 'PoCT would ensure that the test I request is done' at follow-up; however, neither reached statistical significance. While intervention GPs agreed more with the statement 'Current external pathology arrangements are adequate' at follow up, there was no change found in the response from control GPs.

Results to determine whether Device Operators reported a change in attitude to PoCT at follow-up found no change in attitude for the statements relating to PoCT being technically difficult to use or quality assurance being time consuming. However, for the statement relating to quality control (QC) the Trial found evidence of a change in attitude at follow up, suggesting that Device Operators more strongly agreed with the statement that 'QC requirements for PoCT are time consuming'. This is not surprising given that PoCT was a new concept for many of the Device Operators and their knowledge of the processes involved was limited.

It was hypothesised that Pathology Providers would report a change in attitude to PoCT at follow up. The Trial found no evidence of a change in any of the attitude statements. This suggests that Pathology Providers involved in the Trial still disagree that PoCT requires less quality monitoring than

testing performed by pathology laboratories and still agree that PoCT performance should be assisted and monitored by pathology laboratories and will result in less laboratory testing.

### *Satisfaction*

It was hypothesised that there would be a difference in patient satisfaction in the intervention group of the Trial compared to the control group. The Trial findings found strong statistical evidence that PoCT patients on average were more satisfied than control patients in regards to the PoCT testing process, the convenience of not travelling to an outside laboratory and to disease management. This result demonstrates agreement with other published literature regarding patient satisfaction and acceptability of PoCT.<sup>18, 68</sup> Shiach et al.<sup>18</sup> conducted a randomised cross-over trial to investigate the reliability of point of care prothrombin time testing in a community clinic. Patient satisfaction was a secondary outcome. They reported that patients were very satisfied with the amount of information given by staff, 98% of patients conveyed a preference for a community based anticoagulant clinic and no patient expressed a preference for attending the hospital. Chaudry et al.<sup>74</sup> who investigated patient satisfaction with registered nurse managed point of care INR testing in primary care found that the majority of patients (79%) significantly preferred the point of care INR method of testing.

High levels of satisfaction among the intervention group patients compared to control patients were found for disease management, with intervention patients agreeing more on average with the statements that they were more motivated to look after their condition, that having immediate feedback of the test result was important as it allowed the discussion of the management of their condition with their GP and that PoCT strengthened their relationship with their GP. Among intervention patients compared to control patients there was also a significantly greater level of agreement with the statements that they were confident in the test results and that they would rather have blood taken by finger prick than by a needle in their arm.

The Trial results showed no treatment group difference in patient views regarding outside pathology laboratories involving extra time and transport costs. There have been conflicting results from previous studies. Supporting the Trial findings, Stone et al's<sup>60</sup> RCT found that patients were not concerned with extra practice visits as they were retired, or could organise appointments to fit in with their work. The results in the Trial reflect this, as over 54% of Trial patients were retired. However, Cohen et al.<sup>23</sup> who investigated patient attitudes to PoCT for hyperlipidaemia reported that two thirds (67%) of the patient sample indicated that attending an outside pathology laboratory involved extra time and transport costs, yet 39% did not mind going. The average level of agreement with the statement that laboratories have better hygiene was significantly higher in the control group compared to the intervention group.

The results of the GP satisfaction analysis found evidence that intervention GPs on average were more satisfied with PoCT compared to control GPs, although only two of the five satisfaction statements reached statistical between-group significance. However, all statements showed that intervention GPs had higher levels of satisfaction compared to control GPs. Intervention GPs strongly agreed more that the availability of PoCT was useful for clinical practice and they were confident in the accuracy of the PoCT result. They also disagreed more strongly compared to the control GPs that PoCT interrupted the flow of a particular consultation.

The Trial also found that Device Operators showed high levels of satisfaction towards PoCT for all statements. Overall Device Operators were satisfied with their competency in using PoCT devices, they found the devices easy to use and easy to maintain, they were confident in the accuracy of the PoCT test and a majority of them preferred PoCT to conventional pathology testing.

In looking at their levels of satisfaction towards PoCT the Trial found that Pathology Providers strongly agreed that PoCT equipment should be accredited and were non-committal in their responses to the statements about PoCT having sufficient analytical quality and being generally worthwhile in general practice. However, it is difficult to draw any conclusions from the results of the pathology provider analysis as the number of responses was low and their direct involvement in

the Trial was minimal. To the authors' knowledge, this is the first study to evaluate the acceptability and attitudes of Pathology Providers to PoCT.

A number of studies have investigated GP and Device Operator attitudes and satisfaction regarding PoCT in GP; however, no studies were found that have explored Pathology Providers' views. A majority of the published literature reporting health professional satisfaction and acceptability of PoCT did not investigate whether there were statistically significant differences. In addition the studies involved small numbers and used a variety of research questions and methodologies including informal discussions, structured interviews and surveys. Shephard's<sup>68</sup> study, in which statistical tests were completed, found no association between PoCT and increase in Device Operator satisfaction with the service. The Trial findings correspond with results reported in a number of other health professional satisfaction studies. Stone et al's<sup>60</sup> RCT of PoCT for patients with Type 2 diabetes investigated health professional acceptability and satisfaction with the service. Only a small number of nurses and GPs' were interviewed but results showed that nurses found the equipment easy to use and PoCT was viewed as helpful for patient management and job satisfaction. Cohen et al's<sup>23</sup> study investigating GPs' attitudes to PoCT found that a majority of the GPs reported that patient flow was not interrupted by PoCT or that PoCT was time consuming. Overall, the descriptive data shows that most health professionals find PoCT advantageous, reliable, accurate, convenient, easy to use and contributed to patient compliance. Other studies have reported GPs' concerns regarding costs<sup>23</sup> and the time taken to complete tests.<sup>22, 72</sup> In addition, Gillam et al's<sup>65</sup> research showed that GPs also found that the quality assurance and quality control aspects of PoCT were onerous and a limitation to PoCT.

Findings of the Trial suggest that intervention GPs have positively changed their attitudes towards PoCT. Intervention GPs indicated that PoCT helped them with disease management, it allowed them to discuss the result at the time of consultation; it helped to monitor disease, and contributed to patient compliance. In addition, intervention GPs were more satisfied with PoCT. This was supported by the results from the intervention patients who also showed high levels of satisfaction with PoCT and indicated they were more motivated to manage their condition; it strengthened their relationship with the GP and allowed them to discuss the management of their condition at the time of PoCT. Intervention GPs also reported that PoCT did not add time to the consultation or interrupt patient flow and patients indicated they would prefer to have their test done at the time of consultation.

## **11.6. CONCLUSION**

The results from this Trial support patient, GP and Device Operator acceptability of PoCT in a general practice setting. Pathology Providers' attitudes did not alter by the end of the Trial and they were non-committal in their views about the analytical quality of PoCT or having PoCT in general practice. However, they did indicate strongly that PoCT equipment should be accredited. Intervention patients had a significantly higher level of agreement than control patients relating to their satisfaction with the collection process and confidence in the process and they viewed PoCT as strengthening the relationship with their GP and motivational in terms of better managing their condition.

After the introduction of PoCT both intervention GPs and patients found the service beneficial. At follow-up GPs' and patients' agreement with the statements improved relating to the benefits of having an immediate result.

The strengths of this analysis are that a large number of participants were surveyed with response rates ranging from 63% to 90%.



## 12. INFLUENCE OF GEOGRAPHIC LOCATION ON PoCT OUTCOME MEASURES

### SUMMARY OF THE CHAPTER

This chapter describes the results of the analyses undertaken to determine whether there were differences between urban, rural and remote geographic regions in any of the outcomes measured.

To test for evidence of effect modification by geographic location, analyses for clinical effectiveness and stakeholder satisfaction were repeated with a geographic location effect, as well as, an interaction between treatment group and geographic location. Post hoc tests were performed to examine the effect of treatment separately within each geographic region. Descriptive analyses to determine the influence of geographic location were completed for QA test results, standards and accreditation, PoCT vs laboratory test results and SAEs and incidents. Kruskal Wallis analysis was completed for QC results by geographic location.

The key findings of the chapter are:

- analysis of the analytical imprecision observed for QC testing, found in general, no difference across geographic locations. There was no pattern for unacceptable results for QA testing by geographic location for all tests
- some variation was observed between geographic location and the level of agreement between the PoCT and laboratory testing. Remote practices had the widest limits of agreement
- the proportion of dual INR results that satisfied the narrow (89.7% urban, 88.6% rural, 87.6% remote) and expanded (91.6% urban, 91.6% rural, 90.7% remote) criteria was similar across geographic locations
- the proportion of dual readings within 0.5 units for INR by geographic location were similar for results <4.0. For results >4.0 there were lower levels of agreement across all geographic locations, particularly so for remote areas (58.8% compared to 82.3% rural and 68.1% urban)
- evaluation of the (Interim) Standards for PoCT, found that urban GPs were more unsure about applicability than rural and remote GPs, while Device Operator responses did not vary by geographic location
- all urban practices complied fully at the first accreditation visit, while 90% of rural practices and 70% of remote practices complied, the latter requiring review before achieving accreditation. All practices in all regions complied fully at the second accreditation visit
- while some differences in SAEs by geographical location were found, all SAEs were deemed unlikely related to the Trial
- the percentage of operator, patient and Trial related incidents were similar across all geographic regions
- there was no evidence of effect modification by geographic area for any of the hypotheses related to therapeutic control
- patients in the intervention group from rural and remote areas had a higher number of GP visits per person-year compared with the control group ( $p < 0.05$ ), whereas patients in both treatment groups from urban areas had similar number of GP visits
- there was no evidence of effect modification by geographic area for the hypothesis related to patient compliance to disease management (use of medicines)
- there was evidence of effect modification by geographic area for hypotheses relating to the average change in patient attitudes ( $p < 0.05$ )
- there was no evidence of effect modification by geographic area for hypotheses relating to the average change in attitudes for GPs and Device Operators

*cont. next page*

- there was no evidence of effect modification by geographic area for hypotheses relating to satisfaction for patients and GPs.

The key conclusion:

- There were no consistent and significant differences found between geographic locations for any of the parameters measured.

## 12.1. INTRODUCTION

No previous trials and very few observational studies<sup>16, 17</sup> have investigated the influence of geographic location on PoCT in a general practice setting. Access to pathology services in some rural and remote locations is limited and utilisation of PoCT devices provides timely results, particularly for patients treated with anticoagulant therapy. It has been indicated that warfarin is under-utilised in rural and remote areas<sup>186</sup> with Jackson et al.<sup>17</sup> suggesting that the lack of access to pathology services may influence the GPs decision to prescribe warfarin with its narrow therapeutic range and potential for adverse outcomes. The study by Jackson et al.<sup>17</sup> which assessed the clinical usefulness and acceptance of the CoaguChek S PoCT INR device showed that GPs reported a preference to use PoCT compared to pathology laboratory testing and did not think that there would be any problems with having the device available in Australian general practice. Research conducted by Shephard et al.<sup>68</sup> for Aboriginal patients with Type 2 diabetes in a rural setting found a statistically significant reduction in HbA1c test results after the introduction of PoCT with patients more satisfied with the PoCT service compared with usual care. GPs were also confident in the results and thought that the PoCT program improved patient care. Other benefits of PoCT could include less travel time for patients located in rural and remote areas by having a test result and follow-up in the same visit.

## 12.2. AIMS AND OBJECTIVES

The PoCT Trial sought to determine if there were differences between urban, rural and remote geographic regions in any of the parameters being measured. The purpose of this chapter is to describe the results of the influence of geographic location under the areas of safety, clinical effectiveness and stakeholder satisfaction.

The results presented in this chapter relate only to geography. For a full description of the methodology and statistical analyses for each research question refer to the relevant chapter in the report.

## 12.3. METHODS

### 12.3.1. Statistical Analysis

In order to determine whether there were differences between urban, rural and remote geographic regions in any treatment effects measured, analyses for clinical effectiveness and stakeholder satisfaction were repeated with a geographic location effect as well as an interaction between treatment group and geographic location to test for evidence of effect modification by geographic location. *Post hoc* tests were performed to examine the effect of treatment separately within each geographic region.

Where there was evidence of effect modification, this suggested that PoCT was having a different effect on the outcome, depending on the geographic location. In this case, the results of the *post hoc* tests can be used to determine where the differences are. If there is no evidence of effect modification, the results of the *post hoc* tests should be interpreted with caution since there is no evidence to suggest that PoCT is having a different effect on the outcome by geographic location.

Descriptive analyses to determine the influence of geographic location were completed for QA, standards and accreditation, PoCT vs laboratory test results and SAEs and incidents. Kruskal Wallis tests were used to determine the effect between geographic location and the median within-practice imprecision (CV%). These analyses were conducted using SPSS (version 12.0.1).

## **12.4. RESULTS**

### 12.4.1. Safety

Outcome measures related to safety and geography are described in this chapter with a complete description of methodology and overall results in Chapters 5 to 8. To answer the research question: 'Is it safe to perform PoCT in general practice?' a number of key areas were investigated and included:

- competency of Device Operators
- assessment of internal quality control program
- assessment of external quality assurance program
- comparison of PoCT and pathology laboratory test results by test
- standards and accreditation for PoCT in general practice
- SAEs and incidents

#### *12.4.1.1. Competency of Device Operators*

As all Device Operators met the required competency levels to perform PoCT across the life of the Trial, geography was not an influence.

#### *12.4.1.2. Assessment of internal quality control program*

##### *Within-practice imprecision by geographic location*

##### *Methods*

The within-practice imprecision for each QC level was calculated for practices from urban, rural and remote areas, ranked from lowest to highest and the median (50<sup>th</sup> percentile) CV%, as well as the 25<sup>th</sup> and 75<sup>th</sup> percentile CV% determined. Practices must have returned a minimum of five quality control results for each level tested to be included in this data analysis.

##### *Results*

Table 191 summarises the median within-practice imprecision by geographic location and compares the observed performance with the analytical goals for imprecision set for this Trial.

HbA1c: The median within-practice imprecision for HbA1c met the minimum analytical goal of 4% across all three geographic areas.

Urine ACR: The median within-practice imprecision for urine albumin, urine creatinine and urine ACR readily met the optimal analytical goals of 10%, 6% and 12% respectively across all three geographic areas.

Total cholesterol: The median within-practice imprecision for total cholesterol met the minimum analytical goal of 5% across all three geographic areas.

Triglycerides: The median within-practice imprecision for triglyceride met the desirable analytical goal of 7.5% across all three geographic areas.

HDL-C: The median within-practice imprecision for HDL-C met the minimum analytical goal of 6% across all geographic areas except in urban practices for Level 1 LN 5082 and in rural and remote areas for Level 1 LN 5230.

INR: Within-practice imprecision of less than 10% was achieved across all geographic locations.

**Table 191: Summary of median within-practice imprecision by geographic location and comparison with analytical goals for imprecision set for the Trial**

Test	Lot number	Imprecision goal (CV%) set for Trial	Median within-practice imprecision (CV%)							
			QC level 1				QC level 2			
			All	Urban	Rural	Remote	All	Urban	Rural	Remote
HbA1c	27	4%	2.5	3.3	2.2	2.4	2.8	3.4	3.4	2.7
	28	4%	2.9	2.6	2.9	3.0	3.3	3.9	3.2	3.2
UAlbumin	28	10%	5.0	5.8	5.3	4.9	4.1	4.1	4.3	3.8
UCreatinine	28	6%	3.5	3.3	3.8	3.5	3.5	3.3	3.4	3.5
Urine ACR	28	12%	5.0	5.0	5.1	5.0	4.0	3.4	4.0	4.1
Total cholesterol	5082	5%	3.2	3.4	3.1	3.2	3.1	4.1	3.0	2.7
	5230	5%	2.4	2.3	2.1	2.6	3.0	2.8	2.1	3.2
Triglycerides	5082	7.5%	3.9	4.3	3.3	4.5	3.7	3.7	3.2	4.0
	5230	7.5%	5.0	3.8	5.0	5.3	5.7	3.7	5.1	6.1
HDL-C	5082	6%	5.5	6.4	4.9	5.5	3.9	4.5	3.1	4.0
	5230	6%	6.7	5.1	6.5	8.8	4.9	4.7	3.9	5.1
INR	800042	10%*	7.0	7.1	6.1	7.9	na	na	na	na
	800049	10%*	6.4	6.5	6.9	6.2	na	na	na	na

Footnotes: 1. There was insufficient data available to calculate within-practice CV for lipid lot number 6165. 2. An imprecision goal for INR was not set for this Trial

Statistical comparisons were made between the location of testing (urban, rural or remote) and the median within-practice imprecision (CV%), using Kruskal-Wallis Tests. All analyses were conducted using SPSS (version 12.0.1).

For HbA1c, urine albumin, urine creatinine, urine ACR, total cholesterol and INR, there were no significant differences in the median imprecision between urban, rural or remote areas for all QC levels and lot numbers tested.

For triglyceride, there were no significant differences in the median imprecision between urban, rural or remote locations except for QC Level 1 LN 5082 and QC Level 2 LN 5230. For Level 1 LN 5082, rural practices had a significantly lower within-practice imprecision for triglyceride compared with urban or remote practices (rural: 3.30 [2.05, 3.85], urban: 4.25 [3.45, 4.97], remote: 4.45 [3.45, 5.08]; median [25<sup>th</sup>, 75<sup>th</sup> percentiles], p=0.03). For Level 2 LN 5230, urban practices had significantly lower within-practice imprecision for triglyceride compared with rural or remote practices (urban: 3.70 [1.70, 5.60], rural: 5.10 [4.60, 7.40], remote: 6.10 [5.93, 8.23]; median [25<sup>th</sup>, 75<sup>th</sup> percentiles], p=0.03). However, although geographic differences were observed with these two QC levels and LNs, it should be emphasised that the median within-practice imprecision across all locations nonetheless remained within the desirable analytical goal for this analyte.

For HDL-C, there were no significant differences in the median imprecision between urban, rural or remote practices except for QC Level 1 LN 5230 where urban sites had significantly lower within-practice imprecision compared with rural or remote practices (urban: 5.10 [4.50, 8.00], rural: 6.50 [6.10, 7.90], remote: 8.75 [6.38, 10.18], p=0.05). In this case, as reported earlier, the median within-practice imprecision for HDL-C for rural and remote practices was also outside the minimum analytical goal for this analyte.

Thus the results of these statistical analyses indicated that, in general, there was no difference in the analytical imprecision observed for QC testing when conducting PoCT in rural or remote areas compared with urban.

#### 12.4.1.3. Assessment of external quality assurance performance

Quality assurance was assessed in terms of accuracy and precision and in this section results are presented by geographic location.

##### Accuracy

Colour coding as described in Section 5.5.2 was used to give practices an assessment of whether their result was within the clinically acceptable range. Results in Table 192 present the percentage of acceptable results by geographic location for all cycles.

**Table 192: Percentage of acceptable results by geographic location for all cycles**

Test	Green				Orange				Red			
	All	Urban	Rural	Remote	All	Urban	Rural	Remote	All	Urban	Rural	Remote
HbA1c	94.3	93.5	96.5	93.5	4.7	5.8	3.1	4.1	1.0	0.6	0.4	2.0
Urine ACR	98.1	98.9	97.6	97.5	0.8	0.9	1.1	0.6	1.1	0.2	1.3	1.9
Total cholesterol	83.6	87.6	84.6	80.1	12.7	9.9	12.4	14.5	3.7	2.4	3.0	5.3
HDL-C	90.2	91.1	93.6	87.2	6.7	6.9	4.7	7.6	3.2	2.4	1.9	5.3
Triglycerides	92.4	93.3	97.3	86.9	4.6	4.4	1.0	8.0	2.9	2.3	1.7	5.1
INR	94.4	97.1	94.5	91.7	3.1	1.5	1.3	5.9	2.5	1.4	4.2	2.4

There is no pattern by geography for acceptable (green) results for all tests. However, the remote areas generally had the highest number of orange and red results.

#### *Imprecision*

The imprecision quality goals were compared with the median within practice CV% by geographic location for all cycles (Table 193).

**Table 193: Comparison of median within-practice imprecision and quality goals by geographic location**

Test	Imprecision goal	Average all areas	Urban	Rural	Remote
HbA1c	4%	2.6	2.4	2.3	2.6
Urine ACR	12%	2.8	2.7	2.5	3.2
Total cholesterol	5%	5.7	6.1	4.5	8.4
HDL-C	6%	6.6	6.6	5.5	7.9
Triglycerides	7.5%	6.7	6.1	4.8	11.2
INR	10%	7.2	6.2	10.4	9.6

For HbA1c and urine ACR there were no differences by geographic location in the median within practice CVs. However for total cholesterol, HDL-C and triglycerides the remote areas had a higher CV than the urban or rural areas. For INR the rural and remote areas had higher CVs than the urban area.

#### *12.4.1.4. Standards and accreditation for PoCT in general practice*

Results by geographic location showed that there were more urban GPs unsure about the applicability of the various sections of the PoCT Standards to general practice compared to rural and remote GPs (Table 194). However, the majority of Device Operators, regardless of geographic location, agreed that the PoCT Standards were applicable to general practice (Table 195).

**Table 194: Applicability of the PoCT Standards to general practice by GPs and geographic location**

Area of the PoCT standards		Urban	Rural	Remote	Total
		N=39	N=42	N=19	N=100
		Freq (%)	Freq (%)	Freq (%)	Freq (%)
Clinical governance	Missing	3 (7.7)	0 (0.0)	3 (15.8)	6 (6.0)
	No	1 (2.6)	2 (4.8)	0 (0.0)	3 (3.0)
	Unsure	17 (43.6)	11 (26.2)	4 (21.1)	32 (32.0)
	Yes	18 (46.2)	29 (69.0)	12 (63.2)	59 (59.0)
Analytical requirements	Missing	3 (7.7)	0 (0.0)	3 (15.8)	6 (6.0)
	No	0 (0.0)	2 (4.8)	0 (0.0)	2 (2.0)
	Unsure	19 (48.7)	8 (19.0)	4 (21.1)	31 (31.0)
	Yes	17 (43.6)	32 (76.2)	12 (63.2)	61 (61.0)
Staff training	Missing	3 (7.7)	0 (0.0)	3 (15.8)	6 (6.0)
	No	0 (0.0)	1 (2.4)	1 (5.3)	2 (2.0)
	Unsure	8 (20.5)	5 (11.9)	0 (0.0)	13 (13.0)
	Yes	28 (71.8)	36 (85.7)	15 (78.9)	79 (79.0)
Implementation and performance	Missing	3 (7.7)	0 (0.0)	3 (15.8)	6 (6.0)
	No	0 (0.0)	1 (2.4)	0 (0.0)	1 (1.0)
	Unsure	9 (23.1)	5 (11.9)	1 (5.3)	15 (15.0)
	Yes	27 (69.2)	36 (85.7)	15 (78.9)	78 (78.0)
Quality outcomes	Missing	3 (7.7)	0 (0.0)	3 (15.8)	6 (6.0)
	No	0 (0.0)	1 (2.4)	0 (0.0)	1 (1.0)
	Unsure	10 (25.6)	8 (19.0)	4 (21.1)	22 (22.0)
	Yes	26 (66.7)	33 (78.6)	12 (63.2)	71 (71.0)

**Table 195: Applicability of the PoCT standards to general practice by device operators and geographic location**

Area of the PoCT standards		Urban	Rural	Remote	Total
		N=13	N=19	N=23	N=55
		Freq (%)	Freq (%)	Freq (%)	Freq (%)
Clinical governance	Missing	0 (0.0)	2 (10.5)	2 (8.7)	4 (7.3)
	Unsure	3 (23.1)	3 (15.8)	6 (26.1)	12 (21.8)
	Yes	10 (76.9)	14 (73.7)	15 (65.2)	39 (70.9)
Analytical requirements	Missing	0 (0.0)	2 (10.5)	2 (8.7)	4 (7.3)
	Unsure	3 (23.1)	3 (15.8)	5 (21.7)	11 (20.0)
	Yes	10 (76.9)	14 (73.7)	16 (69.6)	40 (72.7)
Staff training	Missing	0 (0.0)	2 (10.5)	1 (4.3)	3 (5.5)
	No	0 (0.0)	0 (0.0)	1 (4.3)	1 (1.8)
	Unsure	1 (7.7)	0 (0.0)	0 (0.0)	1 (1.8)
	Yes	12 (92.3)	17 (89.5)	21 (91.3)	50 (90.9)
Implementation and performance	Missing	1 (7.7)	2 (10.5)	2 (8.7)	5 (9.1)
	Unsure	1 (7.7)	1 (5.3)	0 (0.0)	2 (3.6)
	Yes	11 (84.6)	16 (84.2)	21 (91.3)	48 (87.3)
Quality outcomes	Missing	0 (0.0)	2 (10.5)	2 (8.7)	4 (7.3)
	Unsure	3 (23.1)	2 (10.5)	3 (13.0)	8 (14.5)
	Yes	10 (76.9)	15 (78.9)	18 (78.3)	43 (78.2)

All urban practices complied fully at the first accreditation visit (Table 196) while nearly 90% of rural practices but just less than 70% of remote practices complied. All practices in all regions complied fully at the second visit.

**Table 196: Outcomes of first and second accreditation visits by region**

Accreditation visit	Outcome	Geographic location							
		Urban		Rural		Remote		Total	
		N	%	N	%	N	%	N	%
First visit	Complies fully	8	100	8	88.9	9	69.2	25	83.3
	Complies but requires review	0	0	0	0	2	15.4	2	6.7
	Not comply	0	0	1	11.1	2	15.4	3	10
	Total	8	100	9	100	13	100	30	100
Second visit	Complies fully	8	100	7	100	11	100	26	100
	Not comply	0	0	0	0	0	0	0	0
	Total	8	100	7	100	11	300	26	300

*12.4.1.5. Phase I comparison of PoCT and pathology laboratory test results*

In order to assess the level of agreement between PoCT and pathology laboratory testing for the same patient, the approach suggested by Bland and Altman<sup>77</sup> was adopted (see Section 7.3). Results by geographic location and by test are reported in this chapter. For all tests, results relating to relative differences between PoCT and laboratory test results and regression analysis can be found in Appendix 35.

Results relating to absolute differences between PoCT and pathology laboratory test results by geographic region are presented in Table 197. When considering urban, rural and remote regions separately, the differences between the areas with regard to the level of agreement between the INR PoCT and pathology laboratory test results are small. The level of agreement for total cholesterol is similar in urban and remote areas, with a slightly smaller bias in rural areas and slightly narrower limits of agreement in remote areas. Results for HDL-C relating to absolute differences between PoCT and pathology laboratory test results by geographic region showed that the bias varied substantially between regions and was largest for remote areas. The width of the limits of agreement was similar for the different areas. Triglycerides test results relating to absolute differences between PoCT and pathology laboratory tests revealed considerable difference between the geographic areas. The smallest bias and narrowest limits of agreement occurred in the urban areas, while remote areas showed the widest limits of agreement. The bias for the different geographic regions for HbA1c test results varied somewhat, with positive bias occurring in the remote areas and negative bias occurring elsewhere. The width of the limits of agreement was also substantially greater in remote areas. There were some differences between urban, rural and remote areas between PoCT and pathology laboratory urine albumin test results. The limits of agreement are widest in rural areas and the bias differed somewhat between the regions. Results for ACR relating to absolute differences between PoCT and pathology laboratory test results by geographic region demonstrated some differences between the urban, rural and remote areas. The bias differed for remote areas, compared to urban and rural areas. The limits of agreement were widest for rural areas.

**Table 197: Mean absolute difference in test results and 95% limits of agreement by geographic location and by test type**

Test	Geographic location	Mean absolute difference (bias)	95% confidence interval for mean absolute difference		95% limits of agreement (absolute)		Sample size
INR	Urban	0.0655	0.0377	0.0933	-0.6852	0.8162	728
	Rural	-0.0766	-0.1126	-0.0406	-0.8016	0.6484	406
	Remote	-0.0201	-0.0569	0.0167	-0.8768	0.8366	542
Total cholesterol	Urban	-0.3391	-0.3928	-0.2855	-1.1734	0.4951	242
	Rural	-0.1714	-0.2225	-0.1203	-1.0690	0.7262	309
	Remote	-0.3008	-0.3419	-0.2596	-1.0090	0.4075	296
HDL-C	Urban	-0.0824	-0.1095	-0.0554	-0.5006	0.3358	239
	Rural	0.0128	-0.0098	0.0354	-0.3646	0.3902	279
	Remote	-0.1475	-0.1730	-0.1221	-0.5535	0.2584	254
Triglycerides	Urban	0.0913	0.0395	0.1432	-0.7216	0.9043	246
	Rural	0.2669	0.1998	0.3340	-0.9180	1.4518	312
	Remote	0.2244	0.1460	0.3028	-1.1107	1.5594	290
HbA1c	Urban	-0.0750	-0.1360	-0.0140	-0.8755	0.7255	172
	Rural	-0.0955	-0.1622	-0.0289	-0.9848	0.7938	178
	Remote	0.0336	-0.0762	0.1433	-1.2928	1.3600	146
Urine albumin	Urban	0.7477	0.0838	1.4116	-4.6047	6.1000	65
	Rural	-0.4910	-1.7003	0.7183	-13.2314	12.2494	111
	Remote	-2.4986	-3.6697	-1.3276	-12.5723	7.5750	74
ACR	Urban	-0.0811	-0.2951	0.1330	-1.8070	1.6448	65
	Rural	-0.0338	-0.2262	0.1586	-2.0147	1.9472	106
	Remote	-0.3878	-0.6073	-0.1683	-2.2503	1.4747	72

#### 12.4.2. Clinically relevant agreement – INR results

The proportion (95% CI) of dual INR measurements that satisfied the expanded and narrow criteria by geographic region is shown in Table 198. Across the geographic areas the narrow and expanded criteria were similar.

**Table 198: Percentage of agreement of dual INR measurements (CoaguChek S, laboratory) by using clinically relevant agreement criteria**

Agreement criteria	Urban (95% CI)	Rural (95% CI)	Remote (95% CI)	Combined results (95% CI)
	N=728	N=406	N=543	N=1677
Narrow	89.70 (87.62, 91.81)	88.67 (85.18, 91.58)	87.66 (8.60, 93.09)	88.79 (87.18, 90.26)
Expanded	91.62 (89.37, 93.53)	91.63 (88.49, 94.13)	90.79 (88.04, 93.09)	91.35 (89.91, 92.66)

In the analysis of the difference in each dual INR, the mean difference in the INR values for laboratory INR ranges of <2.0, 2.0-3.0, 3.1-4.0, >4.0 by geographic area were 0.08, 0.09, -0.02, and -0.11 respectively for urban areas. For rural areas it was 0.05, -0.10, -0.11 and -0.09 respectively and for remote areas 0.06, -0.04, -0.05 and -0.36 respectively (Table 199).

The proportion of dual INR measurements within 0.5 INR units for laboratory INR ranges of <2.0, 2.0-3.0, 3.1-4.0 and >4.0 was 95%, 89%, 69% and 68% for urban areas, 92%, 92%, 78% and 82% for rural areas and 93%, 89%, 59% and 50% for remote areas (Table 199).

**Table 199: Agreement of dual INR measurements as a function of increasing INR for all patients by geographic location**

Geographic location	INR Range	Dual measurements	
		Mean difference (INR units)	Percentage within 0.5 INR units
Urban	<2.0	0.08	94.83
	2.0-3.0	0.09	89.24
	3.1-4.0	-0.02	69.44
	> 4.0	0.11	68.18
	Overall	0.07	85.58
Rural	<2.0	0.05	92.06
	2.0-3.0	-0.10	91.60
	3.1-4.0	-0.11	77.63
	> 4.0	-0.09	82.35
	Overall	-0.08	88.67
Remote	<2.0	0.06	93.38
	2.0-3.0	-0.04	88.96
	3.1-4.0	-0.05	58.82
	> 4.0	-0.36	50.00
	Overall	-0.02	85.27

#### 12.4.2.1. Serious adverse events and incidents

There were three key areas relating to SAEs: type of SAE, patients experiencing one or more SAEs and number of SAEs per 10,000 person-years. Details of the methodology and results by treatment group can be found in Section 7.3. The type of serious adverse event by treatment group and

geographic location is shown in Table 200. There were more deaths for control urban, rural and remote patients compared with the patients in the same locations in the intervention practices. The proportion of patients experiencing any SAE was similar by geographic location (Table 201). There was a higher rate of intervention patients in remote and rural areas experiencing any SAE compared with patients in the same locations in the control practices. In the urban area there was a higher rate of any SAE experienced by control patients compared to patients in the intervention group.

Overall, the estimated rate of occurrence of SAEs per 10,000 person-years for all events is slightly higher for urban patients (1548.45) compared with the remote (1268.81) and rural (1268.32) group of patients (Table 202). There was also a higher rate of SAEs per 10,000 person-years for all events in the intervention group for rural and remote patients compared with the patients in the same locations in the control group.

**Table 200: Type of SAE by treatment group and geographic location (weighted estimates\*)**

Type of SAE	Urban patients						Rural patients						Remote patients					
	Control		Intervention		Total		Control		Intervention		Total		Control		Intervention		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Death	17	6.67	0	0.0	17	4.54	9	35.29	11	5.40	20	8.55	15	14.01	30	13.43	45	13.62
Inpatient hospitalisation or prolongation of existing hospitalisation	213	81.63	84	68.42	297	77.42	12	50.00	122	59.79	134	58.76	80	75.82	144	64.83	224	68.37
Life threatening	0	0.0	6	5.26	6	1.68	0	0	0	0	0	0	0	0.0	5	2.12	5	1.44
Newly diagnosed cancer	9	3.35	3	2.83	12	3.19	0	0	0	0	0	0	1	1.25	0	0.0	1	0.40
Other important medical event	18	6.80	22	18.22	40	10.44	4	14.71	71	34.80	75	32.69	9	8.93	44	19.61	53	16.17
Permanent or significant disability or incapacity	4	1.55	6	5.26	10	2.73	0	0	0	0	0	0	0	0	0	0	0	0
Total	261	100.00	122	100.00	383	100.00	24	100.00	205	100.00	229	100.00	105	100.00	222	100.00	327	100.00

\*as the data are weighted estimates which have been rounded up the totals may not add up

**Table 201: One or more SAE by treatment group and geographic location (weighted estimates)**

Type of SAE	Urban patients						Rural patients						Remote patients					
	Control N=840		Intervention N=897		Total N=1737		Control N=447		Intervention N=917		Total N=1364		Control N=671		Intervention N=1196		Total N=1867	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Death	17	2.07	0	0.0	17	1.00	9	1.90	11	1.21	20	1.44	15	2.20	30	2.49	45	2.39
Inpatient hospitalisation or prolongation of existing hospitalisation	134	16.0	61	6.78	195	11.2	8	1.75	70	7.61	78	5.69	71	10.6	129	10.8	201	10.7
Life threatening	0	0.0	6	0.72	6	0.37	0	0.0	0	0.0	0	0.0	0	0.0	5	0.39	5	0.25
Newly diagnosed cancer	9	1.04	3	0.39	12	0.70	0	0.0	0	0.0	0	0.0	1	0.20	0	0.0	1	0.07
Other important medical event	18	2.11	22	2.48	40	2.30	4	0.79	61	6.64	64	4.73	9	1.40	44	3.64	53	2.84
Permanent or significant disability or incapacity	4	0.48	6	0.72	10	0.60	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAE	156	18.5	89	9.93	245	14.1	16	3.49	123	13.4	139	10.2	86	12.7	193	16.1	278	14.9

\*as the data are weighted estimates which have been rounded up the totals may not add up

**Table 202: Number of SAEs per 10,000 person-years by treatment group and geographic location (weighted estimates)**

Type of SAE	Urban patients			Rural patients			Remote patients		
	Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total
Death	145.26	0.00	70.37	147.53	90.14	108.50	159.72	180.03	172.76
Inpatient hospitalisation or prolongation of existing hospitalisation	1776.91	655.44	1198.75	209.00	997.51	745.26	864.43	869.15	867.46
Life threatening	0.00	50.43	26.00	0.00	0.00	0.00	0.00	28.48	18.28
Newly diagnosed cancer	72.93	27.15	49.33	0.00	0.00	0.00	14.20	0.00	5.08
Other important medical event	148.05	174.50	161.69	61.47	580.65	414.56	101.77	262.93	205.22
Permanent or significant disability or incapacity	33.67	50.43	42.31	0.00	0.00	0.00	0.00	0.00	0.00
Total	2176.82	957.95	1548.45	418.00	1668.30	1268.32	1140.12	1340.59	1268.81

12.4.2.2. Incidents – Trial Management Group

Practice reported incidents by geographic location are shown in Table 203. The percentage of operator, patient and Trial related incidents were similar across geographic location. Device related incidents occurred more frequently in rural areas (20.75%) compared to urban (13.51%) and remote areas (11.73%). Rural practices also reported more other incidents (4.40%) than urban (1.35%) and remote (0.62%) areas.

**Table 203: All practice reported incidents by geographic location**

Type of incident	Geographic location						Total	
	Urban		Rural		Remote			
	N	%	N	%	N	%	N	%
Device related	20	13.51	33	20.75	19	11.73	72	15.35
Operator related	8	5.41	9	5.66	7	4.32	24	5.12
Other incident	2	1.35	7	4.40	1	0.62	10	2.13
Patient related	10	6.76	9	5.66	15	9.26	34	7.25
Quality control / quality assurance	20	13.51	12	7.55	16	9.88	48	10.23
Trial related	88	59.46	89	55.97	104	64.20	281	59.91
Total	148	100.00	159	100.00	162	100.00	469	100.00

Patient reported incidents by geographic location are shown in Table 204. As noted in 8.4.4.2 the majority of incidents related to questionnaires and results were similar across all geographic locations.

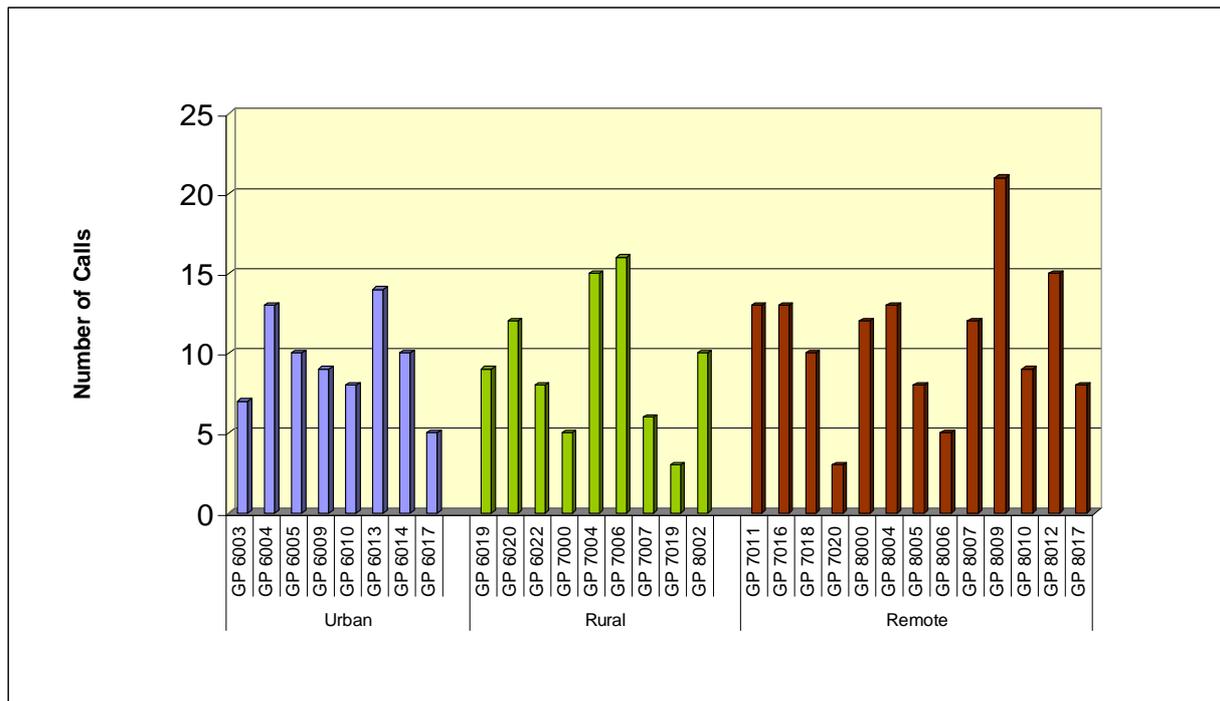
**Table 204: All patient reported incidents by geographic location**

Type of incident	Geographic location						Total	
	Urban		Rural		Remote			
	N	%	N	%	N	%	N	%
Trial procedures	0	0.0	3	2.04	1	0.78	4	0.76
Other	2	0.80	0	0.0	0	0.0	2	0.38
Patient related	62	24.90	39	26.53	40	31.25	141	26.91
Questionnaires	185	74.30	105	71.43	87	67.97	377	71.95
Total	249	100.00	147	100.00	128	100.00	524	100.00

### 12.4.2.3. Incidents – Device Group

Practice reported incidents by geographic location received by the PoCT Device Group are shown in Figure 1. Seventy six calls originated from the eight urban practices (average 9.6 calls per practice), 84 calls from the nine rural practices (average 9.3 calls per practice) and 142 calls from the 13 remote practices (average 10.9 calls per practice).

**Figure 42: Breakdown of help desk calls by practice and geographic region**



### 12.4.2.4. Incidents – QAP Group

There were a total of 143 incidents reported to the QAP Group. Urban practices accounted for 42% of these with 29% from rural practices and 29% from remote practices.

### 12.4.3. Clinical effectiveness

This section of the chapter describes the clinical effectiveness results by geographic location. The key areas investigated include:

- effect of PoCT on improved therapeutic control
- GP visits
- patient compliance with disease management

The influence of geography on the process of care actions and prescribing patterns was not investigated.

#### 12.4.3.1. Effect of PoCT on improved therapeutic control

Table 205 represents the results for outcomes investigating differences between geographic location and the proportion of last test results within target range, whether there was any reduction or any increase in test results from baseline and the proportion of all test results within target range.

There was no evidence of effect modification by geographic location for any of the hypotheses (Table 205).

**Table 205: Test results by geographic location**

Test	Hypothesis 1a (last test result in target range)	Hypothesis 1b (any reduction/increase compared to baseline)	Hypothesis 2 (all test results in target range)
INR	p=0.3064	N/A	p=0.2516
HbA1c	p=0.8308	p=0.8108	p=0.9115
Urine albumin	p=0.9894	N/A	p=0.9745
ACR	p=0.6969	N/A	p=0.5545
Total cholesterol	p=0.6269	p=0.2169	p=0.2897
HDL-C	p=0.5539	p=0.6053	p=0.1086
Triglycerides	p=0.3855	p=0.8266	p=0.4031

#### 12.4.3.2. GP visits

The Trial sought to determine whether the number of GP visits for PoCT patients per person-year was different to the number of GP visits for control patients per person-year and whether there were any geographic location differences. There was strong evidence of effect modification by geographic location ( $p=0.0046$ ) indicating that GP visits varied among the geographic regions. Patients in both treatment groups from urban areas had a similar number of visits per person-year with a rate ratio of 0.94 ( $p=0.4631$ ); whereas, patients in the intervention group from rural and remote areas had a significantly higher number of GP visits per person-year compared with control patients, with rate ratios of 1.24 ( $p=0.0229$ ) and 1.39 ( $p=0.0005$ ) respectively (Table 206). The results of the Trial show that patients in the intervention group had significantly more visits to the GP than patients in the control group, particularly for patients residing in remote locations.

**Table 206: GP visits per person-year by treatment group and geographic location**

Geographic location	GP visit rate per year (intervention)	GP visit rate per year (control)	Rate ratio (intervention vs. control)	95% confidence interval for rate ratio	P-value
Urban	9.90	10.49	0.94	0.81-1.10	0.4631
Rural	10.67	8.61	1.24	1.03-1.49	0.0229
Remote	14.05	10.14	1.39	1.15-1.66	0.0005

An analysis of the Medicare Australia GP visit data by condition provides some insight into visits for the three conditions (Table 207). While this data has some limitations – not all patients had a GP visit – it does help to explain the variation across geographic locations and treatment groups. The descriptive statistics based on the raw data relating to GP visits provides evidence that patients on

anticoagulant therapy were the driving force behind the higher number of GP visits per person-year for the intervention group. This difference is similar across all geographic locations. For diabetes and hyperlipidaemia the overall difference was similar between both treatment groups; however, there were slightly more GP visits per person-year for the rural and remote intervention groups.

**Table 207: Number of GP visits per person-year by treatment group and geographic location**

Conditions	RRMA	Control	Intervention	Total
INR	Urban	14.67	16.77	15.85
	Rural	11.73	18.44	16.49
	Remote	13.11	22.72	18.77
	Total	13.60	19.22	17.01
Diabetes	Urban	11.05	9.51	10.29
	Rural	9.19	9.89	9.69
	Remote	10.52	13.93	12.56
	Total	10.51	11.11	10.86
Hyperlipidaemia	Urban	10.31	9.04	9.67
	Rural	7.89	10.08	9.41
	Remote	9.89	13.27	12.08
	Total	9.65	10.99	10.47

#### 12.4.3.3. Patient compliance with disease management

The Trial sought to determine whether there were treatment differences between geographic location and the proportion of MARS-5 questionnaire responses indicating compliance with disease management in PoCT practices compared to control practices (see Section 9.4.3).

There was no evidence of effect modification by geographic location ( $p=0.1625$ ), that is, there was no evidence to suggest that the effect of treatment varied among the geographic regions.

#### 12.4.4. Participant satisfaction with PoCT

To answer the research question of whether patients and other stakeholders are more satisfied with PoCT than with pathology laboratory testing, two key areas were investigated:

- change in participants' attitudes
- satisfaction towards PoCT

#### 12.4.4.1. Change in participants' attitudes

##### Patients

##### Between-group comparisons

The analysis provided evidence of effect modification by geographic location, indicating that the effect of treatment varied by geography, for each of the three patient attitude statements (Table 208).

**Table 208: Geographic effect modification for a between-group change in patient attitude**

Attitude statement	Effect modification by geographic location
I would prefer to have my tests done at the time of consultation	p=0.0002
Not having to wait for test results would ease my anxiety	p=0.0031
I would prefer tests to be done by/on behalf of my own GP at his/her practice	p=0.0392

For the statement 'I would prefer to have my tests done at the time of consultation' there was strong evidence that the effect of treatment varied by geographic location ( $p=0.0002$ ). The change in mean transformed VAS score from baseline was larger in the intervention group compared to the control group for urban patients ( $p=0.0055$ ), similar between-groups for rural patients ( $p=0.5230$ ) and larger in the control group compared to the intervention group for remote patients ( $p=0.0032$ ) (Table 209).

For the statement 'Not having to wait for test results would ease my anxiety' there was evidence to suggest that the effect of treatment varied by geographic location ( $p=0.0031$ ). The change in mean transformed VAS score from baseline was similar in the intervention group and the control group for urban patients ( $p=0.1596$ ), larger in the rural control group compared to the intervention group ( $p=0.0371$ ) and larger in the intervention group compared to the control group for remote patients ( $p=0.0184$ ) (Table 209).

For the statement 'I would prefer tests to be done by/on behalf of my own GP at his/her practice' there was evidence that the effect of treatment varied by geographic location ( $p=0.0392$ ). The change in mean transformed VAS score from baseline was different in the urban intervention group compared to the control group for urban and rural patients ( $p=0.0004$  and  $p=0.0003$  respectively). No significant difference was observed between the remote intervention group compared to the control group ( $p=0.5537$ ) (Table 209).

**Table 209: Between-group comparisons for a change in patient attitude by treatment group and geographic location**

Attitude statements	Geographic location	Change in mean transformed VAS score from baseline (intervention)	Change in mean transformed VAS score from baseline (control)	Difference (intervention - control)	95% confidence interval for difference	P-value
I would prefer to have my tests done at the time of consultation	Urban	-0.34	-0.15	-0.20	-0.33, -0.06	0.0055
	Rural	-0.34	-0.28	-0.06	-0.23, 0.11	0.5230
	Remote	-0.13	-0.35	0.22	0.07, 0.37	0.0032
Not having to wait for test results would ease my anxiety	Urban	-0.63	-0.53	-0.11	-0.26, 0.04	0.1596
	Rural	-0.68	-0.49	-0.19	-0.38, -0.01	0.0371
	Remote	-0.53	-0.72	0.19	0.03, 0.35	0.0184
I would prefer tests to be done by/on behalf of my own GP at his/her practice	Urban	-0.04	0.22	-0.26	-0.40, -0.12	0.0004
	Rural	-0.11	0.22	-0.32	-0.50, -0.15	0.0003
	Remote	0.09	0.14	-0.05	-0.20, 0.11	0.5537

Note: A lower score indicates a higher level of agreement

#### Within-group comparisons

The analysis indicated the effect of treatment varied by geographic location.

For the statement 'I would prefer to have my tests done at the time of consultation' there was evidence of a decrease in the mean transformed VAS score between baseline and follow-up within each treatment group for urban, rural and remote patients ( $p < 0.05$  in all cases) (Table 210).

For the statement 'Not having to wait for test results would ease my anxiety' there was evidence of a decrease in the mean transformed VAS score between baseline and follow-up within each treatment group for urban, rural and remote patients ( $p < 0.0001$  in all cases) (Table 210).

However, for the statement 'I would prefer tests to be done by/on behalf of my own GP at his/her practice' there was no significant change in mean transformed VAS score from baseline within the urban ( $p = < 0.4254$ ) or remote ( $p = < 0.0596$ ) intervention groups. A significant decrease in mean transformed VAS score was observed within the rural intervention group ( $p = 0.0389$ ). There was also evidence of an increase in the mean transformed VAS score corresponding to a decrease in the level of agreement) from baseline within the urban, rural and remote control groups ( $p < 0.0001$ ,  $p = 0.0032$  and  $p = 0.0182$  respectively) (Table 210).

**Table 210: Within-group comparisons for a change in patient attitude by treatment group and geographic location**

Attitude statements	Treatment group	Geographic location	Mean transformed VAS score at baseline	Mean transformed VAS score at follow-up	Difference (follow-up - baseline)	95% confidence interval for difference	P-value
I would prefer to have my tests done at the time of consultation	Intervention	Urban	0.56	0.22	-0.34	-0.44, -0.25	<0.0001
	Intervention	Rural	0.55	0.22	-0.34	-0.43, -0.24	<0.0001
	Intervention	Remote	0.27	0.14	-0.13	-0.23, -0.04	0.0066
	Control	Urban	0.70	0.56	-0.15	-0.25, -0.05	0.0039
	Control	Rural	0.80	0.52	-0.28	-0.42, -0.14	0.0001
	Control	Remote	0.64	0.29	-0.35	-0.46, -0.24	<0.0001
Not having to wait for test results would ease my anxiety	Intervention	Urban	0.99	0.35	-0.63	-0.74, -0.53	<0.0001
	Intervention	Rural	0.88	0.19	-0.68	-0.79, -0.58	<0.0001
	Intervention	Remote	0.58	0.05	-0.53	-0.63, -0.43	<0.0001
	Control	Urban	1.23	0.70	-0.53	-0.63, -0.42	<0.0001
	Control	Rural	1.05	0.56	-0.49	-0.64, -0.34	<0.0001
	Control	Remote	1.13	0.41	-0.72	-0.84, -0.60	<0.0001
I would prefer tests to be done by/on behalf of my own GP at his/her practice	Intervention	Urban	0.32	0.28	-0.04	-0.14, 0.06	0.4254
	Intervention	Rural	0.40	0.30	-0.11	-0.21, -0.01	0.0389
	Intervention	Remote	0.11	0.20	0.09	-0.00, 0.19	0.0596
	Control	Urban	0.41	0.63	0.22	0.12, 0.32	<0.0001
	Control	Rural	0.56	0.78	0.22	0.07, 0.36	0.0032
	Control	Remote	0.15	0.29	0.14	0.02, 0.26	0.0182

*Note: A lower score indicates a higher level of agreement*

#### 12.4.4.2. General Practitioners

There was no evidence of effect modification by geographic location for any of the GP attitude statements (Table 211).

**Table 211: Between-group comparisons for a change in GP attitude by treatment group**

Category	Attitude statements	Effect modification by geographic location
Disease management	It is helpful to have pathology results at the time of consultation	p=0.5842
	PoCT would allow me to discuss with the patient the implications of the result when it is foremost in both our minds	p=0.4751
	PoCT would help me monitor disease	p=0.5375
	PoCT would contribute to patient compliance	p=0.2731
Work flow	PoCT would interrupt patient flow through my practice	p=0.1493
	PoCT would add too much time to the consultation	p=0.3580
	PoCT would reduce my after hours workload	p=0.6153
Testing	PoCT would ensure that the test I request is done	p=0.2604
	Current external pathology arrangements are adequate	p=0.0632

#### 12.4.4.3. Device Operators

There was no evidence of effect modification by geographic location for any of the Device Operator attitude statements (Table 212).

**Table 212: Comparison for a change in device operator attitude**

Attitude statements	Effect modification by geographic location
PoCT is technically difficult to use	p=0.7754
QA requirements for PoCT are time consuming	p=0.3950
QC requirements for PoCT are time consuming	p=0.6296

12.4.4.4. *Patient satisfaction analysis*

12.4.4.5. *Patients*

There was no evidence of effect modification by geographic location for any of the hypotheses (Table 213).

**Table 213: Patient satisfaction and effect modification by geographic location**

<b>Hypothesis Category</b>	<b>Statement</b>	<b>Effect modification by geographic location</b>
Collection process	I would rather have blood taken by a finger prick than by needle in my arm	p=0.1352
Confidence in the process	Laboratories have better hygiene than Point of Care Testing	p=0.6272
Confidence in the results	I have confidence in the information given by my GP or practice regarding my pathology test result	p=0.8897
Convenience	Not having to travel to an outside laboratory would be convenient	p=0.8905
Cost	Outside pathology laboratories involves extra time and transport costs	p=0.3026
Disease management	Having immediate feedback of the test result for my condition was important as it allowed me to discuss the management of my condition with my GP	p=0.9842
	I am more motivated to look after my condition because of regular Point of Care Testing	p=0.9529
	Point of Care Testing strengthened my relationship with my GP	p=0.9873

12.4.4.6. *General Practitioners*

There was no evidence of effect modification by geographic location for any of the GP satisfaction statements (Table 214).

**Table 214: General Practitioner satisfaction and effect modification by geographic location**

Category	Statement	Effect modification by geographic location
Disease management	PoCT would assist in overall patient care	p=0.4166
	The availability of the PoCT was/would be useful for clinical practice	p=0.9707
Work flow	PoCT interrupted/would interrupt the flow of a particular consultation	p=0.2852
Testing	I am/would be confident of the accuracy of the results provided by the PoCT devices	p=0.1223
	Currently it takes considerable time to receive a test from the laboratory	p=0.6049

12.4.4.7. *Device Operators*

The analysis to determine the Device Operator's satisfaction with PoCT used five statements from the Device Operators' Satisfaction Questionnaire. As shown in Table 189, in all statements, Device Operators across all geographic regions indicated a high level of satisfaction with PoCT. Urban Device Operators showed lowest levels of satisfaction for ease of use and preference for PoCT to conventional pathology testing; however, they indicated higher levels of satisfaction in regard to their competency in using the PoCT device. Rural Device Operators showed lowest levels of satisfaction for competency in using the PoCT device and confidence in the accuracy of the PoCT results.

**Table 215: Device operator satisfaction (descriptive results)**

Statement	Urban	Rural	Remote	Total
I am competent in use of PoCT devices: median (IQ range)	9.4 (8.1-9.6)	8.2 (7.2-9.7)	9.0 (7.7-9.6)	9.0 (7.4-9.6)
PoCT devices were easy to use: median (IQ range)	8.3 (7.0-9.5)	8.5 (7.2-9.7)	9.1 (8.3-9.5)	8.8 (7.6-9.6)
PoCT devices were easy to maintain: median (IQ range)	9.0 (8.8-9.4)	9.1 (7.9-9.8)	8.9 (8.2-9.2)	9.0 (8.2-9.7)
Confident in accuracy of PoCT results: median (IQ range)	8.4 (7.2-8.5)	7.3 (5.8-8.3)	8.5 (7.7-9.2)	8.3 (7.1-9.0)
Prefer PoCT to conventional pathology testing: median (IQ range)	7.9 (6.2-9.2)	8.5 (7.3-9.2)	8.8 (7.4-9.6)	8.4 (7.3-9.4)

#### 12.4.4.8. Pathology Providers

Pathology Providers' satisfaction from baseline to follow-up by geographic location was not undertaken due to the small sample size.

## 12.5. DISCUSSION

The PoCT Trial sought to determine if there were differences between urban, rural and remote geographic regions in any of the parameters being measured. In terms of QC/QA there was no difference in results by geographic location. There was no evidence of any treatment effect by geographic location for hypotheses relating to improved therapeutic control or patient compliance to disease management. There was also no evidence of effect modification by geographic location for hypotheses relating to satisfaction for any of the participant groups or hypotheses relating to the average change in attitudes for GPs and Device Operators. The only evidence of treatment effect by geographic location was for patient change in attitudes and the number of GP visits.

PoCT for quality control testing was conducted to an equivalent analytical standard by practices across geographic regions, and in general, there were no significant difference between the region of testing and the median within-practice imprecision (using Kruskal-Wallis tests). This observation was valid for all tests and QC lot numbers except triglycerides (Level 1 LN 5082 and Level 2 LN 5230) and HDL-C (Level 1 LN 5230). Intuitively, the usefulness of PoCT would be expected to correlate with an increasing degree of remoteness as access to laboratory services decreased. Therefore the observation that there was no difference in the quality of QC testing across the urban, rural and remote practices in this Trial is an important and positive finding.

Acceptable results for QA testing did not differ by geographic location but remote practices generally had the highest number of unacceptable results requiring follow-up. The remote practices showed the most number of outliers and this is then reflected in their imprecision for the EQA, although it was the urban practices that used the help desk most often. These remote practices require the most support and multiple methods should be utilised to do this – telephone support, newsletters and refresher workshops are all useful.

Accreditation results showed that there were more urban GPs unsure about the applicability of the various sections of the (Interim) Standards compared to rural and remote GPs. It is important to note that regardless of geographic location, the majority of Device Operators agreed that the Standards were applicable to general practice, which could reflect working knowledge of the Standards.

There was some variation observed between geographic location and the level of agreement between the PoCT and laboratory testing, with remote practices having the widest limits of agreement. Analysis of clinically relevant limits of agreement for INR by geographic region showed similar rates of agreement against published expanded and narrow criteria as found overall for the Trial. These are comparable with agreements found in other studies.<sup>15, 17-19</sup> For the analysis of proportion of dual readings within 0.5 units, the results were again similar to those found in other studies, although for the higher INR range, the proportion of dual results >4.0 in remote areas the agreement was only 50% of the time compared to urban (68%) and rural (82%) patients. This was a lower percentage of agreement than found by Jackson et al (57%) for practices based in rural Australia<sup>17</sup>. However, the study did not provide a definition of rurality in the study, making direct comparisons difficult. Additionally, rural and remote practices were able to achieve high levels of agreement at the low end of the therapeutic range, where differences in results would have a greater impact on the clinical decision.

Anecdotal evidence suggests that the time taken to transport and analyse blood samples could impact on the reliability of results. A study by Seamark et al.<sup>16</sup> investigated the effect of transportation of INR test results from rural general practice to the central pathology laboratory and

found that samples analysed in five hours or more after collection contributed significantly to differences between PoCT and laboratory test results. In this Trial, the mean distance to the nearest Pathology Provider in remote practices was 57.5 kilometres, ranging from 1-100 kilometres and could be an explanatory factor for the wide limits of agreement seen in the remote locations.

In terms of clinical effectiveness, geography only influenced the number of GP visits which showed that patients in the intervention group from rural and remote areas had a higher number of GP visits per person-year compared with control patients.

While the Trial found no evidence of effect modification by geographic location relating to any of the GP or Device Operator attitude statements, the analysis did indicate the effect of treatment varied by geographic location for all three patient attitude statements. The results of the analysis showed a significantly larger increase from baseline on average for urban intervention patients compared to control patients relating to the statement that they 'would prefer to have their test done at the time of consultation'. In contrast, the increase in average agreement was larger in the control group for remote patients, while the change was similar between-groups for rural patients. Results relating to the statement 'Not having to wait for test results would ease my anxiety' demonstrated a significantly smaller increase in average agreement with the statement among intervention patients in a remote setting compared to control patients, while the opposite result was observed among rural patients. Lack of access to pathology services in remote locations is recognised<sup>17</sup> with many patients having to travel long distances and wait for lengthy periods of time for a test result. The delay in obtaining an INR result for a patient treated on anticoagulant therapy can be life threatening with an immediate test result relieving patient anxiety. Jackson et al.'s study investigating the accuracy and clinical usefulness of INR PoCT in Australian rural medical practice showed that the majority of GPs perceived that their patients would prefer the use of the PoCT device compared to usual pathology testing.<sup>17</sup> Cohen et al.<sup>23</sup> also found that 80% of patients treated for hyperlipidaemia felt their anxiety diminish by the immediate availability of the result.

From a practice perspective, location of the practice may influence the ability to participate in a PoCT program. Many remote practices, as shown in this Trial, were more likely to have only between 1-3 staff working in the practice and a larger percentage of solo practices. From the patient perspective, having a test done at the time of consultation was shown to be preferred and eased patients' anxiety particularly for patients in a remote location.

The lack of geographic differences in the parameters measured in the Trial could be explained by the provision of an extensive support program through localised training, Node Support Officers and a toll free help line. The quality management framework provided in the Trial was supported by practices, validating the importance of providing localised training and ongoing support if PoCT were to be implemented in Australian general practice.

## **12.6. CONCLUSION**

The analysis undertaken in this section focused on the impact PoCT may have on geographic location. Overall, there were no consistent and significant differences found between geographic locations for any of the parameters measured.

## 13. EVALUATION OF THE PoCT TRIAL IMPLEMENTATION

### SUMMARY OF THE CHAPTER

This chapter provides the methods and results of the evaluation of the PoCT Trial in terms of process, implementation and structure, focusing on quality, efficiency and satisfaction.

Participants representing four key groups associated with the Trial were interviewed by an independent researcher. A rating scale was used to assess responses and descriptive analysis was undertaken with the key themes identified from the qualitative questions.

The key findings of the chapter are:

- responders were very satisfied with the communication processes and information provided to participants during the Trial
- communication was seen as playing a key role in the management structure
- reports and documentation were provided in a timely manner and thought to be of very high quality
- the management structure was seen to be effective and the teams staffed appropriately. However, concerns were raised that the Evaluation Team was understaffed and more staff were needed at the developmental stages of the Trial
- the Trial Design was seen as being inadequate in a number of areas.

The key conclusion:

- respondents thought the Trial was well managed, ran smoothly and was a valuable piece of research for Point of Care Testing in Australian general practice.

### 13.1. INTRODUCTION

As part of the Trial evaluation, the Trial Manager was required to evaluate the satisfaction with the PoCT Trial implementation by the Trial Manager from the perspective of the key stakeholders – the funder, the Device Group, the QAP Group, PoCT Management Committee and the PoCT Steering Group.

### 13.2. AIMS AND OBJECTIVES

Evaluation of the PoCT Trial aimed to assess the processes around Trial implementation and structure in terms of quality, efficiency and satisfaction.

### 13.3. METHODS

The evaluation focused on four areas of the Trial. These were:

- the processes associated with implementation including communication, documentation and reporting
- management structure
- contractual arrangements including associated costs and
- Trial Design.

- 

### 13.3.1. Data collection

A qualitative approach was used to collect the data through semi-structured telephone interviews with key participants representing four groups associated with the PoCT Trial: the Trial Management Committee and consultants (including Node Support Officers); Quality Assurance Program; Device Management Group; the funding body (Department of Health and Ageing) and the PoCT Steering Group. The interviews took place between April and May 2007 and were conducted by telephone by an independent researcher not involved in the Trial.

A rating scale was used to assess responses to questions about the overall quality, satisfaction and efficiency of Trial implementation relating to communication, reporting and documentation, and management structure. For each of these questions respondents were asked to provide a reason for their rating. For questions relating to contractual arrangements only those directly affected were asked to comment. All respondents were asked to comment on the Trial Design and were given the opportunity to provide further comments regarding the Trial.

A descriptive analysis has been undertaken with the key themes identified for the qualitative questions.

## 13.4. RESULTS

A total of 16 people representing the various groups/organisations involved directly in the Trial implementation (see Table 216) were interviewed.

**Table 216: Group/organisation and number interviewed**

Area	Number of interviewees
Trial Management Committee/Consultants	9 (including 3 Node Support Officers)
QAP Group	1
Device Management Group	2
Department of Health and Ageing	1
PoCT Steering Group	3

The key themes identified from the qualitative questions are summarised below in Table 217.

**Table 217: Summary of key participants' responses**

Area	Main areas of focus	Results
Process: communication	<p>Follow-up of phone calls</p> <p>Liaison with Management Committee/DoHA</p> <p>Promotional material</p> <p>Progress of Trial</p>	<p>A majority of respondents (15/16) were highly satisfied with the communication provided to them and/or their organisation. Most frequent comments included: prompt response to their queries, kept up-to-date, and timeliness. One respondent summed it up by stating that '<i>communication has been a key to management structure</i>'.</p>

Area	Main areas of focus	Results
	<p>Important incidents</p> <p>Liaison with other contractors e.g. Device Group/Quality Assurance Group</p>	
Process: reporting and documentation	<p>Management Committee/Subcommittee meeting papers</p> <p>Regular reports by Trial Manager and Evaluation Manager</p> <p>Phase I report</p> <p>Protocols</p> <p>Financial reports</p>	<p>A majority of the respondents (14/16) were highly satisfied with the information provided and thought it was of very high quality. Comments such as: succinct, understandable, easy to read, well written and provided on time, were commonly made. As one respondent said <i>'reports were professionally produced, clear, easy to understand and very high quality'</i>.</p> <p>In addition, most respondents (13/16) were very satisfied with the efficiency of the reporting and documentation provided and felt that they received it in a timely manner. Two commented that at times information/documentation was received last minute. However, they were aware that this was, at times, due to other constraints and factors outside the Trial Manager's control.</p>
Management structure	<p>Trial and evaluation staff</p> <p>Management Committee membership</p> <p>Subcommittees</p> <p>Decision making process</p>	<p>11/16 respondents thought that the quality of the management structure was very good. They commented that it worked well, was very effective and appropriate. Some respondents however, suggested that the Management Committee was too large and at times the management structure led to duplication and incomplete information being given to Trial participants.</p> <p>Most respondents (13/16) commented that the staffing mix and skill level of the Trial Management team was appropriate, covered all disciplines and the staff had a good understanding of general practice and research. However, some suggested that the evaluation team was understaffed, that more staff was needed at the developmental stages of the Trial and there was a lack of GP representation on the Steering and Management Committees.</p> <p>Having Node Support Officers (NSOs) in each region was seen as having some positive aspects. Several respondents felt that their ability to provide support at a local level and develop a rapport with the</p>

Area	Main areas of focus	Results
		<p>practice staff were important in terms of the Trial implementation. Some respondents felt that the role of the NSO worked effectively where they were in close proximity to the practices (Adelaide and Victoria) but failed to work as well in New South Wales due to the vast distance between the location of the NSO and the practices. Several respondents (6/16) declined to comment as they had no direct contact with the NSOs.</p> <p>A majority of the respondents thought that the subcommittees were both effective and appropriate. It was suggested that they allowed greater participation and supported the larger Management Committee. Again, lack of GP representation on the subcommittees was cited as a weakness. As one respondent highlighted <i>'more GP involvement would have improved the decision-making process'</i>.</p>
Contractual arrangements	<p>These questions related to the contractual relationships established between DoHA, the Trial Management Group and other groups (Device and Quality Assurance) for the Trial. Therefore, only those to whom this related were asked the questions.</p>	<p>Most of the respondents (5/7) were satisfied with the structure of the contractual arrangements. They felt it worked well and provided the specific expertise needed for the Trial. Others suggested that having three different contracts added to management and communication complexity. It was suggested that <i>'one management structure managing the different activities and subcontracting to the other two groups'</i> would have been more effective. In addition it was thought that <i>'one management structure would have improved communication with practices'</i>.</p> <p>The initial delay in finalising contracts which ultimately postponed the start of the Trial was seen as the main issue that arose from the contractual arrangements. Further variations to contracts and changes to the Trial inevitably raised some issues and were thought to have been <i>'a complicated process'</i>.</p> <p>Of those who commented (6/7), all agreed that the costs provided for the Trial were adequate; however, additional activities required separate funding.</p>
Trial Design	Applicability to General	A majority of the respondents thought that the Trial Design under-estimated the

Area	Main areas of focus	Results
	Practice Useful for Trial management and evaluation management Difficulties encountered	complexities of general practice and did not consider the regional variation in regard to practice and patient numbers which resulted in low recruitment numbers. As one respondent highlighted the <i>'capacity of general practice to take on 3 tests at same time was unrealistic'</i> . It was also suggested that the Trial Design did not consider the complexities of the specific disease groups and the difficulties that would be encountered in working with numerous pathology labs. It was suggested that <i>'a single central lab should have been assigned to measure all lab tests that were performed'</i> .
Additional Comments		Most respondents thought the Trial was very worthwhile, was well managed, and ran smoothly. The Trial was also seen as a <i>'seminal important piece of research in health service delivery in Australia'</i> and it was suggested that it <i>'will provide a significant body of evidence to assess the effectiveness of PoCT in general practice'</i> .

### 13.5. DISCUSSION

Overall, respondents were very satisfied with the communication processes and information provided to participants during the Trial. Communication was seen as playing a key role in the management structure and reports and documentation were provided in a timely manner and thought to be of very high quality.

Most respondents found the management structure to be effective and the teams staffed appropriately. However, concerns were raised that the evaluation team was understaffed and more staff were needed at the developmental stages of the Trial. This reflects the extra work needed in adapting the Trial Design into a workable protocol and implementing it in the general practice setting. In addition, a lack of GP representation on the Trial committees at various levels was highlighted by several respondents as a weakness in the Trial. While the original PoCT Steering Group did have GP representation this was not for the length of the Trial which could explain the comments made by respondents. Having the support of Node Support Officers (NSO) in each region was generally seen as a positive aspect of the Trial. Having the support of a NSO at a local level was seen as a good model that worked effectively; however, thought should be given to the location of the NSO to maximise contact with the practices. For example, the model failed to work effectively in NSW as the distance between the NSO and a significant majority of the practices was too vast.

While most respondents were satisfied with the contractual arrangements and the three separate working groups, it was suggested that one organisation managing the different activities and sub-contracting out to the other two groups would have been much more effective. This would have alleviated the confusion often experienced by practices (who to report to, for what) and reduce the incidence of providing incorrect and/or duplicate information. Another issue raised in regard to the contractual arrangements was the delay in finalising the various contracts which impeded

the start of the Trial. While the initial funding provided for the Trial was seen as adequate, it was important that additional activities necessary for the Trial implementation be funded separately. To ensure the Trial research questions were answered robustly additional work was needed which was not considered in the Trial Design, and therefore not costed in the original budget.

The Trial Design was seen as being inadequate in a number of areas. Overall, the complexities of general practice were underestimated and the regional variation in regard to sample sizes of both practices and patients not considered, resulting in lower recruitment than anticipated. In addition, the Trial Design did not consider the complexities of the specific disease groups and the difficulties that would be encountered in working with the numerous Pathology Providers. The diversity of general practice and utilisation of multiple Pathology Providers impacted not only on the Trial implementation but also on the analysis and comparison of results. Due to the limitations of the Design, extensive time was spent at the start of the Trial to develop a workable protocol and in attempts to reach the recruitment targets.

### **13.6. CONCLUSION**

Overall, respondents thought the Trial was well managed, ran smoothly and was a valuable piece of research for Point of Care Testing in Australian general practice.

Several limitations were identified in undertaking the Trial implementation evaluation. Firstly, the evaluation covered multiple aspects of the Trial; however, many of the key participants interviewed had limited knowledge and/or no direct involvement in some of the areas requiring comment, for example, knowledge of the role of the NSO. Secondly, a key group involved in the implementation of the Trial (the evaluation team) was unable to contribute to the evaluation as they were undertaking this assessment of the Trial Implementation. Their input would have added valuable information to the evaluation given their intimate knowledge of all aspects of the Trial. In future, consideration should be given to outsourcing this component of the evaluation to allow all relevant groups to provide input.

## 14. WOULD THE REGULATORY ENVIRONMENT USED FOR THE TRIAL MEET THE NEEDS OF ALL THE STAKEHOLDERS IF PoCT WERE MADE MORE GENERALLY AVAILABLE?

### SUMMARY OF THE CHAPTER

This chapter outlines the model used in the Trial to implement PoCT from the different stakeholder perspectives (General Practice, Patients, Pathology Providers and the Government), the acceptability of the model and what needs to be considered if these research based results were to be implemented outside of Trial conditions and in routine clinical practice.

The key findings of the chapter are:

- the quality management system which included Device Operator training and certification, IQC, EQA overseen by an accreditation program based on the (Interim) Standards for PoCT in general practice was acceptable to all stakeholders. If PoCT were to be implemented in general practice more widely, it would be necessary for a similar system to be adopted to ensure that the success seen in the Trial could be translated into practice
- that the (Interim) Standards for PoCT in GP were considered appropriate by all stakeholders. It was considered important that practices participate in a quality management system to provide GPs with the confidence that their clinical decisions are based on reliable and accurate results and to ensure patient safety was not compromised
- that intervention practices were required to nominate a GP who was given overseeing authority and responsibility for PoCT. An essential step in introducing PoCT more broadly would be to identify a GP with the primary responsibility for the implementation and management of PoCT within a practice
- that PoCT procedures were required to be conducted in association with an attendance with a GP. However, the manner in which testing was adopted in the practice was not mandated. Intervention practices were provided with protocols to follow for testing. These were seen as beneficial and it would be necessary for PoCT guidelines to be developed to assist GPs with device selection and the development of testing protocols, including interpreting and recording results
- that patients and practice staff found PoCT acceptable in the framework in which it was implemented in the Trial and revealed high levels of satisfaction. The model used in the Trial may have provided reassurance that patient care was not being compromised and operated within a quality framework equivalent to traditional pathology testing
- Pathology Providers indicated that they would like some involvement if PoCT were to be implemented in general practice. Pathology Providers are in a position to provide advice on test results, provide validation of PoCT results and support IQC and EQA and this role needs to be enhanced
- a number of organisations already exist that can take on various aspects of the Trial model. These organisations include Divisions of General Practice, the RACGP, NATA and the RCPA (QAP)
- the Australian Government provided funding for all aspects of PoCT examined in the Trial, many of which are likely to form a part of PoCT in general practice if the model is made more generally available. The Government was involved in the development of the Standards. An important role for the Government would be determining whether the quality management system should be mandatory, whether PoCT should be limited to the chronic disease areas investigated in the Trial, and the MBS fees for testing.

The key conclusion:

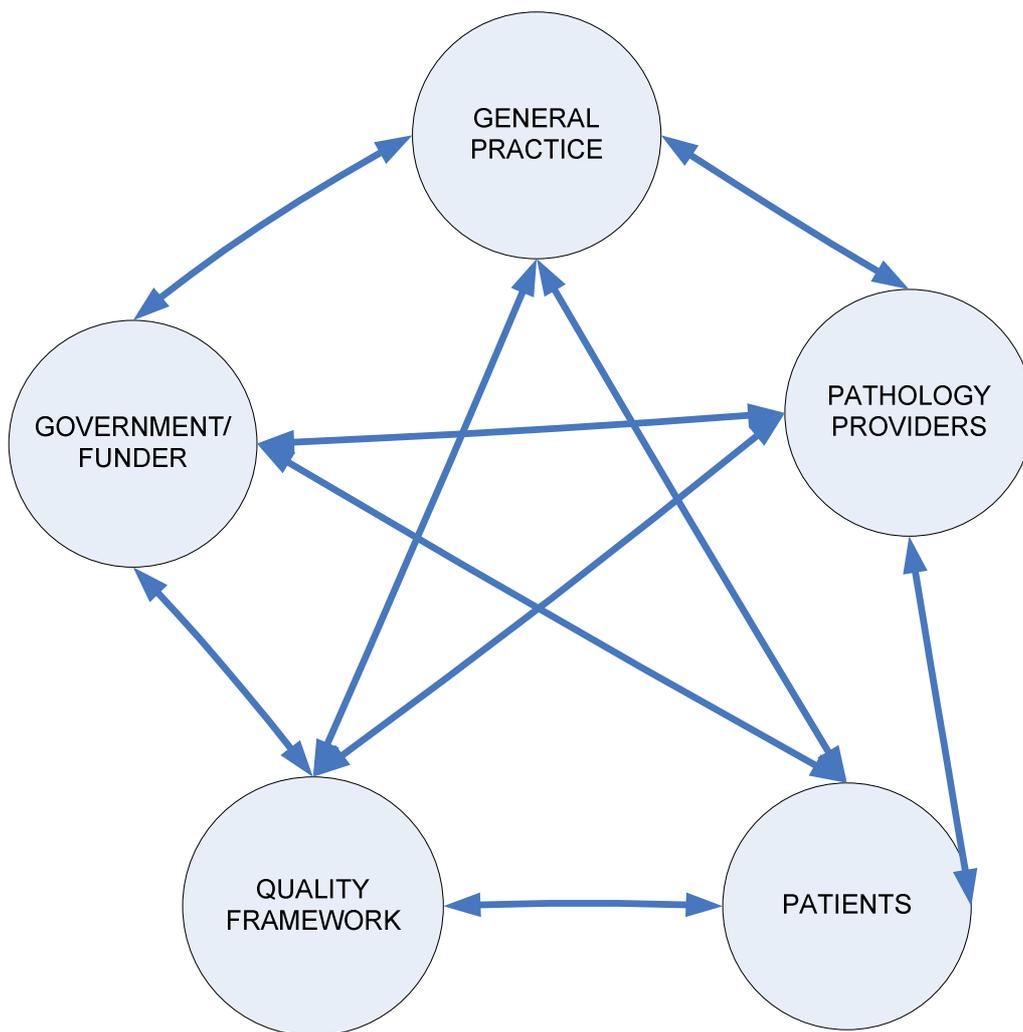
The Trial model provides a framework that has been proven to work within the current regulatory environment and is acceptable to all stakeholders. The Trial model could form the basis of a framework for the implementation of PoCT in GP more broadly.

## 14.1. INTRODUCTION

This chapter focuses on the model used in the Trial to implement PoCT from the different stakeholder perspectives (general practice, Pathology Providers, patients and the Government). In addition, an initial section will look at the quality framework/accreditation framework (under the heading Quality Management System) (see Figure 43).

Following a description of the model from each perspective, the acceptability of the model will be discussed, and what needs to be considered if it were to be implemented into the broader general practice setting. The discussion below is based on the assumption that PoCT would be made available more generally. The model outlined in this chapter has been drawn from the outcomes of the Trial.

**Figure 43: Relationship with key stakeholders for the provision of PoCT more generally**



## 14.2. QUALITY MANAGEMENT SYSTEM

For PoCT to be implemented in the GP setting, an effective quality management system is essential. Clinicians will need reassurance that their clinical decisions are based on reliable, accurate and precise results to ensure that patient safety is not compromised. General practices adhering to a quality management framework for PoCT would provide patients with the reassurance that the process is of a high quality standard, equivalent to traditional pathology laboratory testing.

### *Trial model*

For the Trial, the quality management system included:

- Device Operator training and certification
- internal quality control
- external quality assurance

which was overseen by an accreditation program based on the (Interim) Standards for PoCT in general practice (the Standards).

Complementing these methods was an extensive support program which included a toll free help line and local Node Support Officers for all intervention Practices in the Trial.

The Standards underpinned all quality related activities and their development involved both general practice and pathology laboratory representatives. The goal of the Standards was to ensure that PoCT did not compromise the standard of patient care and clinical decision making. The Standards were tailored to recognise the resources of the non-laboratory environment, aimed to ensure that quality of test outputs was equivalent to the traditional pathology laboratory and defined the minimum standard required for accreditation of PoCT in GP. The evaluation of the Standards provided evidence that all surveyors (scientists and GPs) thought that the Standards provided a realistic and achievable minimum standard for PoCT in general practice. The majority of Trial participants (GPs and Device Operators) also agreed that they were applicable and acceptable to general practice.

The PoCT Trial accreditation program was the culmination of a broad quality management system based on different sets of standards developed by and for different professional disciplines (general practice and pathology), effectively encompassed in the Standards. From a Trial perspective, it was therefore important to involve both disciplines in development of the accreditation process, so a Working Group was established to achieve this. The Working Group included a GP with experience as an accreditation surveyor, scientists with both PoCT experience and laboratory backgrounds, and a Trial representative with practice management experience. A guide for surveyors and a practice accreditation checklist were also developed. In this Trial, the collaborative approach to the implementation of the accreditation process was evidenced as successful and acceptable to both surveyors and practice staff. The guides prepared for the survey teams and practices were reported to be appropriate and useful.

The Trial required that users of the devices were trained and certified with refresher training undertaken 12 months after the initial training to re-cap the QA/QC process and for Device Operators to raise any test-specific issues. As part of the training, Device Operators were provided with a training manual, A3 laminated posters for quick reference and a CD-ROM of the training and resources. Feedback from the refresher training indicated that the training and resources provided were very beneficial.

PoCT, like pathology laboratory testing, requires QC and QA testing to ensure acceptable performance. The limits of acceptable performance for QC were set by the Device Working Group. As this was a first in a general practice setting and the level of performance that practices would achieve for QC testing was unknown, conservative limits for acceptable performance were set. The QC limits for the Trial are deemed to be appropriate, with the possible exception of HbA1c and ACR, where a case for slightly tighter limits could be argued.

The QA used the same limits as currently apply to pathology laboratories and with the exception of lipids, PoCT demonstrated a clinically acceptable performance. Lipid testing should be re-evaluated when a new generation of instruments becomes available.

Overall, the PoCT Trial demonstrated that QC and QA testing can be adapted to the PoCT environment to give acceptable QC and QA results, with support from the RCPA Quality Assurance Pty Ltd for QA and the Device Group for QC, combined with quality training.

*What needs to be considered?*

Overall, the evaluation indicated that the Trial quality management system was able to be successfully implemented and found to be acceptable and supported in the general practice setting. To implement this system more widely, a number of factors need to be considered by policy-makers if these research based results were to be implemented outside Trial conditions and in routine clinical practice. The Trial evaluators have identified some areas that seem necessary to continue to ensure that the success seen in the Trial can be translated into practice. These are discussed below.

The Trial Manager was responsible for coordinating the accreditation process. If PoCT were to be implemented in the general practice setting an identified body would need to undertake this role on a longer term basis. The accreditation process could be integrated as an additional module to the existing general practice accreditation process (RACGP) or it is suggested that NATA could provide this service. The accreditation surveyor team should include a GP and a member who has the appropriate scientific skills to accredit the general practice PoCT service. This surveyor combination used in the Trial was found to be acceptable and appropriate. In the Trial, two accreditation visits took place in 18 months. If PoCT were to be implemented in general practice a decision would need to be made as to whether this would be feasible and financially possible.

If PoCT were to be implemented in general practice it would be important for Device Operators to receive training and regular updates. A possible option for the implementation of a national PoCT training program might be face-to-face on-site training. This could be conducted by a central organisation (or primary training team) with support from PoCT instrument suppliers and regional networks of secondary trainers, although this may be costly when applied at a national level.

The option of conducting training, at least in part, by an on-line module that included a web-streamed video presentation of training is an attractive option as access to training would be available 24 hours a day, seven days a week. A precedent for this approach has been set by the national QAAMS Program for diabetes management in Aboriginal medical services, with a web-streamed video presentation of training now available through the QAAMS Program website. This may be particularly suitable for rural and remote practice staff and for refresher training.

It is proposed that regardless of which model(s) is implemented, certification of such training courses is required and that refresher training/updates occur every 12 months. In the Trial, training was provided by the Device Group, but considerations needs to be given to how this would be applied nationally and what organisation would be in a position to do this.

The practices in the Trial were supported by QC/QA groups. A possible model for QA and QC implementation could include a separate organisation monitoring QC and offering specialist assistance and support for interpretation and actioning QC results for practice staff. This model allows between-practice and within-practice imprecision to be monitored and assessed and advice provided if results are outside defined limits. Another model involves the local pathology laboratory reviewing the QA/QC and providing support to practices for a fee.

Divisions of General Practice (local general practice support networks) are in a position to provide support through; coordination of accreditation visits; dissemination of PoCT guidelines, education and resource material; coordination of initial training/refresher training through existing continuing professional development (CPD) programs; and co-ordination of CPD point acquisition.

### **14.3. GENERAL PRACTICE**

The introduction of PoCT into general practice requires consideration of the current organisational structure within these providers and processes. The PoCT model used in the Trial has highlighted a

number of key points that would need to be taken into account if PoCT were to be implemented on a wider scale.

### *Trial Model*

Clinical governance as stated in the (Interim) Standards for PoCT in general practice 'is a framework of assurance and review for clinical responsibility and accountability'. In the Trial, intervention practices were required to nominate a GP who was given overseeing authority and responsibility for PoCT. This GP was expected to have adequate working knowledge of PoCT and was responsible for ensuring the practice complied with the Standards. This included ensuring only trained staff were using the PoCT devices and their competency levels were maintained, through regular use.

All intervention practices were given the use of three devices for the duration of the Trial. The devices were not to be used for mobile testing and needed to be used at a fixed, suitable place in the practice. In a majority of practices they were easily housed in an existing treatment room. Refrigeration capacity to accommodate the storage of quantities of QA reagents and QC material was also necessary but did not pose a problem for the practices in the Trial. Monitoring of the refrigerator temperature and stock control was incorporated into the Device Operator's role.

Formal training on using the devices was offered to both GPs and practice staff. While some GPs undertook initial training, none operated the devices. A majority of the staff trained as Device Operators were nurses and they incorporated PoCT into their existing roles. To ensure ongoing continuity most practices had two or more trained Device Operators. Practices which initially had only one Device Operator found it necessary to have another staff member trained to help share the workload and cover periods of leave. In some practices where this was not possible PoCT ceased during the Device Operator's absence.

Training to undertake the QA and QC components of the Trial was a very new concept for practice staff. QA and QC testing requires appropriate technique and adequate time to complete. The level of competency maintained and the achievement of acceptable results for the QA/QC surveys during the Trial demonstrated the ability of general practices to successfully fulfil analytical requirements related to PoCT. Device Operators indicated that QA and QC was time consuming; however, the Trial did require multiple QA/QC testing for each of the three devices.

For the Trial, PoCT was required to be conducted in association with an attendance with a GP; however, the GP could determine whether the test was undertaken immediately before, during or after the face-to-face consultation. Trial results indicate that predominately PoCT was being provided as one-on-one patient testing and conducted before the consultation. Results also suggest that PoCT does not impact on patient flow or interrupt the consultation. While the Trial findings indicate that PoCT increased the number of GP visits, the time saved and health benefits need to be considered from a practice perspective. PoCT eliminates the need for follow-up phone calls from either the practice or patient, particularly with INR results. It also provides the GP with a 'window of opportunity' to discuss management changes with patients who may not attend follow-up appointments.

During the Trial intervention GPs could use their discretion as to whether their patient would have a pathology test as well as or instead of a PoC test. While this did occur from time to time, both GPs and Device Operators showed high levels of confidence in the accuracy of the PoCT results. For the purpose of the Trial a protocol was developed to assist intervention practices with implementing PoCT. Sections of the protocol included information on testing frequency, interpretation of results and incident reporting.

For the purpose of the Trial, specific Test Request/Result forms for each of the tests were developed and provided to intervention practices for recording PoC test results. These were provided in hard copy as well as electronic format. Device Operators were required to complete the forms for each test undertaken, submitting a copy to the Trial Manager and storing the duplicate copy in the patient's case notes. Trial results suggest that GPs' most preferred method of receiving PoCT results

was direct download to patient files from the devices while Device Operators' most preferred method was printed results from the devices. Having direct downloads to the patient's file is more in line with current practice for receiving pathology laboratory results and reduce translation error. Having either direct downloads or printed results direct from the devices would also eliminate duplication and potential entry error.

Intervention practices were required to participate in an accreditation program. The Trial demonstrated that with appropriate resources and support practices could meet the required standards to achieve accreditation. Resources provided through the accreditation program and feedback from the Surveyors given to the staff after the accreditation visits were viewed as being highly beneficial.

For the purpose of the Trial, PoCT was to be used for the monitoring of diagnosed conditions and not for initial diagnosis or screening purposes, the three conditions being anticoagulant therapy, diabetes and hyperlipidaemia.

PoCT allows an immediate test result to be available at the time of consultation. This allows GPs to make clinical decisions more quickly and discuss these with the patient while it is uppermost in their minds, which is particularly important for chronic disease management. The Trial has demonstrated that PoCT provides a tool to assist GPs to implement clinical guideline recommendations and engage patients in their care in respect to medication compliance. Other positive aspects of PoCT found in the Trial were that intervention patients indicated that their relationship with the GP strengthened and they were more motivated to look after themselves. Intervention GPs also indicated that PoCT allowed them to discuss care with the patient immediately, it helped monitor disease and assisted with patient medication compliance.

The findings of the Trial indicated that the model used to implement PoCT in general practice was successful and achievable. While anecdotal evidence suggests that it was difficult and time consuming at the start, once processes and systems were in place it became easier and fitted in with current practice.

#### *What needs to be considered?*

An essential step in introducing PoCT into general practice is to have a designated GP in the practice who is given primary responsibility for its implementation and management. It is important that this GP and other GPs using PoCT have a sound understanding of the underlying principles and quality of testing. This knowledge could be obtained through participation in a continuing medical education program.

Prior to implementing PoCT practices need to give consideration to which test/device would benefit their patients and could be accommodated. This includes space and information technology requirements, and being aware of its patient profile to determine if it will generate the volume of tests to retain skill levels and be financially viable. How the testing would be adapted to fit in with an existing practice also needs consideration. This could include in a mini clinic setting, on a one-on-one consultation basis or a combination of methods as long as the philosophy of PoCT (immediate feedback of test result) was maintained. Once introduced, the practice will need to establish protocols for testing. It is essential that PoCT guidelines be developed to assist GPs with device selection and the development of testing protocols, including interpreting and recording results.

Sufficient practice staff need to be formally trained and maintain their competency level through regular testing and regular refresher training/updates. Device Operators, potentially nurses, could undertake their training as part of their professional development.

It is essential that practices participate in a quality management system. This would provide GPs with the confidence that their clinical decisions are based on reliable, accurate results and ensures patient safety is not compromised.

## 14.4. PATIENTS

General practice is the first point of contact for many people with their health needs. Patients with chronic conditions are primarily managed by their GPs. Management of these chronic conditions include regular pathology testing to inform management decisions. Traditionally pathology testing is performed in a laboratory but PoCT enables a test to be performed at the time of consultation and allows a clinical decision to be made immediately. PoCT may be a new concept for many patients and requires some adjustment to how health care would be delivered. It is therefore important when implementing PoCT that patients' needs and requirements are considered.

### *Trial Model*

Patients participating in the intervention group of the Trial were required to have their INR, HbA1c, microalbumin or lipids tested using a PoCT device. The testing was to be conducted as 'usual care'; however, it needed to be linked to a consultation. For some patients, particularly those having INR testing, this required a change in practice. Currently, INR testing is being managed in several ways. Firstly, GPs can request multiple INR tests without the patient being seen. This requires the patient and/or practice to make contact for the result and any changes in management. Secondly, as found in our Trial, some Victorian Pathology Providers offer a service which includes INR testing and medication management. Results from the Trial showed that patients in the intervention group were more satisfied in terms of the collection process for PoCT, had confidence in the process and with results and found it more convenient than going to a laboratory. In addition, they were more satisfied with the management of their disease than patients in the control group.

Chronic disease management requires collaboration between a GP and patient to achieve optimal patient health outcomes. Health care efforts need to be sustained over the long-term with GPs providing management and preventing complications of disease and patients adopting GP recommendations by changing and maintaining healthy behaviour. Patient self management is an important aspect of chronic disease management. Most patients are aware of what behaviours are conducive to good health but this does not necessarily translate into action.<sup>187</sup> The Trial has demonstrated that PoCT engages patients in their care in respect to medication compliance. Other positive aspects of PoCT found in the Trial were that intervention patients indicated that their relationship with the GP had strengthened and they were more motivated to look after themselves.

### *What needs to be considered?*

Patients found PoCT acceptable in the framework in which it was implemented in the Trial and revealed high levels of satisfaction. The model used in the Trial may have provided reassurance that patient care was not being compromised and operated within a quality framework equivalent to traditional pathology testing.

Although the Trial required PoCT to be undertaken in conjunction with a GP visit, this did not negatively impact on patient satisfaction.

For some patients PoCT may not be a suitable or preferred method of testing, therefore, patients need to have the freedom to opt in or out of PoCT. This needs to be considered in implementing PoCT in general practice more broadly.

## 14.5. PATHOLOGY PROVIDERS

### *Trial model*

Prior to the implementation of the PoCT Trial, the pathology industry had been involved in the development of the Trial Design, criteria selection of PoCT devices and development of the (Interim) Standards for PoCT in General Practice. However, Pathology Providers in the live phase of

the Trial had minimal involvement, mainly the electronic download of pathology results, provision of paper pathology results and involvement in the accreditation program.

The Pathology Providers linked to the practices in the Trial were asked their views on PoCT in general practice through the satisfaction surveys distributed at the end of the Trial. The majority of Pathology Providers agreed that they had a role in providing expert advice to GPs performing PoCT and strongly agreed that PoCT in GP should be monitored by laboratories. Supporting this outcome, more than half the GPs in the intervention practices (59%) reported that they had used their local Pathology Provider for assistance with PoCT during the Trial. The GP utilised their local Pathology Provider to double check unusual results and check the accuracy of the PoCT results.

*What needs to be considered?*

The role of Pathology Providers if PoCT were to be implemented into GP more broadly needs further discussion and development. The responses in the satisfaction survey of the Pathology Providers provide some indication of their role. While PoCT in general practice may reduce the number of requests for certain tests to the Pathology Provider, these providers may have a role in providing ongoing support to GPs using PoCT. Pathology Providers are in a position to provide advice on test results, provide validation of PoCT results and support in QC and QA. In a sense, based on the information obtained in the Trial, the role of Pathology Providers in the pre-analytical and analytical phases is reduced, although their role in the post-analytical phase may increase such as with the interpretation of results.<sup>188</sup> The issue this raises then is the funding for such a service.

From the results of the Trial, it seems unlikely that practices that introduce PoCT will use it exclusively for all their patients. In the Trial, the data indicated that practices that were in the intervention group still sent a proportion of their pathology testing to Pathology Providers. Reasons given for using pathology laboratories included: the wishes of the patients; the convenience of laboratories for patients; Device Operators on leave; and that a range of tests were being ordered by the GP at one time and therefore it was easier to have them all undertaken at the pathology laboratory.

PoCT if introduced in general practice, it may also change the way some Pathology Providers provide services. For example, in Victoria, some Pathology Providers currently advise patients on changes to medication based on results of INR tests. Practices provided with this service will need to re-negotiate the support received from their Pathology Provider if they are to implement PoCT.

## **14.6. FUNDER/GOVERNMENT**

*Trial model*

The Australian Government provided funding for all aspects of PoCT examined in the Trial, many of which are likely to form a part of PoCT in general practice if it is made more generally available. This included funding of the training, the devices, consumables, the QC and QA programs, the accreditation program and testing costs through provision of special MBS item numbers for the intervention practices. Additionally, a requirement of the reimbursement was that it was conducted in association with a GP attendance. The selection of the devices for the Trial and their focus of use in chronic disease management were also undertaken by the Government in consultation with key stakeholders. The model also ensured that patients had no out-of-pocket expenses for their involvement in the Trial.

Another important role for the Government was the development of the (Interim) Standards for PoCT in General Practice in collaboration with general practice and the pathology industries. These Standards ensured that for the Trial, the delivery of PoCT in general practice was safe for the Australian community.

*What needs to be considered?*

While the Trial provides a model for implementing PoCT in general practice, there are a number of issues that must be considered from a funder/Government perspective if PoCT were to be made more broadly available. Some of these issues are outlined below.

Establishing the Standards and ensuring that a quality framework exists in Australia if PoCT is made more generally available is likely to be a key role for the Government in collaboration with other stakeholders. As technological developments occur around PoCT, as well as pathology testing, these Standards will need to be reviewed and updated to ensure they meet the needs of the current technology. The responsibility for this may rest with the Australian Government.

Currently, practices wishing to undertake PoCT and receive an MBS fee for testing are required to be deemed an approved Pathology Provider and be accredited through NATA. This is an expensive process, but ensures that PoCT is implemented within a quality framework. However, practices can implement PoCT outside this framework if they are not claiming an MBS fee for the testing. The accreditation process used in the Trial, as outlined above, was shown to be acceptable and feasible. This raises the question of accreditation of practices which undertake PoCT. If PoCT is made more broadly available under a quality framework similar to that utilised in the Trial, consideration must be given to whether this will be mandatory for practices. The related question is then 'how is accreditation funded? – self-funded, subsidised or fully funded by the Government'.

The Trial utilised PoCT devices that had been assessed as acceptable and approved by the Therapeutics Goods Administration (TGA). However, during the Trial, one of these devices was superseded by a new model and new improved technologies or new PoCT devices are likely to be developed in the future. The TGA has the responsibility to register devices used for therapeutic purposes in Australia and to ensure that devices meet acceptable standards for Australia. However, consideration must be given, if PoCT is implemented more broadly, as to whether funding is linked to specific devices and whether for this decision to be made, additional data is required beyond that provided in the TGA assessment. This may require a separate process which can assess devices for use in general practice.

The Trial model focused on devices used to manage chronic disease, rather than those used in screening, although microalbuminuria testing could also fall into the latter category. Consideration needs to be given as to whether or not the implementation of PoCT more broadly should be limited to the chronic disease areas investigated in the Trial.

How PoCT is funded is a key area for discussion if the decision is made to implement PoCT more broadly. It is also interrelated with a number of other decisions such as screening versus disease management and partial or complete funding support for involvement in the quality framework.

If chronic disease remains the focus for PoCT in general practice, linking PoCT funding into existing chronic disease programs such as those relating to diabetes or other programs such as the Service Incentives Payments could be ways of funding or subsidising participation in the quality framework beyond an MBS testing item for the actual testing.

PoCT in a general practice setting is unlikely to ever be cost neutral for a number of reasons. Firstly, economies of scale/scope are unlikely to be achieved because of the volume of testing achievable in general practice – a particular issue in rural and remote areas. Secondly, unlike Pathology Providers, PoCT would only form a small part of the activities undertaken by GPs and practices. This makes direct comparison of costs of testing between Pathology Providers difficult. However, the impact on clinical effectiveness and the satisfaction of participants and benefits to society may offset the expense of PoCT.

## **14.7. CONCLUSION**

The PoCT Trial in a general practice setting included key stakeholders who have a role in PoCT or who are recipients of PoCT. This included GPs, Pathology Providers, patients and the Government. Their role in the Trial ranged from: the development of Standards for PoCT in general practice, the

provision of a QC and QA program for general practice, the development and implementation of the accreditation program, the undertaking of PoCT in a general practice and the assessment of PoCT. These stakeholders as shown in Figure 43 varied in the level of direct input into the Trial components as well as the timing of their involvement, but all were essential for the successful implementation of the PoCT model.

The Trial model provides a framework that has been proven to work within the current regulatory environment and is acceptable to all stakeholders. The Trial model could form the basis of a framework for the implementation of PoCT in GP more broadly.

## 15. HOW THE COSTS OF THE PoC TESTS VARY WITH VOLUME

### SUMMARY OF THE CHAPTER

This chapter describes how the costs of PoCT in general practice vary with volume and how these unit costs compare with unit costs of testing through a pathology laboratory.

Unit costs for the four PoC tests were based on data obtained from the Trial and updated to 2008 values using CPI. Costs were categorised as establishment costs, annual costs, monthly costs and per test costs.

Sensitivity analysis was used to examine the influence of volume on PoCT unit cost.

The key findings of the chapter are:

- the estimated unit cost for PoCT is \$20.02 per test for INR, \$75.88 per test for HbA1c, \$87.80 for ACR and \$66.84 for lipid studies
- for all tests except INR, the unit costs were much higher in general practice compared with pathology practice
- cost per test varies with volume.

The key conclusion:

- the estimated cost per test for PoCT in general practice based on Trial volumes is much higher than the estimated cost for the tests provided through a pathology laboratory.

### 15.1. INTRODUCTION

The objectives of this Chapter are:

- to describe how the costs per test of PoCT in general practice vary with volume, and
- to compare these unit costs with the unit costs of testing through a pathology laboratory.

The calculations in this chapter are from an accounting perspective rather than the economic perspective taken earlier in Chapter 10 of this Report. The main differences are that an accounting perspective is taken on the absorption of fixed costs into the cost per test, and that pathology laboratory fees are adjusted to remove their operating margin (or 'profit').

This chapter prepares the way for a discussion of indicative MBS fees for PoCT in the next chapter.

### 15.2. METHODS

The calculation of the unit costs for the four PoC tests used in the Trial was based on data obtained during the Trial and updated to 2008 values using the CPI.

Costs were categorised as:

- establishment costs (device and initial training)
- annual costs (accreditation, QA program and refresher training)
- monthly costs (QC/QA consumables and Device Operator time for QC and QA testing) and
- per test costs (consumables and Device Operator time).

Establishment costs were converted to an annual amount by straight line depreciation over the assumed three years of useful clinical life. The volume of tests per year was based on the average number of tests performed per practice per month during the Trial. This was then used to absorb the annual and monthly costs so as to calculate a total cost per test. This cost forms the base case. To determine the influence of volume on the cost per test, sensitivity analysis was undertaken using a range of annual numbers of tests per practice and presented graphically.

The estimated PoCT base costs used the cost of accreditation provided in the Trial and not the costs that would currently apply to a Category M laboratory and using the accreditation process provided by NATA. Sensitivity analysis was undertaken using the latter scenario to determine per cost differences using this alternative.

Additionally, the PoCT device used in the Trial for diabetes testing was configured for both HbA1c and Microalbumin. In calculating the base cost for both HbA1c and Microalbumin, the cost for the device and annual maintenance was shared between the two tests. This was based on the proportion of these tests performed during the Trial, namely 60% for HbA1c and 40% for Microalbumin. However, as a practice may use the device for only one test, sensitivity analysis was undertaken to reflect such a scenario.

In order to compare the calculated costs for PoCT with the relevant costs currently applying to testing through a pathology laboratory, information was obtained from Michael Legg & Associates (see Table 222). This firstly adjusts 85% of the MBS fee for each equivalent test at a pathology laboratory to allow for patient episode initiation (PEI), bulk-billing, coning and the percentage of test items attributable (for a lipid test only); and secondly removes the operating margin or profit (21.6% on revenue) to estimate the underlying (operating) costs (see Section 15.3.5) To this has been added the cost of GP/nurse follow-up. Conversely, the costs of Device Operator time for the collection of the specimen are included in the costs of PoCT calculated in Chapter 10.

### 15.3. RESULTS

#### 15.3.1. International Normalised Ratio (INR) testing

The estimated unit cost for the PoCT for INR is \$20.22 per test (Table 218). At the volume experienced in the Trial, the establishment and annual costs (\$9.94) contribute most to the cost per test, followed by the per test costs (\$8.97).

Adjusting the current MBS fee for INR testing in a pathology laboratory as described in the Method section (above) suggests that the cost of this test at the pathology practice is \$18.60 (including PEI).

**Table 218: Estimated unit cost of PoCT for INR**

	Items	\$	Cost per test (\$)¹¹
Establishment costs	Device¹	316.67	
	Initial training ²	600.00	
Annual costs	Accreditation³	561.07	
	QA Program⁴	445.45	
	Refresher training⁵	200.00	
	Subtotal	2,123.20	9.94
Monthly costs	QC/QA consumables⁶	0.10	
	QC Device Operator time⁷	n.a.	
	QA Device Operator time⁸	19.71	
	Subtotal	19.81	1.11

Per test costs	Consumables <sup>9</sup>	6.19	
	Device Operator time <sup>10</sup>	2.78	
	Subtotal	8.97	8.97
	Total cost per test		20.02

Notes:

1. The cost is based on CoaguChek XS, the device available as of June 2008 and adjusted for clinically useful life (3 years ) by straightline depreciation. The device used in the Trial, the CoaguChek S, is no longer available.
2. Training costs are based on Trial data and are for two staff per practice allocated in the first year.
3. Accreditation costs are based on the cost of implementing the accreditation program for the Trial. The costs for providing accreditation through NATA and annual fees associated for category M laboratories are presented in the sensitivity analysis.
4. Based on the RCPA Pty Ltd QA Program used for the Trial, but updated for 2008 prices. This cost assumes that practices will participate in a formal QA process.
5. The Trial provided a refresher training course after 12 months.
6. Consumables associated with QA are based on 2008 prices.
7. As the CoaguChek XS device has an inbuilt QC process, there are no costs associated with QC consumables and thus no Device Operator time for QC.
8. Device Operator time for QA is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
9. The per test consumables include the reagents and gloves and use 2008 prices.
10. Device Operator time for testing includes the actual test, plus note taking and patient collection and is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
11. The volume of tests used to calculate the cost per test is based on the average number of tests per month per practice during the Trial. For INR, the mean number of tests was 214 per annum or 18 per month.

Note: This cost was calculated assuming that the GP's contribution to interpreting the test results is incorporated into the standard GP consultation item.

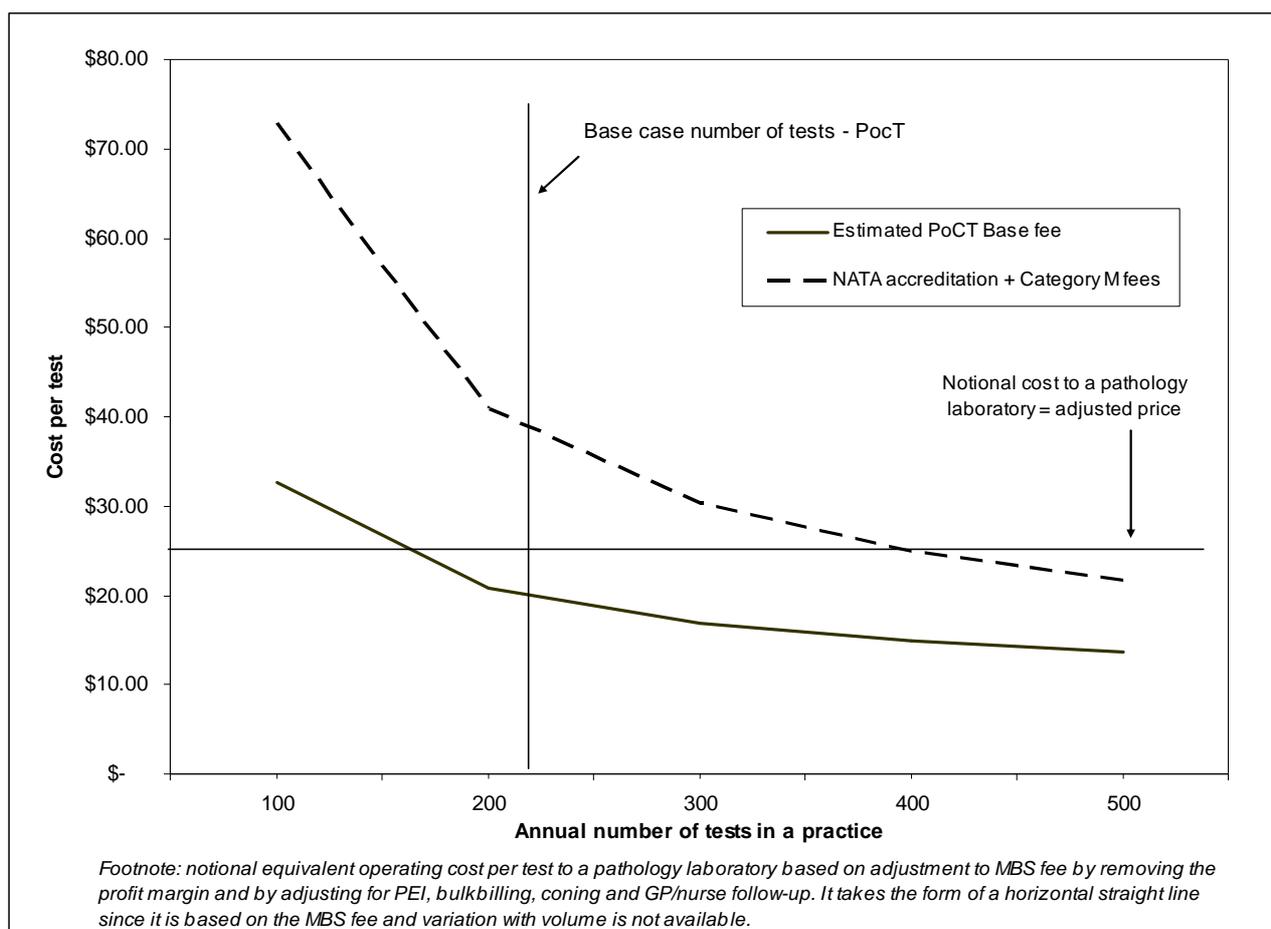
Note: There is no maintenance cost associated with the device as the manufacturer is willing to replace defective devices at no cost.

Note: The amount of general practice infrastructure costs absorbed by a PoC test was assumed to be negligible.

The sensitivity analysis on the cost per test for various volumes of tests per year per practice is shown in Figure 44, as well as an alternative using current NATA accreditation costs and fees for a category M laboratory.

The analysis indicates that the costs per test using the current NATA accreditation process and costs for Category M laboratories almost doubles the PoCT costs per test for practices.

**Figure 44: Sensitivity analysis on cost per test using PoCT for INR**



### 15.3.2. Glycated haemoglobin testing

The estimated cost for the PoCT for HbA1c is \$75.88 per test (Table 219). At the volume experienced in the Trial, the establishment and annual costs (\$49.31) contribute most to the cost per test, with the cost of the device and the QA Program accounting for most of this.

Adjusting the current MBS fee for HbA1c testing in a pathology laboratory as described in the Method section (above) suggests that the cost of this test at the pathology practice is \$10.94 (including PEI).

**Table 219: Estimated unit cost of PoCT for HbA1c**

	Items	\$	Cost per test (\$) <sup>12</sup>
Establishment costs	Device <sup>1</sup>	1,297.01	
	Initial training <sup>2</sup>	600.00	
Annual costs	Accreditation <sup>3</sup>	561.07	49.31
	QA Program <sup>4</sup>	840.91	
	Refresher training <sup>5</sup>	200.00	
	Annual maintenance <sup>6</sup>	92.45	
	Subtotal	3,591.44	
Monthly costs	QC/QA consumables <sup>7</sup>	25.73	

	Items	\$	Cost per test (\$)¹²
	QC Device Operator time <sup>8</sup>	16.90	
	QA Device Operator time <sup>9</sup>	19.71	
	Subtotal	62.34	10.27
Per test costs	Consumables <sup>10</sup>	9.77	
	Device Operator time <sup>11</sup>	6.53	
	Subtotal	16.30	16.30
	Total cost per test		75.88

Notes:

1. The cost is based on DCA 2000 the device available as of June 2008 and adjusted for clinically useful life (3 years ) by straightline depreciation. The cost of the device is shared between HbA1c tests (60%) and Microalbumin (40%) tests.
2. Training costs are based on cost of training based on Trial data and are for two staff per practice allocated in the first year.
3. Accreditation costs are those based on the cost of implementing the accreditation program for the Trial. The costs for providing accreditation through NATA and annual fees associated for category M laboratories are presented in the sensitivity analysis.
4. Based on the RCPA Pty Ltd QA Program used for the Trial but updated for 2008 prices. This cost assumes that practices will participate in a formal QA process.
5. The Trial provided a refresher training course after 12 months.
6. Annual maintenance includes components of the device that need replacing each year such as dust filter, air filter and cleaning kit.
7. Consumables associated with QA are based on 2008 prices.
8. The cost of QC and QA consumables includes the QC reagents and process. There are no costs associated with QC consumables or Device Operator time.
9. Device Operator time for QA is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
10. The per test consumables include the reagents and gloves and use 2008 prices.
11. Device Operator time for testing includes the actual test, plus note taking and patient collection and is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
12. The volume of tests used to calculate the cost per test is based on the average number of tests per month per practice during the Trial. For HbA1c, the mean number of tests was 73 per annum or 6 per month.

Note: This cost was calculated assuming that the GP's contribution to interpreting the test results is incorporated into the standard GP consultation item.

Note: There is no maintenance cost associated with the device as the manufacturer is willing to replace defective devices at no cost.

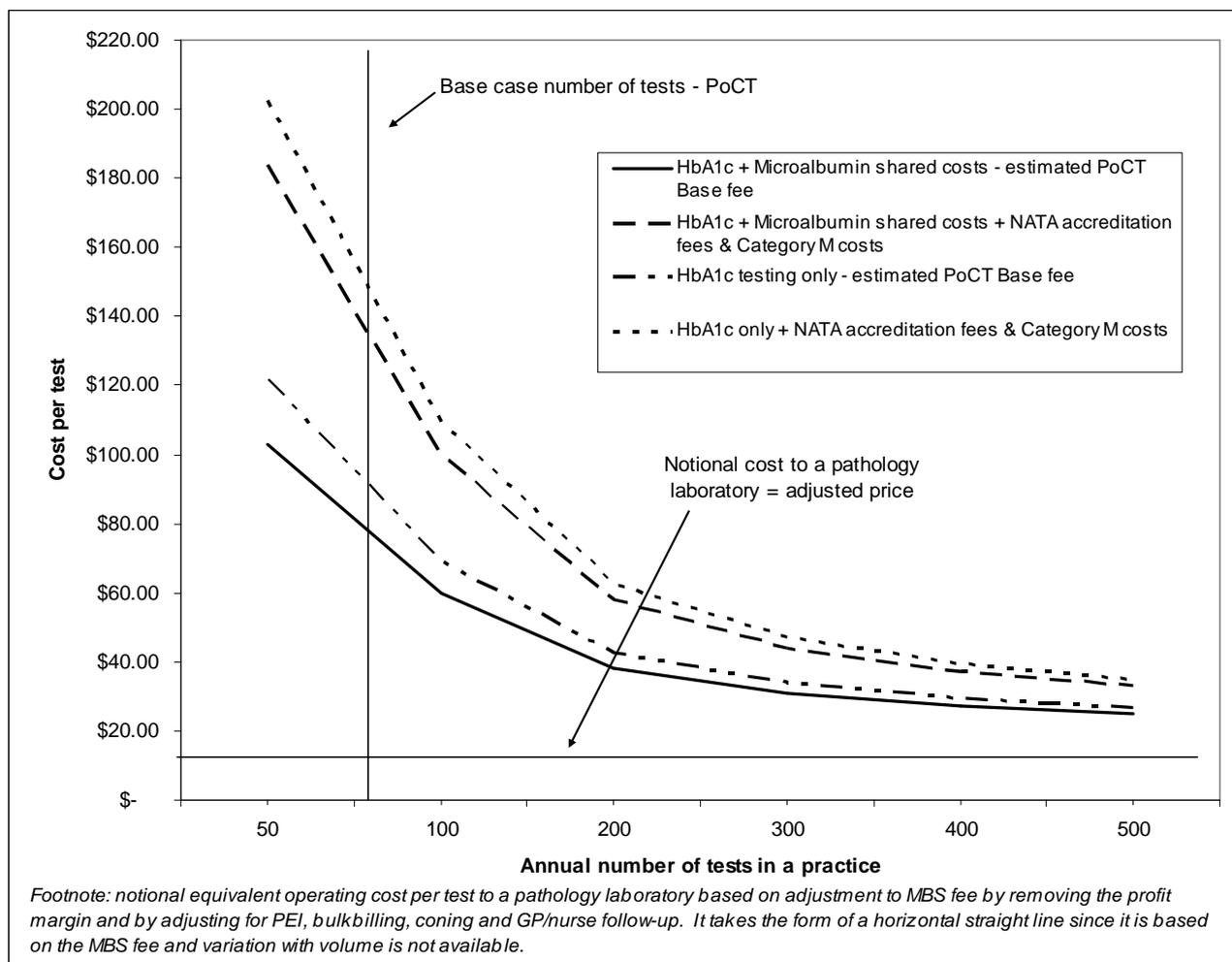
Note: The DCA 2000 analyser will be replaced by a new device, DCA Advanced, later in 2008 and the new device costs more than the DCA2000. However, the cost for the consumables will remain the same.

Note: The amount of general practice infrastructure costs absorbed by a PoC test was assumed to be negligible.

The sensitivity analysis on the HbA1c cost per test for various volumes of tests per year per practice is shown in Figure 45, as well as an alternative using current NATA accreditation costs and fees for a category M laboratory. Additionally the cost per test is also provided for using the device for HbA1c testing alone (i.e. without Microalbumin), which increases the cost per test.

The analysis indicates that the costs per test using the current NATA accreditation process and costs for Category M laboratories almost doubles the PoCT costs per test to a general practice.

**Figure 45: Sensitivity analysis on cost per test using PoCT for HbA1c**



### 15.3.3. Albumin creatinine ratio (ACR) testing

The estimated cost for the PoCT for ACR is \$87.80 per test (Table 220). At the volume experienced in the Trial, the establishment and annual costs (\$58.05) contribute most to the cost per test.

Adjusting the current MBS fee for Microalbumin testing in a pathology laboratory as described in the Method section (above) suggests that the cost of this test at the pathology practice is \$16.56 (including PEI).

**Table 220: Estimated unit costs of PoCT for ACR**

	Items	\$	Cost per test (\$)¹²
Establishment costs	Device¹	869.96	
	Initial training²	600.00	
Annual costs	Accreditation³	561.07	
	QA Program⁴	604.55	
	Refresher training⁵	200.00	
	Annual maintenance⁶	61.99	

	Items	\$	Cost per test (\$)¹²
	Subtotal	2,835.28	58.05
Monthly costs	QC/QA consumables <sup>7</sup>	25.73	
	QC Device Operator time <sup>8</sup>	16.90	
	QA Device Operator time <sup>9</sup>	19.71	
	Subtotal	62.34	15.32
Per test costs	Consumables <sup>10</sup>	9.77	
	Device Operator time <sup>11</sup>	4.66	
	Subtotal	14.43	14.43
	Total cost per test		87.80

Notes:

1. The cost is based on DCA 2000 the device available as of June 2008 and adjusted for clinically useful life (3 years) by straightline depreciation. The cost of the device is shared between HbA1c tests (60%) and Microalbumin (40%) tests.
2. Training costs are based on Trial data and are for two staff per practice allocated in the first year.
3. Accreditation costs are those based on the cost of implementing the accreditation program for the Trial. The costs for providing accreditation through NATA and annual fees associated for category M laboratories are presented in the sensitivity analysis.
4. Based on the RCPA Pty Ltd QA Program used for the Trial but updated for 2008 prices. This cost assumes that practices will participate in a formal QA process.
5. The Trial provided a refresher training course after 12 months.
6. Annual maintenance includes components of the device that need replacing each year such as the dust filter, air filter and cleaning kit.
7. Consumables associated with QA are based on 2008 prices.
8. The cost of QC and QA consumables includes the QC reagents and process. There are no costs associated with QC consumables or Device Operator time.
9. Device Operator time for QA is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
10. The per test consumables include the reagents and gloves and use 2008 prices.
11. Device Operator time for testing includes the actual test, plus note taking and patient collection and is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3rd year plus oncosts.
12. The volume of tests used to calculate the cost per test is based on average number of tests per month per practice during the Trial. For Microalbumin, the mean number of tests was 49 per annum or 4 per month.

Note: This cost is calculated assuming that the GP's contribution to interpreting the test results is incorporated into the standard GP consultation item.

Note: There is no maintenance cost associated with the device as the manufacturer is willing to replace defective devices at no cost.

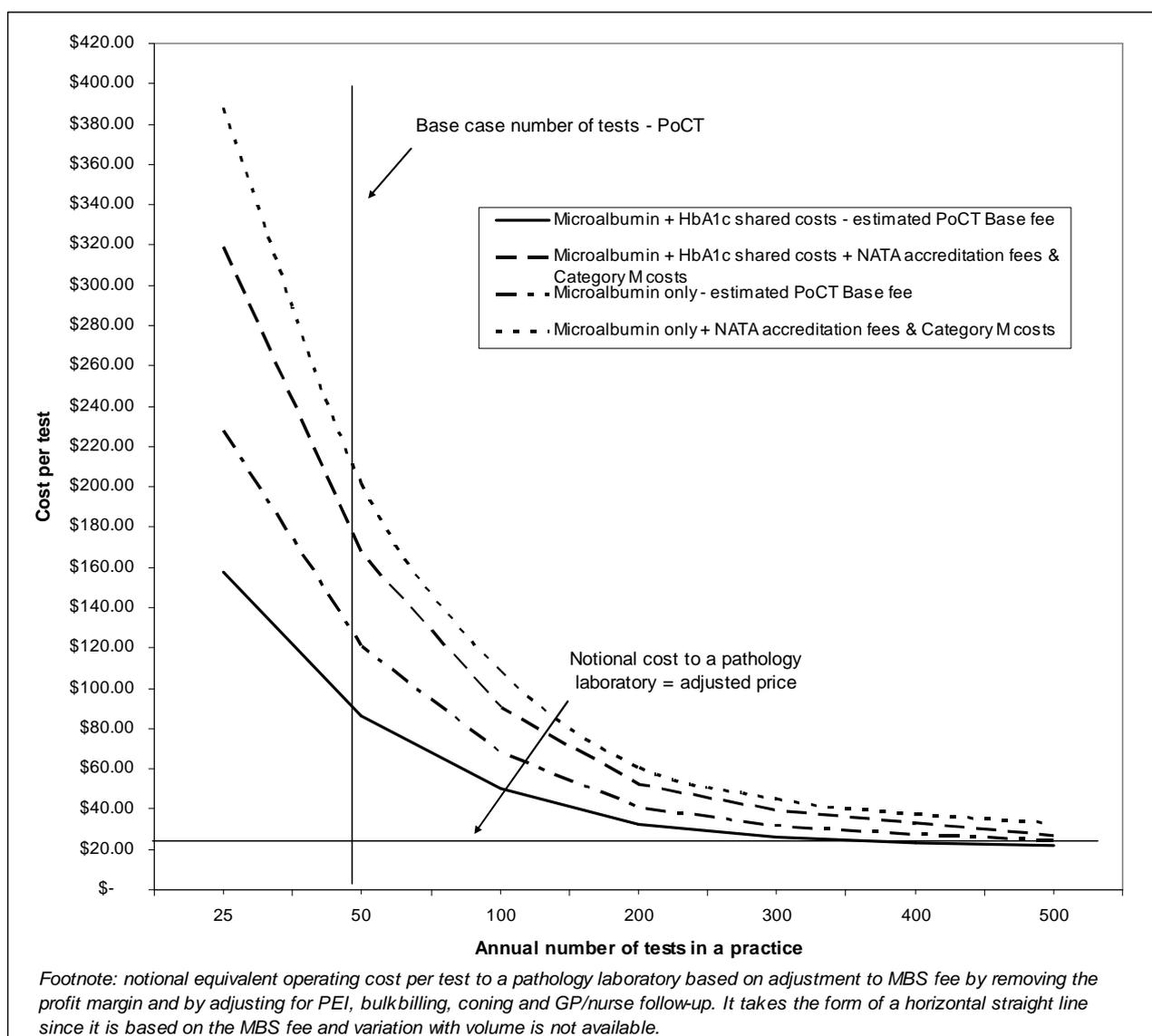
Note: The DCA 2000 analyser will be replaced by a new device, DCA Advanced later in 2008 and the new device costs more than the DCA 2000. However, the cost for the consumables will remain the same.

Note: The amount of general practice infrastructure costs absorbed by a PoC test was assumed to be negligible.

The sensitivity analysis on the Microalbumin (ACR) cost per test for various volumes of tests per year per practice is shown in Figure 46, as well as an alternative using current NATA accreditation costs and fees for a category M laboratory. Additionally the cost per test is also provided for using the device for Microalbumin testing alone (i.e. without HbA1c), which increases the cost per test.

The analysis indicates that the costs per test using the current NATA accreditation process and costs for Category M laboratories almost doubles the PoCT costs per test to a general practice. Using the device only for Microalbumin testing increased the cost to \$123.41 per test.

**Figure 46: Sensitivity analysis on cost per test using PoCT for Microalbumin (ACR)**



#### 15.3.4. Lipid study testing

The estimated MBS fee for the PoCT for Lipids is \$66.84 per test (**Table 221**). At the volume experienced in the Trial, the establishment and annual costs (\$32.99) contribute most to the cost per test.

Adjusting the current MBS fee for lipid testing in a pathology laboratory as described in the Method section (above) suggests that the cost of this test at the pathology practice is \$10.08 (including PEI).

**Table 221: Estimated unit cost of PoCT for Lipids**

	Items	\$	Cost per test (\$)¹²
Establishment costs	Device¹	1,500.00	
	Initial training ²	600.00	
Annual costs	Accreditation³	561.07	
	QA Program⁴	686.36	
	Refresher training⁵	200.00	
	Annual maintenance⁶	80.50	
	Subtotal	3,547.44	
Monthly costs	QC/QA consumables⁷	88.57	
	QC Device Operator time⁸	16.90	
	QA Device Operator time⁹	19.71	
	Subtotal	125.18	
Per test costs	Consumables¹⁰	13.35	
	Device Operator time¹¹	6.53	
	Subtotal	19.88	
	Total cost per test		66.84

Notes:

1. The cost is based on Cholestech LDX Analyser the device available as of June 2008 and adjusted for clinically useful life (3 years) by straightline depreciation.
2. Training costs are based on Trial data and are for two staff per practice allocated in the first year.
3. Accreditation costs are based on the cost of implementing the accreditation program for the Trial. The costs for providing accreditation through NATA and annual fees associated for category M laboratories are presented in the sensitivity analysis.
4. Based on the RCPA Pty Ltd QA Program used for the Trial but updated for 2008 prices. This cost assumes that practices will participate in a formal QA process.
5. The Trial provided a refresher training course after 12 months.
6. Annual maintenance includes components of the device that need replacing each year such as dust filter, air filter and cleaning kit.
7. Consumables associated with QA are based on 2008 prices.
8. The cost of QC and QA consumables includes the QC reagents and process. There are no costs associated with QC consumables or Device Operator time.
9. Device Operator time for QA is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3<sup>rd</sup> year plus oncosts
10. The per test consumables include the reagents and gloves and use 2008 prices.
11. Device Operator time for testing includes the actual test, plus note taking and patient collection and is based on Trial data from the time and motion study and calculated using the SA Nurses Award – Registered nurse 3<sup>rd</sup> year plus oncosts.
12. The volume of tests used to calculate the cost per test is based on the average number of tests per month per practice. For lipids the mean number of tests was 108 per annum or 9 per month.

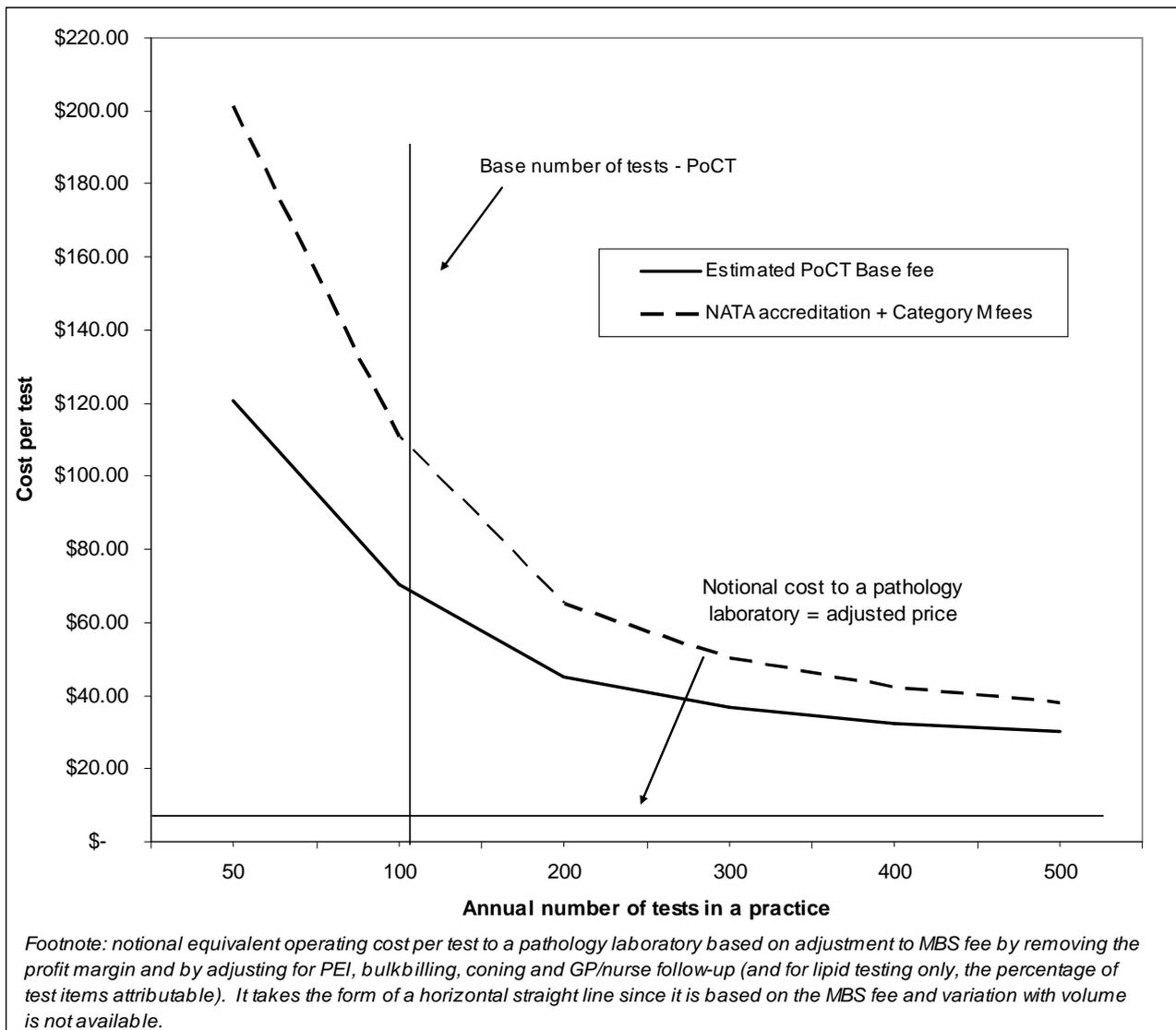
Note: This cost is calculated assuming that the GP's contribution to interpreting the test results is incorporated into the standard GP consultation item.

Note: There is no maintenance costs associated with the device as the manufacturer is willing to

	Items	\$	Cost per test (\$)¹²
replace defective devices at no cost.			
Note: The amount of general practice infrastructure costs absorbed by a PoC test was assumed to be negligible.			

The sensitivity analysis on the Lipids cost per test for various volumes of tests per year per practice is shown in Figure 47, as well as an alternative using current NATA accreditation costs and fees for a category M laboratory. The analysis indicates that the costs per test using the current NATA accreditation process and costs for Category M laboratories almost doubles the PoCT costs per test for a general practice.

**Figure 47: Sensitivity analysis on cost per test using PoCT for Lipids**



### 15.3.5. Comparison with the Costs of Testing Through a Pathology Laboratory

In each of the Figure 44 to Figure 47 a comparison has been provided of the adjusted cost per test when performed through a pathology laboratory. The calculation of these adjusted unit costs is set out in Table 222, which has been provided by Michael Legg & Associates.

**Table 222: Adjusted cost per test in a pathology laboratory**

	Notes	INR	HbA1c	Microalbumin	Lipids
Test MBS Item number 1	1	65120	66551	66560	66512
Average % of test item attributable here	2	100%	100%	100%	40%
Average % of this test billed (after coning)	3	100%	61%	92%	90%
fee at 100% MBS	4	\$14.05	\$17.10	\$20.50	\$17.80
Test MBS Item number 2	5				66536
Average % of test item attributable here	6				100%
Average % of this test billed (after coning)	7				35%
fee at 100% MBS	8				\$11.25
Path Collect PEI MBS Item number	9	73928	73928	73928	73928
% Path Collect	10	90%	60%	60%	60%
Average items per episode	11	1.20	2.40	2.40	2.40
fee at 100% MBS	12	\$17.40	\$17.40	\$17.40	\$17.40
Dr Collect PEI MBS Item number	13	73936, 73938	73936, 73938	73936, 73938	73936, 73938
% Dr or Self-Collect	14	10%	40%	40%	40%
Average items per episode	15	1.20	2.40	2.40	2.40
fee at 100% MBS	16	\$9.80	\$9.80	\$9.80	\$9.80
\$ 100% MBS Test Item 1	17	\$14.05	\$17.10	\$20.50	\$17.80
less attributable to other tests	18	\$0.00	\$0.00	\$0.00	-\$10.68
=	19	\$14.05	\$17.10	\$20.50	\$7.12
less unbilled component	20	\$0.00	-\$6.67	-\$1.64	-\$0.71
<b>Corrected 100% MBS Test Item 1</b>	<b>21</b>	<b>\$14.05</b>	<b>\$10.43</b>	<b>\$18.86</b>	<b>\$6.41</b>
\$ 100% MBS Test Item 2	22				\$11.25
less attributable to other tests	23				\$0.00
=	24				\$11.25
less unbilled component	25				-\$7.31
<b>Corrected 100% MBS Test Item 2</b>	<b>26</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$3.94</b>
Path Collect PEI MBS Item number	27	\$17.40	\$17.40	\$17.40	\$17.40
less attributable to other tests	28	-\$2.90	-\$10.15	-\$10.15	-\$10.15
Corrected 100% Path Collect Item	29	\$14.50	\$7.25	\$7.25	\$7.25
Dr Collect PEI MBS Item number	30	\$9.80	\$9.80	\$9.80	\$9.80
less attributable to other tests	31	-\$1.63	-\$5.72	-\$5.72	-\$5.72
Corrected 100% Path Collect Item	32	\$8.17	\$4.08	\$4.08	\$4.08
<b>100% PEI Item corrected for other tests and pathology-doctor collection weighting</b>	<b>33</b>	<b>\$13.87</b>	<b>\$5.98</b>	<b>\$5.98</b>	<b>\$5.98</b>

	Notes	INR	HbA1c	Microalbumin	Lipids
Add Test item 1	34	\$14.05	\$10.43	\$18.86	\$6.41
Add Test item 2	35	\$0.00	\$0.00	\$0.00	\$3.94
Add PEI Item	36	\$13.87	\$5.98	\$5.98	\$5.98
<b>= Total 100% MBS fees after corrections</b>	37	<b>\$27.92</b>	<b>\$16.41</b>	<b>\$24.84</b>	<b>\$16.33</b>
less discount to rebate level (85%) MBS	38	-\$4.19	-\$2.46	-\$3.73	-\$2.45
<b>= Total 85% MBS Fees after corrections</b>	<b>39</b>	<b>\$23.73</b>	<b>\$13.95</b>	<b>\$21.12</b>	<b>\$13.88</b>
less profit	40	-\$5.13	-\$3.01	-\$4.56	-\$3.00
<b>= Cost at pathology practice</b>	41	<b>\$18.60</b>	<b>\$10.94</b>	<b>\$16.56</b>	<b>\$10.88</b>
<b>Plus: cost of GP/practice nurse follow-up</b>	42	<b>\$5.94</b>	<b>\$5.94</b>	<b>\$5.94</b>	<b>\$5.94</b>
<b>= Comparative cost through pathology practice</b>	43	<b>\$24.54</b>	<b>\$16.88</b>	<b>\$22.50</b>	<b>\$16.82</b>
<b>Notes</b>					
1. MBS Item numbers in effect as at 1-Jul-08. The most common MBS item used to bill the test has been chosen. This is most relevant to Lipids where >90% would be billed at this item (5 or more chemistries) and in most cases more than 10 tests would be done.					
2. For all but Lipids the MBS Item used is specific to the test. For Lipids we assume that 2 of the 5 tests being paid for covers the cholesterol and triglyceride measurements. In practice it is likely to be an overestimate since more than 10 tests are mostly reported.					
6. Because only the highest 3 pathology test items can be billed for GP requested pathology items, some tests do not get billed. The quoted figures represent the experience of one large laboratory over a year for the relevant items.					
4. MBS Schedule fee as at 1-Jul-08					
5. MBS Item number for HDL Cholesterol					
6. Specific item for HDL Cholesterol so 100%					
7. Because only the highest 3 pathology test items can be billed for GP requested pathology items some cannot be billed. The quoted figures represent the experience of one large laboratory over a year for the relevant items.					
8. MBS Schedule fee as at 1-Jul-08					
9. Assume Path Collect specimens are taken in an APP not associated with a laboratory (Item 73928). This would be true for almost all of these patients					
10. The proportion of patients collected that are collected by the pathologist. Data from one large laboratory that reflects national data overall.					
11. The number of pathology test MBS services associated with the PEI for this test.					
12. MBS Schedule fee as at 1-Jul-08					
13. Assume the rest of the patients are collected either by the doctor or self-collect in the case of urine. MBS Item numbers in effect as at 1-Jul-08.					
14. The proportion of patients collected that are collected by Dr or Self. Data from one large laboratory that reflects national data overall.					
15. The number of pathology test MBS services associated with the PEI for this test.					
16. MBS Schedule fee as at 1-Jul-08					
17. From line of note 4					
18. Less the value that is attributable to the other tests that would and is billed under this item					
19. Add line of note 17 & 18					
20. Discount because of the tests done that cannot be billed under Medicare because of the coning rule for GP pathology					
21 Add line of note 19 & 20					
22. From line of note 8					

	Notes	INR	HbA1c	Microalbumin	Lipids
23.	Less the value that is attributable to the other tests that would and is billed under this item				
24.	Add line of note 22 & 23				
25.	Discount because of the tests done that cannot be billed under Medicare because of the coning rule for GP pathology				
26.	Add line of note 24 & 25				
27.	From line of note 12				
28.	Less the value that is attributable to the other tests that would and is billed under this item				
29.	Add line of note 27 & 28				
30.	From line of note 16				
31.	Less the value that is attributable to the other tests that would and is billed under this item				
32.	Add line of note 31 & 32				
33.	Fee from the PEI component attributable here after correction for other MBS items in an episode and pathology-doctor collection weighting				
34.	From line of note 21				
35.	From line of note 26				
36.	From line of note 33				
37.	The equivalent Pathology MBS Item at 100% covering the same elements as for PoCT				
38.	Assume that the tests will be 'bulk-billed' then take off the discount to 85% rebate				
39.	The equivalent Pathology MBS Item at 85% covering the same elements as for PoCT				
40.	Assume that profits for the industry are the same as that published for the largest private pathology provider, Sonic Healthcare - 10 year average to June 2007 of 22.2%, 21.6% in the last reporting year. Assume then 21.60%				
41.	Cost of test at pathology practice assuming that profit is spread evenly over all MBS items and that the average profit is the same as for the biggest practice				
42.	Cost of GP/practice nurse follow-up time to inform the patient is based on the Time and Motion Study which formed part of the cost-effectiveness analysis for the Trial. Costs of follow-up were shared 50/50 between GP and practice as this reflected the nature of the follow-up as reported by practices.				
43.	This includes the cost of pathology practice for teach test with the addition of cost of GP/practice nurse follow-up.				

## 15.4. DISCUSSION

The estimated unit costs for PoCT in a general practice setting have been based on data collected by the Trial and updated to 2008 prices. The volumes of tests used in the calculations were based on the mean number of tests per practice per month (see Appendix 36). Volumes have been expressed per practice since each practice is only likely to install one device of each type.

The practices recruited to the Trial range from large urban practices to solo practices in remote locations and this is reflected in the range of tests per month. For the more remote practices, the scope to increase testing is limited by the population base.

The sensitivity analysis undertaken on the impact on the cost per test of varying volumes indicates that, for all tests investigated; this is high in the base case but reduces substantially with a corresponding increase in the annual number of tests in a practice. These results suggest that the volume of testing required to reach pricing parity with the adjusted cost for the equivalent test conducted by a pathology laboratory (virtually all such tests are bulk-billed) may be unattainable in most current general practices. This is probably due to the economies of scale and scope to be found in pathology laboratories but not in general practice.

How reflective the Trial volumes were of tests per practice needs further consideration. The Trial Design protocol provides Medicare Australia data projecting a higher per practice testing rate –

INR 432 tests per year; HbA1c 108 tests per year and Lipids 288 tests per year. The number of Microalbumin tests was 48 per annum which is the same rate as the Trial data. The profile of practices recruited for the intervention group does differ from the national profile in some attributes. Only 10% of intervention practices were solo practices compared to the national profile of 37% from the Annual Survey of Divisions of General Practice.<sup>189</sup> However, among the intervention practices, 40% were 3-5 GP practices and 23% had 5 or more GPs. The Division data shows nationally that 39% of practices have 2-5 GPs and 16% have of six or more GPs.<sup>189</sup>

In the absence of relevant data, the unit costs of the equivalent tests when performed by a pathology laboratory are assumed to be constant over the range of volumes studied. This is unlikely to be true in reality, but nevertheless may be tolerable since this information is being used for an indicative comparison.

When expressed so as to cover equivalent types of resource use, the only test for which the unit costs of the PoCT and the pathology laboratory are even close at the volume in the Trial is for INR. This is related to the higher volume of testing for these patients (every 4-6 weeks if stable) and the lower cost of the device. However, the point estimate of the ICER for this test has been demonstrated in the economic evaluation to be dominated by its comparator. Hence the test is unlikely to be recommended in its present form.

In summary, the estimated cost per test for PoCT based on Trial volumes is much higher than the estimated cost for the tests provided through a pathology laboratory.

## 16. INDICATIVE MBS FEES FOR THE PoC TESTS USED IN THE TRIAL

### SUMMARY OF THE CHAPTER

This chapter describes the methodology and results of estimating a set of indicative MBS fees for the PoCT in general practice.

The calculation of an indicative MBS fee for each PoC test was based on cost-plus pricing and the assumption of an allowance for an operating margin of 17% on revenue within the 100% MBS fee.

The key findings of the chapter are:

- indicative MBS fee for INR is \$24.12 per test (100% MBS fee with operating margin of 17%)
- indicative MBS fee for HbA1c is \$91.42 per test (100% MBS fee with operating margin of 17%)
- indicative MBS fee for ACR is \$105.78 per test (100% MBS fee with operating margin of 17%)
- indicative MBS fee for Lipids is \$80.53 per test (100% MBS fee with operating margin of 17%)
- the impact of indicative MBS fees for PoCT on the ICERs indicated that all tests showed that the point estimate of the ICER remained in the same quadrant as the base case.

The key conclusions:

- unless the typical GP can substantially reduce the amount of resources used in PoCT or the volume in routine best practice turns out to be considerably higher or there are other cogent reasons, then the fee for PoCT of HbA1C, microalbumin (ACR) and/or lipids would have to be substantially higher than the fee for an equivalent test performed by a pathology laboratory;
- While the indicative MBS fee for INR in general practice is lower than for the equivalent test in a pathology laboratory, it has already been demonstrated (in Chapter 10) that the INR PoCT is dominated by its comparator and so is not justified.

### 16.1. INTRODUCTION

The objective of this chapter is to provide an estimate of a set of indicative MBS fees for PoCT in general practice. It is emphasised that these estimates are indicative, and they should be interpreted in the light of the underlying assumptions and the nature of the data available.

For convenience these fees are expressed in 2008 values.

This work is based on the accounting framework used in the previous chapter.

In Chapter 15 it has been demonstrated that the unit costs for all the PoCT studied are related to their volume. This is because of the need to absorb the fixed costs of device purchase, initial and refresher training, accreditation and QC/QA. At the volumes experienced in the Trial, the unit costs of all but the INR PoC test are far higher than the adjusted costs for the equivalent tests when performed through a pathology laboratory. In turn, the INR PoCT is dominated (i.e. is less effective and has a higher cost) by its pathology laboratory counterpart.

### 16.1.1. Economic evaluation is not commonly used to set prices

It is important at the outset to be clear that economic analysis as exemplified in this report has only a limited role in the determination of fees and prices. This is because the objective of any trial-based cost-effectiveness analysis is to estimate whether the proposed health care intervention represents an increase in overall welfare (i.e. value for money) at the levels of resource use observed in the trial. This kind of analysis does not aim to test whether the prices and the quantities of resources used are themselves at their most efficient levels.

The PoCT Trial studied effectiveness amongst a set of practices that were willing to volunteer to be part of the study of an innovation in patient testing. The unit costs and the quantities that were measured were those that were either actually incurred in this particular study or were specified in the Trial Protocol – the latter including the test fee(s). The general practices were able to claim a special MBS fee for the PoCT set equal to 100% of the equivalent fee when testing was done through a pathology laboratory. In turn, they received the devices and testing consumables free of charge, and QA/QC costs were covered, so that all the practices had to pay for were the Device Operator time, with GPs follow-up being considered part of the occasion of service during which the test was ordered. Thus, the return to the practice was higher than if all the expenses that would be incurred in routine practice had been recognised.

As is usual, it was not possible within the limits of the Trial Design to assess whether these unit costs and quantities were those that would apply to best efficient practice should one or more of these tests be approved for MBS listing generally across Australia. Perhaps all that can be said is that the practices were willing to volunteer for the Trial under the conditions set, and that some adjustments for efficiency were possible, especially in that some of the larger practices ran miniclinics so that testing could be performed for consecutive patients, thereby reducing the cost.

Cost-effectiveness was evaluated at the test fee specified in the Trial Protocol through a determination from the Minister's delegate specifically for the Trial. However, it remains to be seen whether GPs behaviour will change at different fee levels. Moreover, the Trial cannot determine the likely total volume of tests likely to be performed at the MBS fee, and hence the total expenditure implications for the Australian Government.

### 16.1.2. What is the appropriate operating margin to allow in these estimates?

It is unclear if the current policy is to include a profit margin on an MBS item fee. It is reasonable for GP to regard it as desirable that some profit element to contribute to general operating costs.

A 17% profit margin has been included as one possible option when calculating the MBS fee. This is based on how the MBS fees are calculated for many other pathology tests. It will, of course, be for the Government to determine how the MBS fee will be calculated if it decides to fund PoCT under Medicare.

## 16.2. METHOD

The calculation of an indicative MBS fee for each PoC test was based on cost-plus pricing with the following assumptions:

- MBS fee/rebate for this service is 100%, as for other similar items (eg M2 items)
- an allowance for an operating margin of 17% on revenue.

### 16.3. RESULTS

Indicative MBS fees in 2008 dollars for all the PoC tests evaluated in this Trial are calculated in Table 223. An indicative operating margin of 17% was used as explained in the method (above).

**Table 223: Indicative 100% MBS fees for PoCT with inclusion of an operating margin of 17% on revenue**

	INR	HbA1c	Microalbumin (ACR)	Lipids
Estimated PoCT base cost (CP) (from Chapter 15)	\$20.02	\$75.88	\$87.80	\$66.84
SP = CP*100/83 =100% indicative MBS fee	\$24.12	\$91.42	\$105.78	\$80.53
<i>ie Profit = SP-CP</i>	\$4.10	\$15.54	\$17.98	\$13.69
<i>SP = selling price = revenue; CP = cost price</i>				

A comparison between the indicative MBS fee for PoCT and the current MBS fee for the equivalent tests through a pathology laboratory is shown in Table 224.

**Table 224: Comparison of indicative 100% MBS fees for PoCT and adjusted MBS fees for equivalent testing through a pathology laboratory**

	INR	HbA1c	Microalbumin (ACR)	Lipids
PoCT MBS fee (100%) <sup>a</sup>	\$24.12	\$91.42	\$105.78	\$80.53
Pathology laboratory MBS fee (85%), adjusted (from Chapter 15) <sup>b</sup>	\$24.54	\$16.88	\$22.50	\$16.82
Difference	-\$0.42	\$74.54	\$83.28	\$63.71
<sup>a</sup> from Table 223. <sup>b</sup> includes GP/practice nurse follow-up. PEI included in adjusted pathology laboratory fee, but not in PoCT fee.				

#### 16.3.1. Impact of indicative MBS fees for PoCT on incremental cost effectiveness ratios (ICERs)

To assess the impact of the indicative MBS fees for PoCT on the economic evaluation undertaken in Chapter 10, the ICERs were recalculated for each test. Using the base case from the economic evaluation (Chapter 10), the establishment costs (device and training costs), QA and QC costs and testing costs (Device Operator time and consumables) were removed and the estimated unit cost of PoCT with and without profit was inserted. The estimated unit cost of PoCT was discounted back to 2006 prices to be comparable to the Trial reference year. The results are provided in Table 225.

**Table 225: Sensitivity analysis showing impact of 100% indicative MBS fee for PoCT on ICER by test**

		<b>INR</b>	<b>HbA1c</b>	<b>ACR</b>	<b>Lipids</b>
Estimated unit cost of PoCT (from Table 1)	Estimated unit cost for PoCT <sup>1</sup>	\$20.02	\$75.88	\$87.80	\$66.84
	GP profit (see Table 223)	\$4.10	\$15.54	\$17.98	\$13.69
	Estimated unit cost of PoCT with profit [MBS fee 100%]	\$24.12	\$91.42	\$105.78	\$80.53
	Estimated unit cost PoCT with profit discounted back to 2006	\$22.95	\$87.00	\$100.66	\$76.63
Base case with all direct costs (from Chapter 10)	Total cost PoCT per patient: intervention	\$3,297	\$3,676	\$1,727	\$2,732
	Total cost PoCT per patient: control	\$3,150	\$3,672	\$1,954	\$2,202
	Outcome - intervention	0.5701	0.6548	0.7739	0.1592
	Outcome - control	0.6147	0.5618	0.7418	0.1066
	Cost difference = intervention - control	\$147	\$4	-\$228	\$600
	Outcome difference = intervention - control	-0.0446	0.093	0.0321	0.0526
	<b>ICER (per patient in target range)</b>	<b>Dominated</b>	<b>\$40</b>	<b>Dominant</b>	<b>\$10,082</b>
Substituting indicative MBS fee 100% into base case	Total unit cost PoCT per patient: intervention	\$3,378	\$3,695	\$1,754	\$2,838
	Total unit cost PoCT per patient: control	\$3,150	\$3,672	\$1,954	\$2,202
	Outcome - intervention	0.5701	0.6548	0.7739	0.1592
	Outcome - control	0.6147	0.5618	0.7418	0.1066
	Cost difference = intervention - control	\$228	\$23	-\$200	\$636
	Outcome difference intervention- control	-0.0446	0.093	0.0321	0.0526
	<b>ICER (per patient in target range)</b>	<b>Dominated</b>	<b>\$244</b>	<b>Dominant</b>	<b>\$12,096</b>
Notes:					
1. 2008 prices, to be discounted					
2. Discounted to 2006 prices using CPI					
3. All costs rounded to nearest whole dollar					
4. ICERs are point estimates					

In this sensitivity analysis, when using the indicative MBS fee 100% for PoCT fee, all tests showed that the point estimate of the ICER remained in the same quadrant as for the base case.

#### 16.4. DISCUSSION

The set of MBS fees for PoCT in general practice calculated in this chapter must be recognised to be indicative, and should be interpreted in the light of the underlying assumptions and the nature of the data available.

While the amount of the operating margin is subject to debate, it is clear that using the suggested level of 17% will mean that the indicative MBS fees per test with exception of INR will be higher in general practice than the current MBS fees for the equivalent tests through a pathology laboratory. If adopted, these fee levels in general practice for all tests except INR could be anticipated to change GP behaviour substantially from that found in the Trial, and their political acceptability must be in doubt.

There is also the question as to whether any comparison between PoCT and pathology laboratory testing should be considered at 85% or 100% of the MBS fee. In Table 224, the grounds for adding a co-payment as well as an allowance for profit to the 85% MBS fee for PoCT are open to debate. It remains to be seen whether all PoCT will be bulk-billed; if not, the GP would receive two amounts above the actual costs to the practice.

It has thus been argued that it is not appropriate to propose an 85% MBS fee as profit is already built in. For instance, the benefits for Group M2 "Services provided by a practice nurse on behalf of a medical practitioner" are only listed at 100% of the MBS fee. This group covers services such as pap smears, wound management and immunization, provided in a similar way to how PoCT was.

It should also be noted that the calculations in this chapter have not included a fee for specimen collection for PoCT, perhaps based on item 73938 ("collected by or on behalf of the treating practitioner"). This has been because the Trial-based costs of PoCT include these costs, which in turn have been the basis of the indicative MBS fees.

## **16.5. CONCLUSION**

In summary, the indicative MBS fees per test for HbA1C, microalbumin (ACR) and lipids are substantially higher in general practice than the current MBS fees for the equivalent tests through a pathology laboratory. While the indicative MBS fee for INR in general practice is lower than for the equivalent test in a pathology laboratory, it has already been demonstrated (in Chapter 10) that the INR PoCT is dominated by its comparator and so is not justified.

Unless the typical general practice can substantially reduce the amount of resources used in PoCT or the volume in routine best practice turns out to be considerably higher or there are other cogent reasons, then the fee for PoCT of HbA1C, microalbumin (ACR) and/or lipids would have to be substantially higher than the fee for an equivalent test performed by a pathology laboratory. One possible reason might be that adopting a PoCT strategy might be more cost-effective overall than continuing with the present situation - even using the proposed fees in this chapter rather than the actual resources used in the Trial (see the sensitivity analysis in Table 3). Another possible reason might be where population access is a problem and the GP would be willing to provide PoCT despite a lower return in order to avoid the follow-up visit and make available access for other patients - this is more an equity than an economic issue.

One possible way to lower the unit price to the patient might be to negotiate lower charges with the providers of QC/QA and perhaps even for Medicare Australia to rebate the cost of the PoCT devices to the GP.



## 17. CONCLUSION

The diagram outlined as Figure 48 has summarised the study findings. The results are outlined under the following headings:

### **Is it safe to perform PoCT?**

There are several hypotheses under this heading which have been linked to the seven tests examined during the Trial.

The Trial found it was safe to perform PoCT as assessed by:

- the competency of Device Operators
- analytical standards achieved for quality control (QC) testing (overall)
- quality assurance (QA) performance for HbA1c and ACR
- agreement between PoCT and laboratory results
- compliance with the Standards (accreditation)
- SAEs attributable to PoCT, SAEs per person year (overall) and
- the proportion of patients experiencing one or more SAE (overall).

However, for some areas the results were less clear and may require further investigation. These include:

- QC results did not meet the analytical goals for imprecision for one QC level for HDL-C
- QA acceptable levels of accuracy were not clear for INR, total cholesterol (all areas), HDL-C and triglyceride results in remote locations
- QA results did not meet the imprecision analytical goals for total cholesterol, HDL-C and triglycerides. Remote locations showed more imprecision and require further investigation.
- differences in SAEs per person year for some tests by geographic area were found and
- the proportion of PoCT patients who experienced one or more SAE for rural and remote locations was higher compared with control patients.

### **Is the effectiveness of PoCT the same or better than for the same tests using pathology laboratory testing?**

There are several hypotheses under this heading which have been linked to the seven tests examined during the Trial.

The Trial found that the effectiveness of PoCT was the same or better (non-inferior) than pathology testing for the following areas:

- the proportion of patients within target range for HbA1c, urine albumin, ACR, total cholesterol and triglycerides (non-inferior)
- the proportion of tests within target range for INR, HbA1c, urine albumin, ACR, total cholesterol and triglycerides (non-inferior)

- the proportion MARS-5 responses indicating compliance with disease management (non-inferior)
- the number of GP visits for PoCT patients per person year was different (greater) than control patients for all tests
- PoCT GPs undertook a greater number of processes of care actions for INR and microalbumin compared to those carried out by control GPs.

However, for some areas the results were less clear and may require further investigation. These include:

- the proportion of PoCT patients who had results within target range was not the same or better for intervention patients who underwent INR and HDL-C testing when compared with control patients
- the proportion of tests within the target range in PoCT practices was not the same or better for intervention patients who underwent HDL-C testing when compared with control patients
- the processes of care actions in PoCT GPs were similar to those carried out by control GPs for total cholesterol, HDL-C, triglycerides, and HbA1c.

#### **Is it the same or more cost-effective to perform PoCT compared with pathology laboratory testing?**

The incremental cost-effectiveness ratio for PoCT versus laboratory testing showed the following:

- providing ACR using a PoCT device appeared to dominate its comparator in a general practice setting
- on the other hand, INR using PoCT was dominated
- the other two tests (HbA1c and lipids) generated health gains but at an extra cost.

#### **Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?**

There are several hypotheses under this heading which have been linked to PoCT overall.

In terms of attitudes and satisfaction towards PoCT the Trial found:

- an improvement in attitudes in most areas over the Trial period for patients, GPs and Device Operators
- more satisfaction with PoCT in most areas for patients, GPs and Device Operators
- the only stakeholder group where no change in the level of satisfaction with PoCT was found was the Pathology Providers.

#### **Are there differences between urban, rural and remote geographic regions in any of the parameters measured?**

Overall, in terms of whether there were differences between urban, rural and remote geographic regions in any of the outcomes measured the Trial did not find any consistent and significant differences.

## **Would the regulatory environment used for the Trial meet the needs of all the stakeholders if PoCT were to be made more generally available?**

The Trial model utilised for PoCT in general practice provides a framework that can be utilised if PoCT is made more generally available. This model incorporates all stakeholders – GPs, patients, Pathology Providers and the Government/funder.

## **What would the appropriate MBS fees be for the PoCT tests selected to be in the Trial?**

The estimated unit cost for PoCT in general practice was calculated based on data collected during the Trial and updated to 2008 prices are:

- \$20.22 per test for INR
- \$75.88 per test for HbA1c
- \$87.80 per test for microalbumin
- \$66.84 per test for lipid studies.

Allowing for a profit margin of 17% on revenue, the indicative 100% MBS fees for PoCT in general practice are:

- \$105.78 per test for microalbumin
- \$91.42 per test for HbA1c
- \$24.12 per test for INR
- \$80.53 per test for lipid studies

## **The role of PoCT in chronic disease management**

The PoCT Trial in a general practice setting was formulated with the notion that PoCT could assist general practitioners and patients with the management of chronic illness, particularly cardiovascular disease and diabetes which are endemic in Australia and which are National Health Priorities<sup>190</sup>. It is appropriate to review the results of the Trial in this context and determine the role PoCT has in the management of chronic conditions in Australian general practice.

The chronic disease model is a theoretical framework developed by Wagner<sup>191</sup> which describes six key components that can improve the quality of care for people with chronic conditions in a general practice setting. Effective chronic disease care as recommended by the chronic care model is characterised by members of a primary care practice team who organise and co-ordinate patient care through a series of interactions during which they elicit and review data concerning patient perspectives and other critical information about the course and management of the condition(s), help patients set goals and solve problems for improved self-management, adjust therapy to optimise disease control and patient well-being and ensure follow-up.<sup>140</sup> Underpinning this is a structure that can support this model of care which includes decision support (evidence-based guidelines for optimal care integrated into daily practice through reminders), clinical information systems (reminder systems to help the team comply with guidelines and provide feedback and registers for planning care) and delivery system design (accommodates practice teams with clearly delineated roles).<sup>164, 192</sup> An important aspect of the chronic disease model is the patient's perception of their illness and health care will be more effective if it is delivered in collaboration with the patient, allowing patients an active role in their care.<sup>164</sup>

The question is "What role does PoCT have in this structure?" and particularly in the various components of the model such as assisting GPs in providing optimal quality of care, improved health outcomes and engaging patients in their self-management. This can be answered by linking the results of the Trial to the chronic disease model outlined above.

Firstly, in terms of adjusting therapy to optimise disease control, for all tests except for INR and HDL-C, PoCT improved the therapeutic control of Trial patients.

Secondly, in terms of patient self-management, Trial patients in the intervention group reported improved compliance to medication, although there were no differences between-groups in lifestyle activities. The results of the patient satisfaction survey showed that PoCT patients reported significant improvements in their relationship with their GP and greater motivation in managing their condition. Additionally, the ability to have immediate feedback on their results was seen by PoCT patients as significant. This provides evidence that PoCT helped to actively engage patients in their own care.

Thirdly, in terms of follow-up, the intervention group had significantly more visits per-person year than the control group, allowing GPs and/or the primary care team to have a greater opportunity to monitor the patients' illnesses. The intervention group also had testing more frequently than the control group (decision support), which was in-line with evidence-based guidelines. For anticoagulant therapy, the guidelines suggest testing every 4-6 week if the patient is stable. The PoCT group had testing every 4.3 weeks compared with 5-6 weeks in the control group. Diabetes guidelines recommend testing of HbA1c every six months and ACR/urine albumin every 12 months. The PoCT group had testing every seven months compared with eight months in the control group for HbA1c and every 12 months for ACR/urine albumin compared with 2 years in the control group. Lipid management guidelines recommend testing every 6-12 months. The PoCT group had testing every nine months compared with 13-14 months in the control group.

However, in terms of use of evidence-based guidelines, the PoCT Trial had mixed results. While the frequency of testing was more in-line with guidelines, the processes of care actions by GPs based on the guidelines did not show a clear improvement in the intervention group. For example, adherence to the diabetes annual cycle of care actions was not greater in the intervention group when compared with the control group. This may partly relate to the focus on GP actions rather than the actions of the primary health care team.

The cost-effectiveness analysis shows that PoCT is not cost-effective for any of the tests examined during the Trial, with the exception of ACR testing. The decision to fund PoCT in a GP setting needs to consider the value society places on maintaining a patient within target range. In making this decision, the role of PoCT in the chronic disease model should be considered. The Trial has shown that, in a number of areas, PoCT fits into the chronic disease model developed by Wagner. In the areas of patient self-management, optimising therapy and regular follow-up, PoCT has been shown to be effective. For other aspects of the chronic care model, such as decision support, it is less clear. PoCT is a tool that can be utilised as part of a primary care model for managing patients with chronic illness.

Figure 48: Traffic light diagram summarising the results of the PoCT Trial

Question	Method	Result																							
		Anti-coagulant				Hyperlipidaemia												Diabetes							
		INR				Total cholesterol				HDL-C				Triglycerides				HbA1c				Microalbumin			
		Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem
1. Is it safe to perform PoCT?	Competency level of Device Operators																								
	QC results within acceptable performance range																								
	Accuracy - QA results meet required QA performance levels for pathology laboratories*																								
	Precision - QA results meet the required QA performance levels for the pathology laboratories*																								
	Results of the PoCT device for each patient closely agree with results obtained from pathology laboratory testing																								
	All intervention practices meet accreditation standards																								
	SAEs attributed to PoCT																								
	The number of SAEs reported in PoCT patients per person-year is the same as or fewer than in control patients*																								

Question	Method	Result																							
		Anti-coagulant				Hyperlipidaemia												Diabetes							
		INR				Total cholesterol				HDL-C				Triglycerides				HbA1c				Microalbumin			
		Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem
	The proportion of PoCT patients who experience one or more SAE is the same as or less than control patients*																								
<b>2. Is the effectiveness of PoCT the same or better than for the same tests using pathology laboratory testing?</b>	The proportion of PoCT patients who have results within target range is the same as or greater than control patients																								
	The proportion of tests within the target range in PoCT practices is the same as or greater than control practices																								
	Number of GP visits for PoCT patients per person-year is different than control patients*																								
	The proportion of MARS-5 responses indicating compliance with disease management in PoCT patients is the same as or greater than control patients																								
	The processes of care actions undertaken by PoCT GPs is different than the processes of care actions undertaken																								

Question	Method	Result																							
		Anti-coagulant				Hyperlipidaemia												Diabetes							
		INR				Total cholesterol				HDL-C				Triglycerides				HbA1c				Microalbumin			
		Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem	Total	Urb	Rur	Rem
	in control GPs**																								
<b>3. Is it the same or more cost-effective to perform PoCT compared with pathology laboratory testing?</b>	Incremental cost-effectiveness ratio**																								
<b>4. Are patients and other stakeholders more satisfied with PoCT than with pathology laboratory testing?</b>	Patient attitudes*																								
	GP attitudes*																								
	Device Operator attitudes*																								
	Pathology Provider attitudes*																								
	GP satisfaction*																								
	Patient satisfaction*																								
	Device Operator satisfaction*																								
	Pathology Provider satisfaction*																								
* analysis not undertaken by test ** analysis not undertaken by geographic location																									
Coding: <span style="color: green;">■</span> Results support PoCT <span style="color: orange;">■</span> Results less clear <span style="color: red;">■</span> Results do not support PoCT																									



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## **SEE SEPARATE DOCUMENT FOR APPENDICES**

Appendix 1: Design for a Trial and an Evaluation Framework for the Introduction of Point of Care Testing into General Practice in Australia

Appendix 2: Consensus guidelines for warfarin therapy (2000)

Appendix 3: Principles of care and guidelines for the management of diabetes mellitus (1996) and Diabetes management in general practice (2004/05)

Appendix 4: Lipid management guidelines (2001)

Appendix 5: PoCT Request and Result Form by condition

Appendix 6: TGA and Roche CoaguChek S product safety notice

Appendix 7: Device Group CoaguChek S interim PoCT testing protocol

Appendix 8: Trial process for CoaguChek S product safety notice

Appendix 9: PoCT Trial Evaluation Protocol

Appendix 10: Systematic review electronic database search terms

Appendix 11: Email sent to primary investigators of PoCT trials

Appendix 12: PoCT systematic review data collection forms

Appendix 13: Excluded papers

Appendix 14: Weighted scoring matrix for selection of practices

Appendix 15: Baseline Questionnaires – Patients, Practices, GPs, Device Operators and Pathology Providers

Appendix 16: Patient baseline characteristics by condition and geographic location

Appendix 17: Percentage of QC results in acceptable, warning and action zones using QC limits set for the Trial

Appendix 18: Relative limits of agreement for all tests

Appendix 19: Definition of SAEs used in the Trial

Appendix 20: SAE and incident reporting forms used in the PoCT Trial

Appendix 21: PoCT Trial stopping rules

Appendix 22: SAE results using practice reporting - method 1

Appendix 23: PoCT Trial rules for combining test results

Appendix 24: Medicare Australia data request

Appendix 25: List of process of care actions based on guidelines for each condition

Appendix 26: Case note audit data collection sheets

Appendix 27: Medicines and lifestyle questionnaire

Appendix 28: Prescribing patterns - Anticoagulant therapy

Appendix 29: Prescribing patterns – Diabetes

Appendix 30: Prescribing patterns - Hyperlipidaemia

Appendix 31: Results of medication compliance questionnaires by treatment group, condition and questionnaire

Appendix 32: Comparison of costs and ICERs for each test excluding hospital costs

Appendix 33: Impact of sensitivity analysis on ICER for the PoCT tests for all variables

Appendix 34: Participant change in attitude hypotheses indicating type of data transformation

Appendix 35: Absolute and relative limits by geographic location for each test

Appendix 36: Number of PoCT test results per practice by month and year