

# IMPLEMENTATION OF POINT-OF-CARE TESTING: CURRENT APPLICATIONS AND THE IMPACT ON PATIENT EXPERIENCE

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## Contents

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Contents .....	i
Thesis abstract .....	v
List of Tables .....	vi
List of Figures .....	viii
List of Appendices .....	x
List of Abbreviations .....	xi
Acknowledgments.....	xiii
<b>Chapter One: Introduction</b> .....	<b>1</b>
1.1 Overview of chapters .....	1
1.2 World health.....	3
1.3 The National Health Service.....	4
1.3.1 History of the National Health Service (NHS) .....	4
1.3.2 The new NHS .....	6
1.3.3 Current challenges faced by the NHS .....	7
1.4 Pathology testing .....	8
1.5 Point-of-Care Testing.....	9
1.5.1 POCT in the new NHS .....	10
1.6 NHS Health Checks .....	11
<b>Chapter Two: Point-of-Care Testing literature review</b> .....	<b>13</b>
2.1. Introduction .....	13
2.2 Applications of POCT .....	15
2.2.1 Example applications of POCT in hospital care .....	15
2.2.2 Applications of POCT in emergency care .....	16
2.2.3 Applications of POCT in primary care .....	17
2.2.4 Applications of POCT in the community.....	20
2.3.1 Lateral flow immunochromatographic assays .....	25
2.3.2 Biosensors.....	27
2.3.4 Microfluidics.....	30
2.3.5 Spectrophotometry .....	30
2.3.6 Blood gas and pH analysis.....	32
2.3.5 Haematological particle analysis .....	32
2.4 Patient satisfaction with POCT .....	33
2.5 Patient management of condition .....	36

2.6 Impact of POCT on healthcare professionals .....	38
2.6.1 Prescribing .....	39
2.7 Considerations relating to POCT.....	39
2.7.1 Analytical performance and quality of POCT .....	40
2.7.2 Training in POCT .....	47
2.7.3 Cost of POCT .....	50
2.8 Conclusion .....	52
<b>Chapter Three: On-site pathology testing in primary care: current positioning of Point-of-Care Testing in the UK.....</b>	<b>54</b>
Abstract .....	54
3.1 Introduction .....	55
3.2 Method.....	57
3.2.1 Designing the questionnaire .....	57
3.2.2 Piloting the questionnaire.....	58
3.2.3 Questionnaire Launch.....	58
3.2.4 Telephone survey .....	59
3.3 Results.....	60
3.3.1 amendments arising from the pilot.....	60
3.3.2 Participant characteristics .....	60
3.3.3 Awareness of POCT .....	60
3.3.4 POCT tests used in primary care.....	60
3.3.5 POCT operators .....	61
3.3.6 Training in POCT .....	62
3.3.7 Consideration of quality .....	62
3.3.8 Attitudes towards the use and adoption of POCT.....	62
3.3.9 Future use of POCT in primary care .....	63
3.3.10 Anecdotal evidence.....	64
3.4 Discussion .....	65
3.4.1 Strengths and limitations.....	65
3.5 Conclusion .....	67
<b>Chapter 4: Point-of-Care Testing in the community setting .....</b>	<b>68</b>
Abstract .....	68
4.1 Introduction .....	69
4.1.1 Public Health & the NHS Health Check .....	69
4.1.2 Delivering NHS Health Checks in the community.....	70
4.1.2.1 Cholestech LDX .....	73

4.1.2.2 The Health Bus.....	73
4.1.3 Salford Demographics.....	74
4.1.4 Published research.....	76
4.1.5 Rationale for current study .....	78
4.1.6 Research aims.....	78
4.2 Methods .....	79
4.2.1 Questionnaire design and pilot.....	79
4.2.2 Recruitment and follow-up.....	83
4.2.3 Conducting Health Checks and collecting data.....	84
4.3 Results.....	87
4.3.1 Participant characteristics .....	87
4.3.2 Baseline Health Check Results .....	89
4.3.2.2 Baseline referrals .....	92
4.3.3 Follow-up Health Check results.....	93
4.3.4 Questionnaire results .....	97
4.3.5 Results of participants aged 40+ subgroup.....	107
4.3.6 Statistical analysis (all participants) .....	110
4.3.7 Statistical analysis (participants aged 40+) .....	114
4.4 Discussion .....	116
4.4.1 Criticisms of the Health Check procedure.....	120
4.4.2 Strengths and weaknesses of the study .....	122
4.5 Conclusion .....	125
<b>Chapter 5: The influence of workplace Health Checks on health behaviour ....</b>	<b>126</b>
Abstract .....	126
5.1 Introduction.....	127
5.2 Methods.....	130
5.2.1 Design of interview questions and prompts .....	130
5.2.2 Pilot.....	132
5.2.3 Sampling and data collection .....	132
5.2.4 Analysis .....	133
5.3 Results.....	135
5.3.1 Result of pilot.....	135
5.3.2 Uptake and characteristics .....	135
5.3.3 Stimuli of positive health behaviour changes .....	136
5.3.3.1 Availability.....	137
5.3.4 Indicators of negative health behaviour changes or no changes.....	145
5.3.5 Participant opinion on NHS Health Checks.....	152
5.4 Discussion .....	157

5.4.1 Limitations of the study .....	159
5.5 Conclusion .....	160
<b>Chapter Six: Analytical and operator performance of a Point-of-Care Testing device used in the community setting .....</b>	<b>161</b>
Abstract .....	161
6.1 Introduction .....	162
6.1.1 The POCT device .....	163
6.2 Methods .....	168
6.2.1 Setting and participants .....	168
6.2.2 Testing process .....	168
6.2.3.1 Comparator .....	172
6.3 Results .....	174
6.3.1 Accuracy and repeatability .....	174
6.3.2 Total cholesterol results .....	178
6.3.3 HDL cholesterol results .....	179
6.3.4 TC/HDL results .....	179
6.3.5 Glucose results .....	179
6.3.6 Clinical significance .....	189
6.4 Discussion .....	195
6.4.1 Limitations of the study .....	198
6.5 Conclusion .....	200
<b>Chapter Seven: Overall discussion and conclusion .....</b>	<b>201</b>
References .....	211

**Introduction:** Point-of-Care Testing (POCT) also widely known as Near Patient Testing (NPT), is pathology testing performed at or near the site of patient care, offering several advantages over traditional pathology testing: it is portable, provides rapid results, uses smaller sample sizes and can be used for patient self-testing (PST). Due to these differences, it is conceivable that the implementation of POCT in place of laboratory testing could have an impact on patient experience; therefore, the aim of this research was to investigate this impact. The specific objectives of the study are to identify where and how POCT is currently used, to assess its impact on patient outcome and experience within a community setting and to evaluate its performance in the community setting.

**Methods:** A survey was performed to gain insight on the extent to which POCT is used within UK primary care, how well established it is and general attitudes toward its use. A cross-sectional study, employing both quantitative and qualitative methods was conducted with patients receiving local authority provided NHS Health Checks in the community, where POCT is used to measure cholesterol and glucose. The analytical and operator performance of the POCT used was also assessed.

**Results:** UK primary care staff were aware of POCT; 86% of respondents reporting that their surgery used some form of POCT on a regular basis. It appeared, however, that POCT operators were not always trained and that the quality of results obtained was not always considered. The use of POCT in community-based NHS Health Checks was well received and enabled the screening of individuals who would not normally access healthcare. However, the programme as a whole did not instigate significant improvements in the cardiovascular health of the participants, unless the participant was referred for further testing. The POCT used produced results that were significantly different from the reference value, producing clinically significant changes in outcome.

**Conclusion:** The use of POCT should be tightly managed in every setting, including the community. This management should include regular quality checks to ensure patient results are accurate and that clinical management decisions are appropriate.

## List of Tables

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Table 2.1 – Locations of POCT use.....	15
Table 2.2 – POCT parameters and clinical applications.....	23
Table 4.1 – Self reported characteristics of Health Check participants.....	87
Table 4.2 – Participant baseline Health Check results.....	89
Table 4.3 - Participant follow-up Health Check results.....	94
Table 4.4 – Participants in indicator risk categories.....	96
Table 4.5 – Baseline and follow-up answers to question 1 of the Health and Lifestyle questionnaire.....	98
Table 4.6 - Baseline and follow-up answers to question 2 of the Health and Lifestyle questionnaire.....	98
Table 4.7 - Baseline and follow-up answers to question 3 of the Health and Lifestyle questionnaire.....	99
Table 4.8 - Baseline and follow-up answers to question 4 of the Health and Lifestyle questionnaire.....	99
Table 4.9 - Baseline and follow-up answers to question 5 of the Health and Lifestyle questionnaire.....	99
Table 4.10 – Percentage of participants aged 40+ in indicator risk categories.....	108
Table 4.11 – Subgroup change in CVD risk score.....	114
Table 5.1 – Semi-structured interview participant characteristics.....	136
Table 6.1 – Market review of POCT cholesterol devices.....	166
Table 6.2 – Study result accuracy and reproducibility indicators.....	176
Table 6.3 – Shift tables comparing group result vs. ALTM for total cholesterol referral.....	185
Table 6.4 - Shift tables comparing Group One vs. ALTM for cholesterol referral.....	185
Table 6.5 - Shift tables comparing Group Two vs. ALTM for cholesterol referral.....	186
Table 6.6 - Shift tables comparing Group Three vs. ALTM for cholesterol referral.....	186
Table 6.7 – Shift table displaying the agreement between Group One and ALTM results for total cholesterol in reference to Framingham risk score categories.....	187



Table 6.8 - Shift table displaying the agreement between Group Two and ALTM results for total cholesterol in reference to Framingham risk score categories.....	188
Table 6.9 - Shift table displaying the agreement between Group Three and ALTM results for total cholesterol in reference to Framingham risk score categories.....	188
Table 6.10 - Shift table displaying the agreement between Group One and ALTM results for HDL cholesterol in reference to Framingham risk score categories.....	189
Table 6.11 - Shift table displaying the agreement between Group Two and ALTM results for HDL cholesterol in reference to Framingham risk score categories.....	190
Table 6.12 - Shift table displaying the agreement between Group Three and ALTM results for HDL cholesterol in reference to Framingham risk score categories.....	190

## List of Figures

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Figure 1.1 – NHS development timeline.....	5
Figure 2.1 – Model of laboratory testing used in primary care.....	18
Figure 2.2 – Model of POCT used in primary care.....	19
Figure 2.3 – POCT lateral flow assay diagram.....	25
Figure 2.4 - Lateral flow assay detection zone.....	27
Figure 2.5 – Operation of POCT biosensor.....	28
Figure 2.6 – Components of a spectrophotometer.....	31
Figure 2.7 – Bland-Altman plot of agreement between laboratory and POCT for INR measurement.....	46
Figure 3.1 – POCT in primary care telephone survey flow diagram.....	59
Figure 3.2 – Results of parameters tested as POCT in primary care.....	61
Figure 3.3 – Operators of POCT in primary care.....	61
Figure 3.4 - Primary care staff opinion of POCT.....	63
Figure 4.1 – Community based NHS Health Check procedure.....	72
Figure 4.2 – Image of the health bus.....	73
Figure 4.3 – Salford vs. UK indicators of deprivation and health.....	75
Figure 4.4 – Sample collection for POCT cholesterol/glucose.....	85
Figure 4.5 – Application of sample to cassette for POCT cholesterol/glucose...	85
Figure 4.6 – Insertion of cassette to POCT device.....	85
Figure 4.7 –Consort diagram displaying baseline and follow-up Health Check participants.....	93
Figure 4.8 – Results of exercise type at baseline and follow-up.....	101
Figure 4.9 - Results of number of physical activities at baseline and follow- up.....	102
Figure 4.10 - Results of hours spent exercising at baseline and follow-up.....	103
Figure 4.11 – Graph of subgroup ANCOVA analysis of CVD risk change.....	113
Figure 5.1 – Flow diagram of semi-structured interview questions.....	131
Figure 5.2 – Flow diagram of additional semi-structured interview questions.....	132
Figure 5.3 – Example of thematic network diagram.....	134
Figure 5.4 – Consort diagram of semi-structured interview participants.....	135
Figure 5.5 – Thematic network of stimuli for health behaviour change.....	137
Figure 5.6 - Thematic network of barriers to health behaviour change.....	145

Figure 5.7 - Thematic network diagram of participant opinion of NHS Health Checks.....	152
Figure 6.1 – Test methodology for analytical performance analysis.....	168
Figure 6.2 – Test principle for Cholestech LDX measurement of cholesterol.....	170
Figure 6.3 - Test principle for Cholestech LDX measurement of glucose.....	171
Figure 6.4 – Bland-Altman plot of Group One vs. ALTM TC results.....	180
Figure 6.5 - Bland-Altman plot of Group Two vs. ALTM TC results.....	180
Figure 6.6 - Bland-Altman plot of Group Three vs. ALTM TC results.....	181
Figure 6.7 - Bland-Altman plot of Group One vs. ALTM HDL results.....	181
Figure 6.8 - Bland-Altman plot of Group Two vs. ALTM HDL results.....	182
Figure 6.9 - Bland-Altman plot of Group Three vs. ALTM HDL results.....	182
Figure 6.10 - Bland-Altman plot of Group One vs. ALTM TC/HDL results.....	183
Figure 6.11 - Bland-Altman plot of Group Two vs. ALTM TC/HDL results.....	183
Figure 6.12 - Bland-Altman plot of Group Three vs. ALTM TC/HDL results.....	184
Figure 6.13 - Bland-Altman plot of Group One vs. ALTM glucose results.....	184
Figure 6.14 - Bland-Altman plot of Group Two vs. ALTM glucose results.....	185
Figure 6.15 - Bland-Altman plot of Group Three vs. ALTM glucose results.....	185
Figure 6.16 – Mean difference plot for all groups vs. ALTM for total cholesterol.....	186
Figure 6.17 - Mean difference plot for all groups vs. ALTM for HDL cholesterol.....	187
Figure 6.18 - Mean difference plot for all groups vs. ALTM for TC/HDL cholesterol.....	187
Figure 6.19 - Mean difference plot for all groups vs. ALTM for glucose.....	188

## List of Appendices

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All appendices can be found on the accompanying pen drive.

### Chapter Three

Appendix 3.1 – MMU research ethics for primary care POCT survey

Appendix 3.2 – Primary care POCT survey

Appendix 3.3 - Raw primary care POCT survey results

### Chapter Four

Appendix 4.1 – NHS Health Check pre-screening form

Appendix 4.2 - NHS research ethical approval letter

Appendix 4.3 – Baseline Health and Lifestyle questionnaire

Appendix 4.4 – Follow-up Health and Lifestyle questionnaire

Appendix 4.5 – Participant Information Sheet

Appendix 4.6 – Participant consent form

Appendix 4.7 – Patient assessment form

Appendix 4.8 – Audit C alcohol questionnaire

Appendix 4.9 - Referral guidelines

Appendix 4.10 - Raw Health Check data

Appendix 4.11 - Raw Questionnaire data

### Chapter Five

Appendix 5.1 – Introduction to semi-structured interviews

Appendix 5.2 – Group One transcribed semi-structured interviews

Appendix 5.3 – Group Two transcribed semi-structured interviews

### Chapter Six

Appendix 6.1 – Raw total cholesterol results

Appendix 6.2 – Raw HDL cholesterol results

Appendix 6.3 – Raw total cholesterol/HDL cholesterol results

Appendix 6.4 – Raw glucose results

## List of Abbreviations

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ANCOVA - Analysis of covariance  
BOS – Bristol Online Surveys  
CBC – Complete blood count  
CHD – Coronary Heart Disease  
CHDW - Community health development workers  
CKD – Chronic kidney disease  
CPA - Clinical Pathology Accreditation  
CVD – Cardiovascular Disease  
DALY – Disability-adjusted life years  
DHA - District health authority  
DMARD - Disease-modifying anti-rheumatic drugs  
DVT - Deep vein thrombosis  
FAD -Flavin adenine dinucleotide  
GMC - General Medical Council  
GOx - Glucose oxidase  
HCT - Haematocrit  
HGB - Haemoglobin  
HIPW - Health improvement project workers  
LA – Local Authority  
LFA - Lateral flow assays/Lateral flow immunochromatographic assay  
LYM – Lymphocyte  
LYM% - Lymphocyte percentage  
MCH - Mean cell haemoglobin  
MCHC - Mean cell haemoglobin concentration  
MCID - Minimum clinically important difference  
MCV - Mean cell volume  
MPV – Mean platelet volume  
MSM – Men-who-have-sex-with-men  
MXD# - Total content of monocytes, basophils, and eosinophils  
MXD% - Relative content of monocytes, basophils, and eosinophils  
NCMP - The National Child Measurement Programme  
NEUT# - Total content of neutrophils  
NEUT% - Relative content of neutrophils

NHS – National Health Service  
NHSHC - National Health Service Health Check  
NICE – National Institute for Health and Care Excellence  
NPT – Near Patient Testing  
PCO<sub>2</sub> - Partial pressure of carbon dioxide  
PCT – Primary Care Trust  
PHE – Public Health England  
PLT - Platelet  
PO<sub>2</sub> - Partial pressure of oxygen  
POCT – Point-of-Care Testing  
PST – Patient self-testing  
QALY – Quality-adjusted life years  
QC – Quality Control  
RBC - Red blood cell  
RCT - Randomised controlled trial  
RDW-CV - Relative distribution width of red blood cells by volume, coefficient of variation  
RDW-SD - Relative distribution width of red blood cells by volume, standard deviation  
SHA – Strategic Health Authority  
SHIS – Salford Health Improvement Service  
SMBG - Self-monitoring of blood glucose  
SO<sub>2</sub> - Oxygen saturation  
STD – Sexually transmitted disease  
TAT – Turnaround Time  
VLBWI - Very low birth weight infants  
WBC - White blood cell  
WHO – World Health Organisation  
YLDs – Years lived with disability  
YLL – Years of life lost  
5YFV – 5 Year Forward View

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## Chapter One: Introduction

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### 1.1 Overview of chapters

This thesis details the findings of four original research studies. The studies focus on the use of Point-of-Care Testing (POCT) outside the hospital setting.

#### Chapter One - Introduction

This introductory chapter provides a context in which to read the thesis, as well as a rationale behind the research undertaken.

#### Chapter Two – Literature review

A comprehensive review of POCT related literature. This chapter covers topics including: POCT technology; world healthcare systems; applications of POCT; advantages of POCT; disadvantages of POCT and quality considerations.

#### Chapter Three – POCT within primary care

This chapter reports the results of a survey and focus group of primary care staff. The study aimed to gather data on how well established POCT is in primary care in the UK. Key areas of interest included: which test parameters were carried out using POCT; which staff members operated the POCT equipment; training received by POCT operators; awareness of quality issues and general attitudes towards the use of POCT within primary care.

#### Chapter Four – NHS Health Checks: POCT in the community setting

The aim of the research reported in this chapter was to explore the patient impact of NHS Health Checks provided in the community by non-medical staff. With the increasing promotion of community healthcare, it is important to assess the impact that this may have on the patient. This open-label study was conducted with a local authority's health improvement service. Participants recruited to this study received a Health Check as per normal care and then an additional Health Check at least 12 weeks later. The primary outcome was the change in the participant Qrisk2 (10 year cardiovascular disease risk) score. Questionnaires

were also used to assess participant well-being; health behaviours and experience of the Check.

#### Chapter Five – The influence of workplace Health Checks on health behaviour

28 semi-structured interviews were conducted with participants of the community Health Check study (Chapter Four). The aim of this qualitative research was to explore and understand the factors that influence lifestyle choices and to assess whether receiving an NHS Health Check had any effect on those choices.

#### Chapter Six – Analytical and operator performance of POCT in the community

This chapter reports the findings of a study that assessed the analytical and operator performance of the POCT used to deliver the Health Checks in the community. Known external quality assessment (EQA) samples were tested by three groups: health improvement staff in the community setting; expert user in the community setting and expert user in the laboratory setting. The results were compared to the all laboratory trimmed mean (ALTM) to give an overall picture of analytical performance. Shift tables were used to display any clinical significance arising from variation in results.

#### Chapter Seven – Overall discussions and conclusions

Key points and findings of the chapters are drawn together in this final chapter. Recommendations are made for the future use of POCT.

## 1.2 World health

The picture of global health has changed. In 1990, the three leading risk factors for disease burden were childhood underweight, air pollution from solid fuels and tobacco smoking, including second hand smoke. Disease burden is a measurement of the impact of a health problem, taking in to account several indicators including cost, morbidity and mortality. Disease burden is often discussed in terms of quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs), both terms quantify the number of years lost due to disease (YLL).

By 2010, tobacco smoking is still one of the leading risk factors, however, the other two leading risk factors have changed and now include high blood pressure and alcohol consumption (Lim *et al.*, 2012). These three risk factors are modifiable, therefore theoretically it should be possible to reduce global disease burden by making healthy lifestyle changes.

## 1.3 The National Health Service

### 1.3.1 History of the National Health Service (NHS)

The NHS was founded in 1948 under a Labour government. It was based on the recommendations of the Beveridge Report, chaired by the economist Sir William Beveridge. The report recommended the “*comprehensive health and rehabilitation services for prevention and cure of disease*” and stated: “*Medical treatment covering all requirements will be provided for all citizens by a national health service*” (Beveridge, 1942).

Over the years, the NHS has seen many changes; some of the main changes are displayed in Figure 1.1. In 1973, under the reforms, regional, area and District Health Authorities (DHAs) replace regional hospital boards, taking over public health and other services from local authorities in the process (Webster, 1996). DHAs, which were responsible for both the finances and the provision of services in the NHS, were replaced in 2002 with primary care trusts (PCTs) and strategic health authorities (SHAs), which provided regional management for the NHS and oversaw the work of primary care trusts (PCTs).

303 PCTs were established and given responsibility for approximately 80% of the NHS budget. In 2005, a government paper outlined plans create changes in the way that services are commissioned using local clinicians in the design of services. The aim of the paper was to roll-out practice-based commissioning; develop primary care trusts (PCTs) to support practice-based commissioning; and to review the functions of strategic health authorities (SHAs) to support commissioning and contract management (Department of Health, 2005).

In 2006, Strategic health authorities (SHAs) were reduced from 28 to 10 and many primary care trusts merged to form 152 from 303.

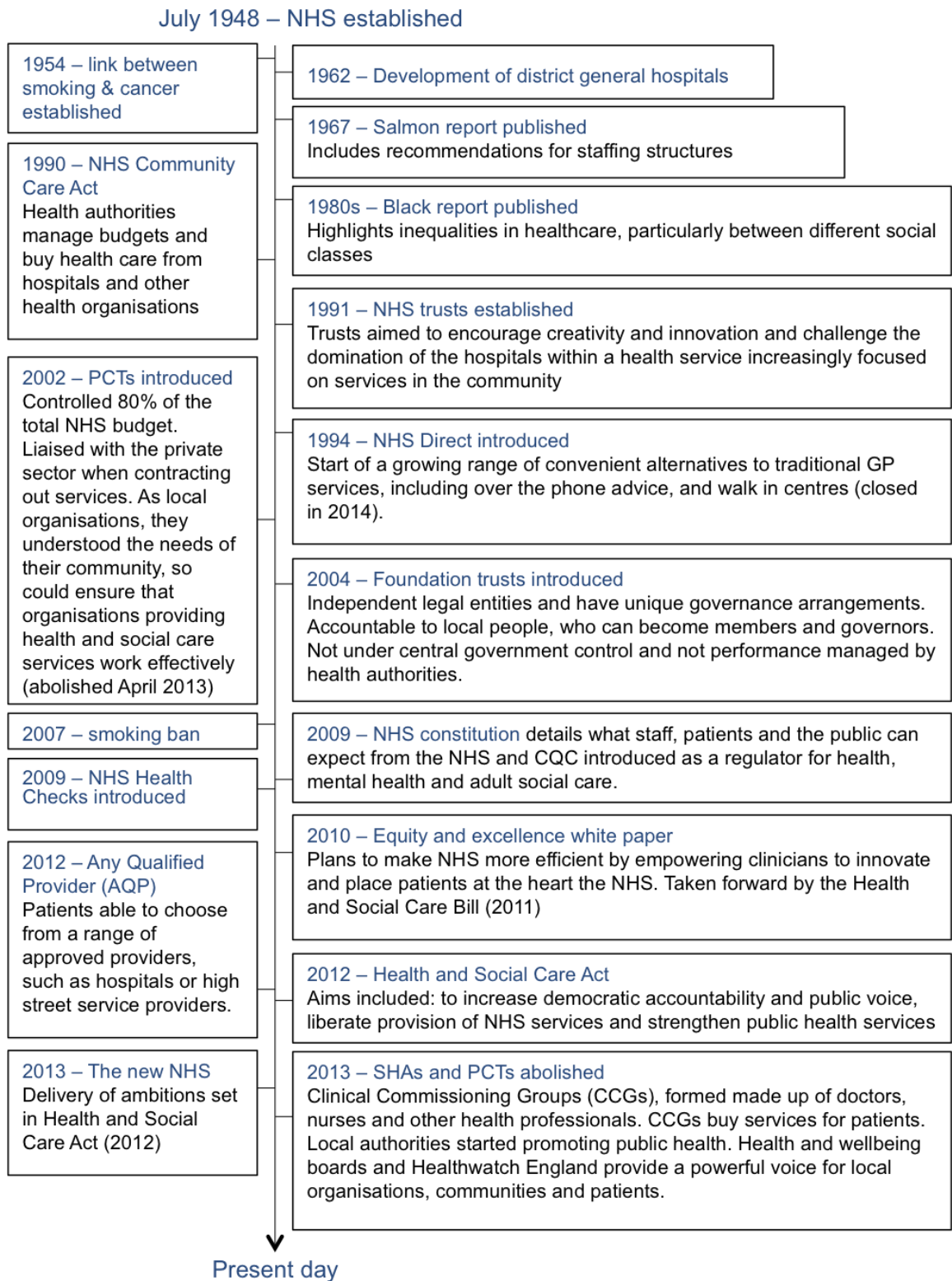


Figure 1.1 timeline displaying development of the NHS, with particular reference to structural and strategic changes, as well as cardiovascular disease

### 1.3.2 The new NHS

As shown in Figure 1.1, all SHAs and PCTs were abolished on 1 April 2013 as part of the coalition government reforms of the NHS. With the new NHS system, NHS England is responsible for purchasing primary care services and some specialised services. Clinical Commissioning Groups (CCGs) commission most of the hospital and community NHS services in the local areas for which they are responsible.

Many of the recent structure and culture changes within the NHS came about as a result of the Health and Social Care Act (2012) and the Francis Report (2013), which detailed the inquiry into failings at Mid-Staffordshire NHS Foundation Trust.

The Health and Social Care Act 2012 proposed to create an independent NHS Board, increase GPs' powers to commission services, strengthen the role of the Care Quality Commission, cut the number of health bodies e.g. Primary Care Trusts and Strategic Health Authorities and promote innovation (Department of Health, 2012).

The Francis Report was commissioned in 2010 following failings at the Mid Staffordshire NHS Foundation Trust between 2005 and 2009. The report addresses a range of issues, including: the recruitment, training and competency of staff; the regulation of care services; the science of quality measurement; the degree to which NHS staff feel empowered and the role of public voice (Francis, 2013). A subsequent report, published in 2014 by the Nuffield Trust, highlights the problems faced in trying to implement the recommendations made in financial and resource limited times (Thorlby *et al.*, 2014). Evidence suggests that the recent cuts to healthcare budgets may widen the gap of health inequalities between the poor and the affluent in the UK (Barr *et al.*, 2014).

In October 2014, the 5 Year Forward View (5YFV) was published, which sets out NHS England's strategy for the NHS for the next five years. The document emphasises a movement towards a new relationship with patients and public, where prevention and self-management is key and again encourages expansion and strengthening of primary and community care. It also highlights a £30bn

funding gap that cannot be closed without more funding, alongside further action on demand and efficiency (NHS England, 2014).

### *1.3.3 Current challenges faced by the NHS*

In recent years the NHS has been criticised for failing to meet standards, particularly within emergency care, hospital care and general practice.

The cause of these failings is multifaceted.

Over the last 30 years, average life expectancy in the UK has increased from 70.8 to 79.1 years for men and 76.8 to 82.2 years for women (ONS, 2015), this increase creates an ageing population. Whilst the population living longer is a positive factor, it also means that there is an increased section of the population that is living with one or more conditions, which are often complex, requiring on-going, specialist care.

There appears to be an increasing issue with people adopting unhealthy lifestyles. Consuming excess alcohol; having a poor diet; physical inactivity and smoking are all lifestyle choices that greatly increase the risk of developing disease, such as diabetes or heart disease. The National Child Measurement Programme (NCMP) measures the height and weight of around one million school children in England every year. In 2014/15, 19.1% of children aged 10-11 were obese and a further 14.2% were overweight (PHE, 2016). These numbers have been steadily rising over the past 20 years (van Jaarsveld and Gulliford, 2014), suggesting that the problem is set to continue.

Accident and Emergency (A&E) departments are under increasing pressure from rising numbers of patients who do not actually require emergency treatment, resulting in a 35% increase in attendances over the past 10 years (The King's Fund, 2015). This problem has arisen from several factors including attendees suffering with mental health problems who cannot access support elsewhere; difficulties in discharging elderly and frail patients who may not have support at home once ready for discharge due to cuts in social care budgets and patients, particularly those aged 18 to 34, who bypass GP services as they cannot make an appointment that fits around work (Citizens Advice Bureau, 2014). It is thought that these issues played a large part in the poor performance of A&E

departments against their target of 95 per cent of patients spending no longer than four hours in A&E (The King's Fund, 2015).

In the early days of the NHS, the main objective was to tackle disease. Today, patients expect so much more from the service, from mental health and social care, contraception, antenatal and maternity services, vaccination programmes and the fast, efficient processing of our medication and appointments.

#### 1.4 Pathology testing

Pathology is described by the Royal College of Pathologists to be the “*science at the heart of modern medicine*” which aims to explain why and how people fall ill and reveal targets for their treatment (RCPath, 2013). Using laboratory tests, it is possible to define the success or failure of both the progress and the final outcome of that treatment.

Diagnostic testing has been around for hundreds of years, with some of the earlier examples including examination of urine and faeces (Price *et al.*, 2004). The results of pathology tests are extremely important, it is estimated that they affect around 60-70% clinical management decisions including the prescription of medication, admissions, referrals and discharge from hospital (Forsman, 1996; Seddon *et al.*, 2001).

In 2008, following a report of the review of the NHS pathology services in England, chaired by Lord Carter of Coles, it was estimated that 70–80% of all health care decisions affecting diagnosis or treatment are influenced by laboratory results (Carter, 2008). The report focussed on improving quality and patient safety, improving efficiency and identifying the mechanisms for delivering change and recommended that the consolidation of pathology services would achieve many of the intended outcomes. At the time of issue of the report, over 500 million clinical biochemistry and 130 million haematology tests were carried out, over 50 million microbiology requests were processed and over 13 million histopathology slides and 4 million cytology slides were examined each year with around 35-45% requested through primary care. This frequency had increased around 10% each year between the years of 2005 to when the report was done,



2008. This increase is thought to continue exponentially over the next few years, the number of tests done in 2013 would have been approximately 805million for biochemistry, 209 million haematology and 80 million microbiology tests.

The United States has led a movement toward the consolidation of laboratories into 'core laboratories' and 'laboratory service networks'. This has since spread throughout Europe and has taken effect in the UK (Price *et al.*, 2004). After a review of the NHS pathology services, Lord Carter of Coles (2008) suggested that pathology services in England be consolidated. Today, hospital trusts in the East of England the East and West Midlands are adopting a 'hub and spoke' approach to pathology testing where larger 'hub' laboratories process the routine, non-urgent samples and smaller 'spoke' laboratories deal with the urgent samples (Illman, 2013). This 'hub and spoke' model is widely used across the more developed countries. There are currently 240 full-service pathology laboratories in the United Kingdom, it has been suggested that they could be reduces to 60 in a 10 year period if the 'hub and spoke' model was used countrywide (Illman, 2013). With a decreased provision of lab

### 1.5 Point-of-Care Testing

Point-of-Care Testing (POCT), also widely known as Near Patient Testing (NPT), is pathology testing performed at or near the site of patient care, in a location distinct from a normal hospital laboratory with the quick availability of results (Khunti, 2010; Cramb, 2004). POCT makes use of miniaturised versions of laboratory technologies, making many clinical pathology based tests available in a range of settings. The tests can be performed by a range of users, including laboratory staff, healthcare staff and patients, making use of a wide variety of instruments. Through the availability of rapid results, POCT enables immediate, informed decisions relating to patient care. Compared to laboratory testing, the flexibility provided by POCT in test location and test operator means that POCT is ideal for use in a much wider range of settings and scenarios. POCT is used in many areas, including: surgical theatres, intensive care, accident and emergency

(A&E), general wards, general practice, home visits, sports medicine, patient self-testing and the general community.

### 1.5.1 POCT in the new NHS

The NHS reforms aim to create a focus on quality and improving outcomes whilst increasing the accountability of the NHS; strengthening clinical leadership; shifting responsibility and decision making for public health to local authorities; promoting outsourcing of services and creating a competitive market place (Department of Health, 2012; National Health Service, 2013).

The Health and Social Care Act (2012) highlights “*Evolving clinical practice and technology means that some services that previously could only be provided in an acute hospital can now be provided in a local health centre, GP surgery or even the patient’s own home*” (Department of Health, 2012).

POCT has the ability to accommodate many of the above aims as it can facilitate more community based care whilst still providing effective pathology testing.

POCT could also add competition to the market place where the NHS commissions external companies to provide pathology services to the NHS, for example IntraHealth, a primary healthcare company separate to the NHS.

IntraHealth has an anticoagulation monitoring service for INR, which has been adopted by some NHS primary care sites, particularly in the North East of England (IntraHealth, 2013).

Another aim of the NHS reforms is to reduce spending. Lord Carter of Coles (2008) reported that £2.5 billion was spent on pathology testing per year, with the likelihood that pathology testing was set to rise in frequency by around 10% per annum this figure can only be larger today. The largest portion of this annual spend is on staffing. POCT could help reduce spending in this particular part of the budget, as a smaller workforce would be required. The NHS already employs the majority of POCT users in the primary care setting as nurses, GPs and healthcare assistants.

## 1.6 NHS Health Checks

This chapter has highlighted the global problem that is CVD, the priority of prevention over cure and the pressure to treat patients outside the hospital setting. One programme that incorporates these three themes is the NHS Health Check scheme.

The theoretical basis of screening centres around the identification of unrecognised disease or defect by the application of testing. The objective is to distinguish between apparently well individuals who are likely to have a disease and those who probably do not (Wilson and Jungner, 1968).

In 2009, the NHS Health Check (NHS HC) programme was implemented in the UK. The programme screens for risk factors of cardiovascular disease (CVD), diabetes, kidney disease and some forms dementia in 40-74 year olds, making it a type of 'case-finding' screening. The scheme aims to prevent CVD by identifying modifiable risk factors e.g. hypercholesterolaemia or hypertension and advising the patient on how to reduce their risk, either through lifestyle changes or prescription of relevant drugs.

An NHS HC involves questions around lifestyle and family medical history; assessment of alcohol intake; measurement of glucose and cholesterol levels; height, weight and waist circumference; blood pressure assessment; pulse reading and calculation of CVD risk score using a risk calculator. The scheme is primarily implemented within primary care where eligible patients are invited to the Check by their GP practice or they are checked opportunistically during a GP or nurse consultation.

In April 2013, local authorities (LAs) became responsible for public health services. Some LAs provide community NHS Health Checks through their health service, which employs non-medical staff, trained specifically to perform NHS Health Checks, utilising POCT for the analysis of cholesterol and glucose levels, in a variety of locations e.g. supermarkets and workplaces.

It is because of the availability of POCT that screening programmes involving analysis of blood samples, like NHS Health Checks, can be brought into the community. The advantage of performing Health Checks in this way is that it

frees up clinician time, as well as having a greater chance of accessing 'hard-to-reach' patients who would not normally attend primary care and therefore would not receive an opportunistic Health Check from their GP.

Although there is a plethora of evidence that supports identification and modification of CVD risk factors in reducing the morbidity and mortality of CVD (Espeland, 2007; Lakka *et al.*, 2002; Turner *et al.*, 1998), the NHSHC scheme has come under criticism for being a waste of time and money, a cause of unnecessary worry and a task that some healthcare professionals have little interest in performing (Krogsbøll *et al.*, 2012; Capewell *et al.*, 2015). Chapters Four, Five and Six of this thesis investigate the outcomes of NHSHCs performed in the community setting as well as the quality of the POCT used to perform them.

### 2.1. Introduction

This chapter reports relevant literature concerned with Point-of-Care Testing (POCT), with particular reference to its advantages, disadvantages, applications and current technologies.

Point-of-Care Testing (POCT), also widely known as Near Patient Testing (NPT), is pathology testing performed at or near the site of patient care, in a location distinct from a normal hospital laboratory with the quick availability of results (Khunti, 2010; Cramb, 2004). The tests can be performed by a range of users, from patients to laboratory staff, using a range of instruments.

POCT represents one of the fastest growing segments of the diagnostics market (Kazmierczak, 2011), with the most common POCT tests are glucose, urine dipstick, INR, D-dimer, haemoglobin and lipid profile tests (Liikanen and Lehto, 2013). Typically, a good POCT device should have the following characteristics: short time to results (< 15 minutes), portable, require only sample volumes, multifunctional, use self-contained reagents, self-calibrated and ability to connect to other systems or networks (Sista *et al.*, 2008).

POCT provides many advantages over laboratory based testing. As most devices enable a quick turnaround time from sample collection to provision of results, faster informed clinical decisions can be made, which could be vital in an emergency setting. In a non-emergency setting, this attribute is considered very convenient as a patient can be tested and the results discussed in one consultation. This is convenient for both the healthcare professional and patient, freeing up appointment time and reducing the number of appointment visits for the patient, for example in the primary care setting. Rapid results can also reduce worry for the patient, as the wait for test results can sometimes be stressful. The prospect of a less stressful wait for results could encourage more patients to be tested for sexually transmitted diseases (STDs) and therefore impact on the transmission of STDs. A study by Horwood *et al.* (2015) surveyed

a cohort of men-who-have-sex-with-men (MSM) (n=134). The survey reported that 84% would be more likely to be tested for HIV, 91% more likely tested for gonorrhoea, 90% more likely tested for chlamydia and 90% more likely tested for syphilis if the tests were available as rapid POCT (Horwood *et al.*, 2015).

As POCT negates the need for many of the steps required in traditional laboratory testing, illustrated in Figures 2.1 and 2.2. Time-dependent changes in labile analytes, analytes that regularly or continuously undergo change, such as lactate and glucose can be avoided (Kazmierczak, 2011) through the use of POCT due to the simpler testing method.

Through avoiding some of these steps, it is also possible that POCT could avoid some of the errors typically associated with laboratory testing. Inappropriate sample preparation can occur in the laboratory, often POCT devices are automated and so sample preparation is performed internally (Drenk, 2001). Misidentification of patients is also far less likely with POCT as it is often performed with the patient present.

POCT can provide greater patient comfort than laboratory testing. Typically, POCT devices only require a small sample size e.g. 2-3 drops of capillary blood, negating the need for large volumes of blood or plasma, which when analysed in the laboratory are traditionally obtained by venepuncture, which patients can find uncomfortable or even traumatic and time consuming.

As most POCT devices are designed to be portable, employing features that are easy to use, the range of locations and situations in which testing can take place is vast when compared to laboratory testing. These features enable testing to take place in the community setting, performed by non-healthcare or laboratory staff.

## 2.2 Applications of POCT

Table 2.1 summarises the locations in which POCT can be utilised and the potential benefits that it may provide. Due to the portable nature of POCT, it can also be used in prison and military settings e.g. for drugs of abuse and sports medicine e.g. lactate as a measure of athletic performance (Price *et al.*, 2004).

Location	Application	Potential benefit
Intensive care unit (ICU)	Monitor vital parameters	Early recognition of life-threatening conditions, Improving mortality and morbidity. Reduce length of stay
Operating theatre	Monitoring during operative procedures e.g. Coagulation testing in cardiac surgery, anaesthetics	Reduce post-operative care requirement Convert to day care
A&E	Testing for rapid triage and treatment	Quicker to diagnose and initiate treatment, reduced length of stay in A&E
Ambulance	Pre-hospital testing e.g. cardiac markers, blood gases	Faster triage through A&E Earlier intervention
Primary care	Management of long term conditions	Convenience and patient comfort
Community	Screening and management of long term conditions	Better access to relevant population
Home	Management of long term conditions	Better awareness of condition Motivation to manage condition Avoid need to attend hospital Avoid cost of transport Avoid time off work

Table 2.1 Summary of locations and scenarios in which POCT can be applied, with reference to potential benefits.

### 2.2.1 Example applications of POCT in hospital care

Generally, the laboratory staff of a hospital will manage the POCT. Some hospitals have POCT coordinators whose role is specifically to manage the POCT undertaken across the hospital. As shown in Table 2.1, POCT has many applications within the hospital setting, with the advantages it provides being put to best use in critical situations, where fast turnaround times are key.

In neonatal intensive care, blood sampling for laboratory testing is a major cause of blood loss and anaemia in neonatal intensive care. Mahieu *et al.* (2012) found that, compared with laboratory testing, the use of POCT decreased the total

blood taken for electrolyte testing by 23.7% and 22.2% for bilirubin testing. In addition, fewer very low birth weight infants (VLBWI) required blood transfusion (38.9% vs. 50%,  $p < 0.05$ ) as the number of transfusion/infants decreased by 48% (1.57 vs. 2.53,  $p < 0.01$ ) (Mahieu *et al.*, 2012).

In the operating theatre, excessive blood loss, that requires transfusion of blood products, sometimes occurs in patients undergoing cardiac surgery, in particular cardiopulmonary bypass. Blood loss and transfusion requirements in these patients may be reduced with a better control of heparin treatment and its reversal. POCT can provide the rapid results required to make faster clinical management decisions and avoid unnecessary blood transfusions (Prisco *et al.*, 2003). This avoidance of unnecessary transfusions has been shown to provide significant benefits with respect to clinical outcomes (Weber *et al.*, 2012).

### *2.2.2 Applications of POCT in emergency care*

As previously explained in Chapter One, emergency departments are facing huge amounts of pressure to meet targets and are quite often failing due to a number of constraints. Early recognition and treatment of illness are directly linked to the survival rate of critically ill patients (Rooney and Schilling, 2014). For this reason, POCT could greatly improve a patient's chance of survival due to the rapid availability of test results. Examples of POCT tests in the emergency setting include cardiac markers, blood lactate and coagulation. Cardiac markers, such as Troponins, are tested as an indicator of myocardial injury. A study conducted by Than *et al.* (2012) reported that POCT returned results 42.1 minutes quicker than the laboratory, on average (Than *et al.*, 2014). Similarly, a randomised controlled trial conducted by Goodacre *et al.* (2011) found a 20% greater discharge rate during the initial evaluation process when POCT was performed compared to laboratory testing (Goodacre *et al.*, 2011).

Elevated blood lactate levels are sensitive marker of impaired tissue perfusion and anaerobic metabolism in patients with suspected sepsis (Scott *et al.*, 2012). A study by Goyal *et al.* (2010) found that the use of POCT with a capillary blood sample saved 151 minutes on average compared to whole-blood lactate levels that were taken at the discretion of the treating physician (Goyal *et al.*, 2010).



Immediate assessment of coagulation status, for example by performing international normalised ratio (INR), partial thromboplastin time, haemoglobin, and/or platelet count tests has been shown to aid the initiation of thrombolysis therapy for those suspected of suffering an ischemic stroke (Lahr *et al.*, 2013). Studies have shown that POCT produces coagulation results 30 to 50 minutes quicker than the laboratory (Walter *et al.*, 2011; Weber *et al.*, 2013).

In all cases, this fast TAT results in quicker clinical management decision, which, in the emergency setting has a positive impact on clinical outcomes. For example, patients who receive initiation of sepsis treatment within the first 3 to 6 hours after admission to the emergency department have improved mortality rates of 16% (Dellinger *et al.*, 2013; Rivers *et al.*, 2001). Although test for test POCT often proves to be more expensive than laboratory testing, the benefits that POCT provides appear to outweigh any downsides. It is thought that the development of POCT will change the way in which emergency medicine is practiced (Rooney and Schilling, 2014).

### *2.2.3 Applications of POCT in primary care*

Healthcare for common and chronic conditions is mostly provided by primary care (Seddon *et al.*, 2001) and so it is important to make sure appropriate pathology provisions are available in this setting as well as in secondary care. Typical POCT tests that may be performed in primary care include: urine dipstick testing, blood glucose and coagulation e.g. international normalised ratio (INR). However, there is little documentation of which POCT are used in primary care and who performs them, hence the research undertaken in Chapter Three.

Figures 2.1 and 2.2 are two models of how pathology testing in primary care can be organised.

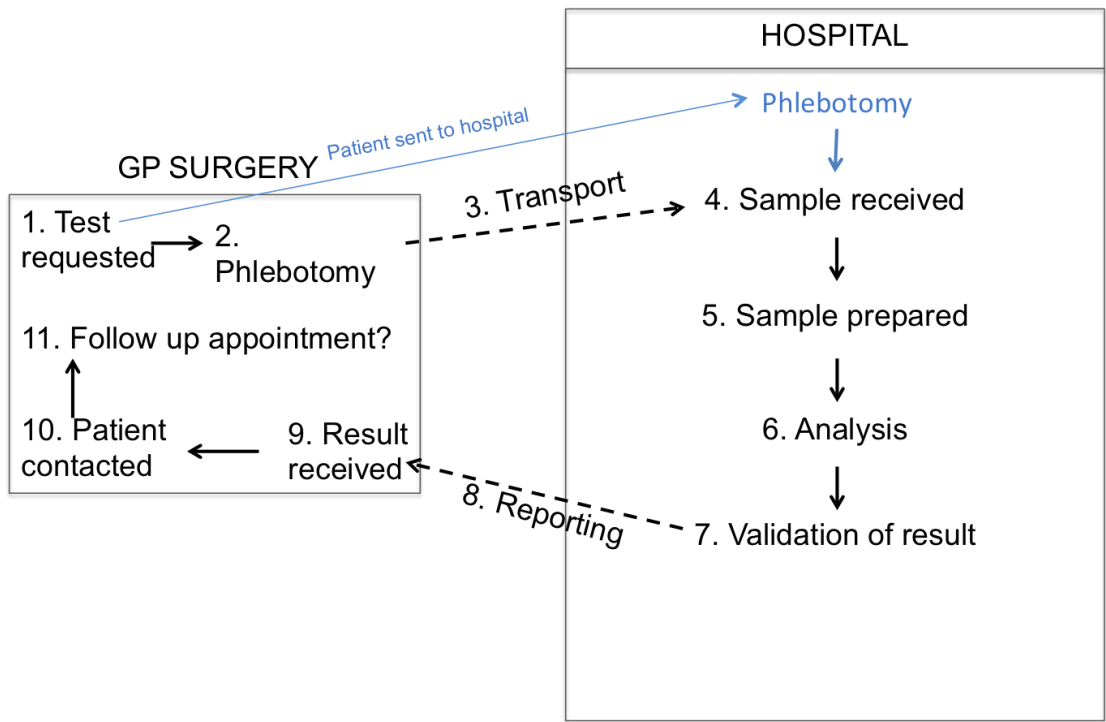


Figure 2.1: Diagram of how the traditional model of pathology laboratory testing operates within primary care. The blue line represents an additional step, which may be taken if the GP practice cannot take venous sample(s).

The traditional model of pathology testing has been in place for many years and is highly organised. The quality of results is generally high because laboratories have to be Clinical Pathology Accreditation (CPA) inspected, they run internal quality checks, and they take part in external quality control schemes where results are compared nationally and internationally.

The pathology staff are highly trained, a biomedical scientist must now have an undergraduate degree in biomedical science or closely related subject, relevant experience in working in a laboratory and they must also be registered with the Health and Care Professions Council (HCPC). Registration with the HCPC requires completion of an academic programme plus a period of training in an Institute approved laboratory (IBMS, 2013). Additionally, due to the fact that pathology laboratories have a high throughput of tests using large mainline analysers, the traditional model is relatively cost effective on a cost per test basis.

There are some drawbacks to the traditional model of pathology testing. Not all sites of primary care are situated close to the main hospital laboratory, meaning that the availability of pathology testing can be limited or that the process can take a longer period of time due to greater transport times being required. Generally, due to the nature of the traditional model of pathology testing, results are not obtained as quickly as they are in POCT. In some cases, this delay of results can be detrimental because it can have a knock on effect of delaying the recognition or treatment of a condition. In turn this could lead to a plethora of negative outcomes such as more appointments/hospital admissions, longer hospital stays, worsening of the patient's condition and undue worry and upset. The majority of sample processing errors occur within the pre-analytical phase (specimen collection and pre-analytical sample handling), this is mainly down to incorrect information on the request form (Turner *et al.*, 2013) or individual or system defects (Da Rin, 2009). By comparison POCT can avoid some of these potential errors because no request forms are required. However, central laboratories can also overcome some of these potential errors by using advanced information technology and robotics. In some hospitals the implementation of such technology has been shown to improve accuracy and clinical efficiency of the laboratories and resulted in an all-round reduction in errors (Da Rin, 2009).

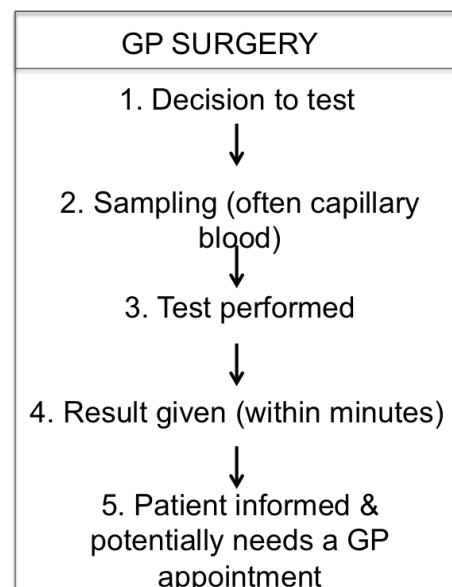


Figure 2.2: Model of POCT procedure within primary care

#### 2.2.4 Applications of POCT in the community

Due to POCT generally being transportable and easy to use, it is increasingly being used in screening initiatives, such as the NHS Health Checks, and at home by patients, especially those with long-term conditions, for example diabetes.

##### Patient self-testing (PST)

When a device is deemed to be simple and have a low risk for erroneous results by the Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) then it can be CLIA waived. For a test to be classified as 'simple' it must be fully automated and provide a direct read-out of results, without interpretation (Corbin *et al.*, 2012). A CLIA waived device can be operated by individuals without a professional pathology testing (FDA, 2014).

When a device is CLIA waived it is also approved for home use. This means it can be used for patient self-testing (PST), also known as patient self-monitoring. PST is particularly useful for patients with chronic conditions that are prescribed long-term medication because it allows the patient to self-test and monitor at their convenience. For example, patients with diabetes can monitor their glucose levels using a variety of hand-held glucometers, this is known as self-monitoring of blood glucose (SMBG). Monitoring glucose levels gives the opportunity to achieve specific levels of glycemic control and prevents hypoglycaemia. The main aim of self-monitoring blood glucose is to maintain a more constant glucose level by collecting detailed information about blood glucose levels at many time points. The availability of blood glucose values can help aid the adjustment of a therapeutic regimen (Benjamin, 2002).

For patients with diabetes mellitus type 1, studies have shown that increased self-monitoring is directly correlated with improved health outcomes, for example, reduction of HbA1c (Evans, 1999). A systematic review by Welschen *et al.* (2005) examines 6 randomised, control trials and concludes that SMBG groups show a statistically significant decrease of 0.39% HbA1c compared to control groups, in patients with diabetes mellitus type 2, not treated by insulin. A decrease of 0.39% in HbA1c is expected to reduce the risk of microvascular complications by approximately 14% (Stratton, 2000).

However, other studies conducted have produced varying findings. An article analyzing data from the third National Health and Nutrition Examination Survey (NHANES III) concluded that, for patients with diabetes mellitus type 2, there was little correlation between SMBG frequency and glycemic control (Harris, 2001). However, the credibility of the NHANES III study design has also been questioned as it was a cross-sectional analysis of patient behaviour and glycemic control, therefore, a cause-and-effect relationship would be difficult to determine.

#### Patient self-adjustment

In certain cases, some patients can adjust their medication themselves according to the results they generate using their POCT device, this is known as self-adjustment.

Programmes such as Dose Adjustment For Normal Eating (DAFNE), for patients with diabetes mellitus type 1, train patients in how to estimate the carbohydrate in each meal and to inject the right dose of insulin. A randomised control trial conducted by the DAFNE study group (2002) found that DAFNE training produced significant improvements in glycaemic control, well-being, quality of life and treatment satisfaction (DAFNE, 2002).

POCT can be utilised by patients taking anti-coagulants, e.g. Warfarin. POCT devices are used to measure international normalised ratio (INR), this is a derivative of a prothrombin time test, used to determine the clotting tendency of blood.

A systematic review by (Heneghan *et al.*, 2006) reported that simple self-monitoring tests could reduce the risk of stroke by half in thousands of people who are medicated with warfarin. Patients who are capable of performing self-monitoring and self-adjusting together are less likely to have a thrombolytic event and have lower mortality rates than those who only self-monitor. However, Heneghan (2006) warns that not all patients are suitable for self-monitoring and that those who are identified as capable should be properly educated in the procedure (Heneghan *et al.*, 2006). A 2 year randomised control trial assessing 100 patients found that approximately two thirds of patients are suitable for anticoagulant self-management (Sidhu, 2001), this is a significant portion of the warfarin prescribed population.

There are other factors to consider on implementation of PST. A systemic review by Connock *et al.* (2007) suggests that PST is actually more expensive than normal care in some cases, estimating the adoption of patient self-monitoring of anticoagulation therapy would cost the NHS an additional £8–14 million per annum (Connock *et al.*, 2007).

### Screening initiatives

POCT is increasingly being used in a range of community locations, from pharmacies to supermarkets to busses. The general idea is that the POCT operator, e.g. pharmacist, identifies at-risk patients and refers them to the next level of care for possible diagnosis and treatment (Rodis and Thomas, 2006). Screening initiatives that take place in the community, rather than primary care setting aim to capture ‘hard-to-reach’ patients who would not normally visit their GP.

Blood glucose and cholesterols are measured using POCT in the community by local authority health services as a means of delivering NHS Health Checks. Originally, NHS Health Checks were exclusively delivered in general practice by healthcare professionals. In 2013, local authorities were given a budget to spend on health. Some local authorities have used some of this budget on providing Health Checks in community locations, for example supermarkets, workplaces and on bespoke health busses. It would not be possible to deliver Health Checks by this method without the provision of POCT. Chapters Four, Five and Six investigate the impact of these Health Checks on the patients that receive them as well as assessing the quality of the POCT results produced.

### 2.3 POCT Technology

POCT can perform many of the tests that are offered in a laboratory, only it makes use of miniaturisation of the technology in order to give automation and integration of several processes on one single device (Mugele and Baret, 2005). POCT was originally used for to blood chemistry, electrolytes, blood gases, clotting and pregnancy testing. More recently, POCT has now been extended to drugs of abuse, cardiac markers, and infectious diseases (Sista *et al.*, 2008).

Table 2.2 displays some of the main POCT test available, categorised in accordance with their clinical application.

Clinical application	Parameters available as POCT tests
Acute-phase proteins	C-Reactive Protein (CRP)
Allergy in-vitro diagnostics	Allergy specific Immunoglobulin E (IgE)
Blood gasses	Acidity (PH), partial pressure of carbon dioxide (pCO <sub>2</sub> ), Partial pressure of oxygen (pO <sub>2</sub> )
Cardiac markers	Troponin T (TnT), Troponin I (TnI), myoglobin, Creatin kinase MB isoenzyme (CK-MB), B-type Natriuretic Peptide (BNP/NT-pro-BNP)
Coagulation	Activated clotting-time (ACT), activated partial thrombo-plastin time (aPTT), prothrombin time (PT, INR), D-dimer, platelet function tests, ex-vivo bleeding time
Diabetes mellitus	Glucose, Glycated haemoglobin (HbA <sub>1c</sub> ), microalbumin, continuous glucose monitoring
Drug monitoring	Therapeutic drugs, alcohol, amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates
Electrolytes	Sodium (Na <sup>+</sup> ), Potassium (K <sup>+</sup> ), Chloride (Cl <sup>-</sup> ), Calcium (Ca <sup>++</sup> <sub>ion</sub> ), Magnesium (Mg <sup>++</sup> <sub>ion</sub> )
Enzymes	Amylase, alkaline phosphatase, Creatine kinase (CK), aspartate aminotransferase (AST), alanine aminotransferase (ALT), Gamma-glutamyl transferase (γ-GT)
Fertility	Human chorionic gonadotropin (hCG), Luteinising hormone (LH) follicle stimulating hormone (FSH) and sperm count
Haematology	Haemoglobin, haematocrit, erythrocytes, leukocytes, thrombo-cytes, CO-Oximetry
Infectious agents	Human immunodeficiency virus (HIV), infectious mononucleosis, Chlamydia trachomatis, Trichomonas vaginalis, Plasmodium falciparum and vivax, Influenza A and B, Steptococcus A and B
Metabolites	Cholesterol, HDL-cholesterol, triglycerides, creatinine, urea, uric acid, bilirubin, lactate, ammonia
Rheumatology	Antibodies against mutated citrullinated vimentin (anti-MCV)
Urine diagnostics	Urine strips (pH, protein, glucose, ketones, bilirubin, uro-bilinogen, nitrite, leukocytes, erythrocytes), microalbumin, NMP22 bladder carcinoma check

Table 2.2 Table displaying many of the current tests available as POCT, categorised in accordance with their clinical application.

POCT tests can broadly be divided into three different platforms: non-instrumental systems, portable analysers and bench-top analysers.

Type 1: Non-instrumental systems where the equipment is often disposable, such as a reagent test strip, and can measure single or multiple analyte(s) and may also include some procedural controls. The strips are composed of a porous matrix that has been infused with dried reagents. These are qualitative tests that determine a plus/minus or positive/negative result. Detection in these tests ranges from chemical indicator reactions to immunological reactions (Luppa *et al.* 2011). Examples of these tests include pregnancy tests, urine dipsticks and tests for the detection of infectious agents.

Type 2: Small portable analysers, which can often be held in one hand are quantitative test devices which often have the majority of the test occurring on the disposable test strips needed for each test, the reader is simply used for the determination and output of results (Luppa *et al.* 2011). Examples of these devices include blood glucose meters, cholesterol checks and coagulation monitors that can test parameters such as the international normalised ratio (INR). Most of the hand held POCT devices operate using closed continuous flow through channels that are either etched into a solid surface such as silicon or are moulded from polymeric materials into a matrix (Mugele and Baret, 2005).

Type 3: Large, bench-top analysers that are less portable and designed for use in small laboratories and clinics often test for multiple analytes. These analysers tend to use more complex analytical principals, including: particle counting for haematology, spectrophotometric substrate and enzyme-activity measurement, sensor-based blood gas analysis and immunoassays (Luppa *et al.* 2011).

Advancements in detection, recognition, fluidics, transduction and analytical processing have made testing for parameters such as those in Table 2.2 possible as POCT.



### 2.3.1 Lateral flow immunochromatographic assays

Lateral flow immunochromatographic assays or Lateral flow assays (LFAs) are designed to confirm the presence or absence of a compound or a derivative of it. The analyte is recognised through the use of its antibodies.

LFAs consist of strips of a carrier material which contains dry reagents that are activated by applying a liquid sample and results are usually given with a simple 'positive/negative' display. LFAs are simple and easy to use, with high sensitivity and selectivity (Posthuma-Trumpie *et al.*, 2009).

The most common examples of POCT that use LFAs include pregnancy testing, testing for infection by specific pathogens, testing for organ failure e.g. heart or kidneys and tests for drugs of abuse.

LFAs are often referred to as "dipsticks" but this is an incorrect use of the term as real dipstick assays do not facilitate the flow of liquid through a membrane like an LFA does, instead they are based on immunoblotting principles (Posthuma-Trumpie *et al.*, 2009).

The principal behind LFAs is the movement of a liquid along a strip of polymeric material whilst moving through various zones that contain attached molecules that interact with the analyte. Figure 2.3 illustrates the operating sites of a typical LFA.

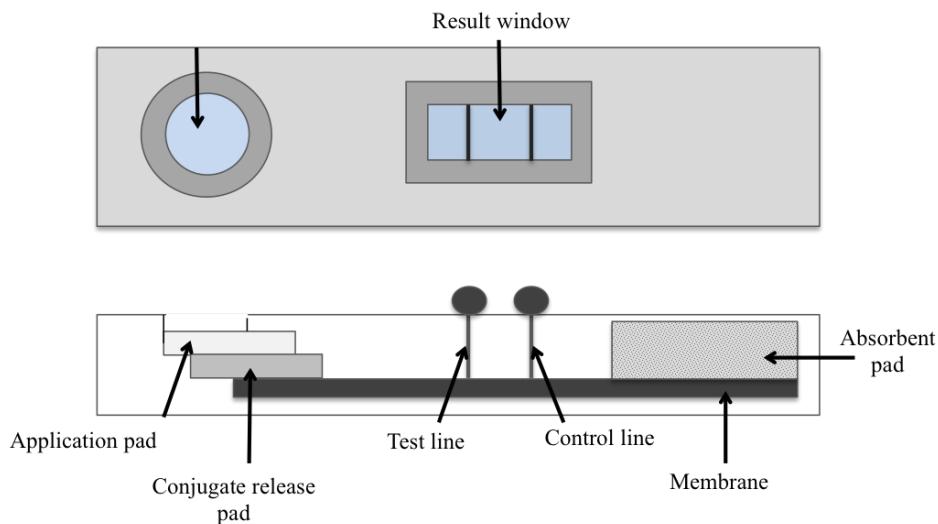


Figure 2.3 A typical POCT 'sandwich format' lateral flow immunochromatographic assay

Typically an LFA will consist of an application window where the sample will be introduced. The sample then runs along the application pad, through the conjugate release pad, the site at which the labeled analyte or recognition element(s) are dried. The labels used are made of very small (15-800 nm) coloured/florescent nanoparticles that can move with ease through the membrane and designed for optical detection. The nanoparticles are often made of colloidal gold, a suspension of small particles of gold in a liquid (Lim *et al.*, 2012; Byzova *et al.*, 2010) or less often they are liposomes which are dyed with fluorescent or bioluminescent materials, the advantage of this is that they can allow a quantitation of the response as well as the normal visualisation (Posthuma-Trumpie *et al.*, 2009).

After it has been through the conjugation pad, the sample runs along the membrane strip, using capillary force, where it encounters the detection zone. The detection zone consists of a test line and control line. At the test line there is an antibody to the analyte and so here the sample analyte and labeled analyte from the conjugate pad compete for the binding sites of the antibody. A response is seen, in this case a visible deposit, if the sample analyte is captured (Gordon and Michel, 2012) this is demonstrated in Figure 2.4. At the control line there is an antispecies immunoglobulin G, a response here confirms that the sample has flowed through the strip sufficiently.

Because the captured label concentrates sufficiently above the background of unbound label to become visible, no wash step is required (Gordon and Michel, 2012).

In addition, it is possible to have more than two strips in the detection zone, they can be used to measure multiple analytes or give semi quantitative results (Posthuma-Trumpie *et al.*, 2009).

There is also an absorbent pad attached to the end of the membrane strip, this is used to maintain the movement of the liquid towards it (Posthuma-Trumpie *et al.*, 2009).

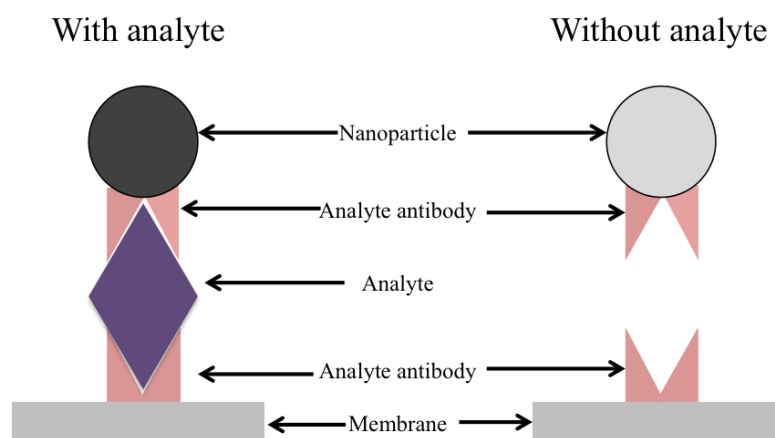


Figure 2.4 Diagram of a LFA detection zone. The image on the left with the analyte present gives an increasing signal; the image on the right with an absence of analyte will not provide a signal.

Depending on the analyte used, an LFA can be used to detect or monitor; infectious agents such as influenza and *Streptococcus pneumoniae*; metabolic disorders such as renal disease and diabetes; toxic compounds such as sulfadimidine which is an antibacterial, as well as the detection of other factors such as human chorionic gonadotropin (hCG) for pregnancy testing (Posthuma-Trumpie *et al.*, 2009).

More sophisticated examples of a POCT LFA include detection of cardiac markers like CK-MB. Whole blood or plasma can be applied, which then migrates through a filter into a reaction chamber containing dry fluorescent-labelled antibodies. The sample remains in the chamber for a time determined by a reaction gate. The reaction gate then becomes hydrophilic on contact with the sample. After this, the liquid migrates by capillary action to a reagent reservoir through channels that pass the capture antibodies. The results are read in an automatic reader and given on-screen (Gordon and Michel, 2012).

### 2.3.2 Biosensors

The technology behind POCT often involves the use of biosensors (Luppa *et al.*, 2011). Biosensors are classified by the International Union of Pure and Applied Chemistry (IUPAC) as analytical devices that detect analytes using “*specific biochemical reactions mediated by isolated enzymes, immunosystems, tissues,*

organelles or whole cells to detect chemical compounds usually by electrical, thermal or optical signals” (IUPAC, 1997). Figure 2.5 illustrates the basic set up of a POCT system that uses biosensors.

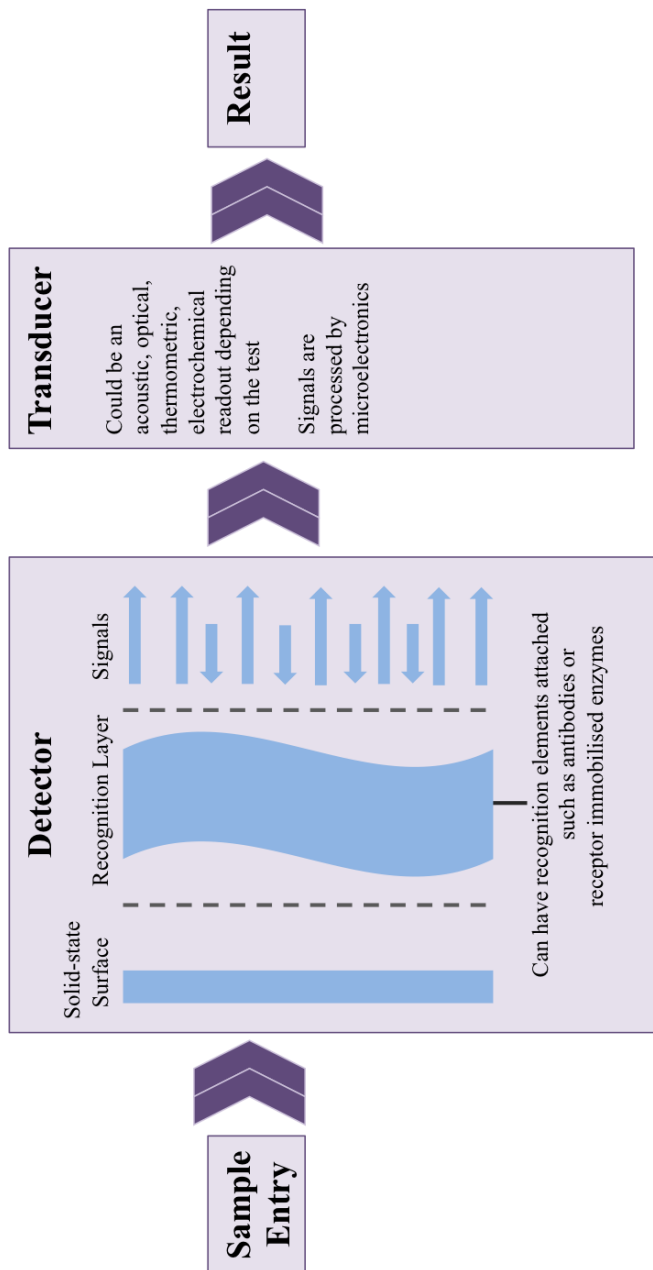


Figure 2.5 Diagram illustrating the operation of biosensors in POCT

Biosensors have been developed for many POCT tests.

Over the past 50 years, biosensors for blood glucose have been frequently developed and improved. Glucose biosensors account for approximately 85% of the market (Yoo and Lee, 2010).

As illustrated in Figure 2.5, there are three main parts of a biosensor: the biological recognition elements that differentiate the target molecules in the presence of various chemicals, the transducer that converts the bio-recognition event into a measurable signal and the signal processing system that converts the signal into a readable form (Updike and Hicks, 1967; Hiratsuka *et al.*, 2008). Transducers can be classified into five main groups: electrochemical, optical, thermometric, piezoelectric, and magnetic. Glucose biosensors tend to be electrochemical.

Electrochemical sensors can be subdivided into potentiometric, amperometric or conductometric types (Pearson *et al.*, 2000; Thévenot *et al.*, 2001; Habermuller *et al.*, 2000). Enzymatic amperometric glucose biosensors are the most common devices commercially available. Amperometric sensors monitor currents generated when electrons are exchanged between a biological system and an electrode (Turner *et al.*, 1999).

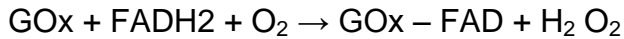
Glucose measurements are based on interactions with one of three enzymes: hexokinase, glucose oxidase (GOx) or glucose-1-dehydrogenase (Price, 2003). Whilst hexokinase is often used as the reference method for measuring glucose using spectrophotometry in the laboratory setting, GOx is the standard enzyme for biosensors in POCT (Bankar *et al.*, 2009).

#### Example of the process of glucose measurement by biosensor

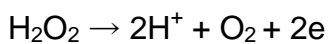
Immobilised GOx catalyses the oxidation of  $\beta$ -D-glucose by molecular oxygen producing gluconic acid and hydrogen peroxide, using the redox cofactor, flavin adenine dinucleotide (FAD). FAD is the initial electron acceptor and is reduced to FADH<sub>2</sub>, as shown below.



FADH<sub>2</sub> reacts with oxygen, thereby regenerating it, leading to the formation of hydrogen peroxides, as shown below.



Hydrogen peroxide is oxidized at a catalytic anode (see below). The electrode recognizes the number of electron transfers, and this electron flow is proportional to the number of glucose molecules present in blood.



Glucose is sensed electrochemically, either by measuring oxygen consumption, measuring the amount of hydrogen peroxide produced by the enzyme reaction or by using a diffusible or immobilised mediator to transfer the electrons from the GOx to the electrode (Yoo and Lee, 2010).

#### 2.3.4 Microfluidics

POCT tests using microfluidics require no sample preparation and produce results in a short time period. Because of microfluidics use in POCT technology, fluid handling has evolved from passive capillarity in absorbent matrices, such as nitrocellulose or fused silica, to the use of active fluid handling (Sista *et al.*, 2008). Some POCT devices can actively drive fluids through channels to perform testing for electrolytes, metabolites, blood gases, coagulation and more recently, immunoassays.

#### 2.3.5 Spectrophotometry

Spectrophotometry is the mainstay of automated clinical chemistry analysis and is based on two principles: that substances absorb light at different wavelengths and that the amount of light absorbed is proportional to the amount of substance

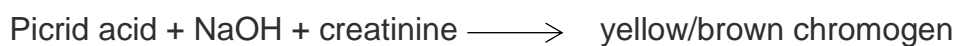
present (Arneson and Brickell, 2007). Beer's law states that  $A = a b c$ , Where A is absorbance, a is absorptivity, b is the length of the light path through the substance and c is the concentration of the substance.

Absorption units represent the light absorbed by the subject substance only and therefore an increase or decrease in light absorbed is proportional to the concentration of the substance.

Typical components of a bench-top POCT device that conducts spectrophotometry are: light source, monochromator, sample well, photodetector and output screen.

Figure 2.6 illustrates the set up of a typical spectrophotometer. The light source emits light in visible or ultraviolet wavelength ranges. The monochromator is used to eliminate unwanted wavelengths and allow desired light to reach the sample, typically this could be a filter or a prism. The photodetector detects the light that is transmitted through the sample and converts the light energy into electrical energy and the readout component displays the concentration (Arneson and Brickell, 2007).

In POCT, spectrophotometry is used to measure substrate and enzyme-activity. An example of this is the measurement of creatinine as a biomarker for chronic kidney disease (CKD). Creatinine goes through the Jaffe reaction to form a yellow/brown coloured product or chromogen, as below:



The chromogen formed is measured for its ability to absorb visible light (Arneson and Brickell, 2007).

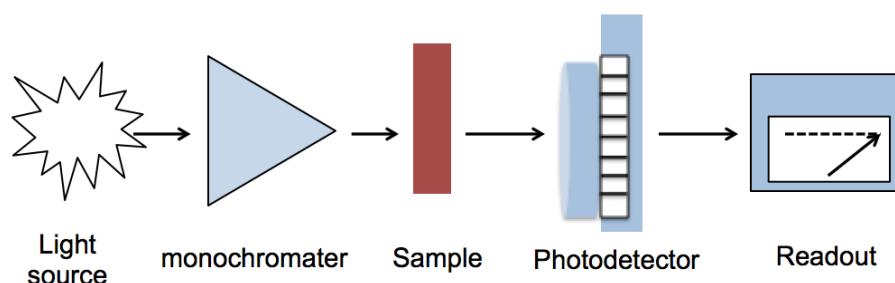


Figure 2.6 Basic components of a spectrophotometer

### 2.3.6 Blood gas and pH analysis

Blood pH, partial pressure of oxygen (PO<sub>2</sub>), partial pressure of carbon dioxide (PCO<sub>2</sub>) and oxygen saturation (SO<sub>2</sub>) are detected using a series of electrodes and spectrophotometric methods (Luppa *et al.* 2011). For example, SO<sub>2</sub> is measured as oxyhaemoglobin vs. total haemoglobin by a spectrophotometer, measuring multiple absorbance readings at various wavelengths (Arneson and Brickell, 2007). Compared to laboratory blood gas analysers, POCT blood gas analysers require little maintenance and are simple to use, with ongoing calibration and validation.

Some analysers may also have the addition of a CO-oximetry unit.

#### CO-oximetry

A CO-oximeter can identify the oxygen carrying state of haemoglobin in a blood specimen and is helpful in defining the causes of conditions such as hypoxia and hypoxaemia. A CO-oximetry unit uses multi-wavelength spectrophotometry to measure the typical absorption spectra of the different haemoglobin species. Oxyhaemoglobin can be distinguished from carboxyhaemoglobin and can determine the oxyhaemoglobin saturation, which is the percentage of oxygenated haemoglobin compared to the total amount of haemoglobin (Luppa *et al.* 2011). In the case of a patient that presents with carbon monoxide poisoning (CO), the CO-oximeter will detect the levels of each haemoglobin and will report the oxyhaemoglobin saturation as markedly reduced.

### 2.3.5 Haematological particle analysis

The technology used in the POCT bench-top analysers (type 3) harnesses traditional techniques for the counting of haematological particles, namely cytometry. Flow cytometry can measure multiple characteristics of individual haematological particles flowing single file in a stream. Light scattering at different angles can distinguish differences in size and internal complexity and light emitted from fluorescently labelled antibodies can identify a range of cell surfaces and cytoplasmic antigens (Brown and Wittwer, 2000).



A full or complete blood count (CBC) can be performed by a number of bench-top POCT analysers, providing counts for: white blood cell (WBC); red blood cell (RBC); haemoglobin (HGB); Haematocit (HCT); mean cell volume (MCV); mean cell haemoglobin (MCH); mean cell haemoglobin concentration (MCHC); platelets (PLT); lymphocyte count (LYM); lymphocyte percentage (LYM%); total content of monocytes, basophils, and eosinophils (MXD#); relative content of monocytes, basophils, and eosinophils (MXD%); total content of neutrophils (NEUT#); relative content of neutrophils (NEUT%); relative distribution width of red blood cells by volume, standard deviation (RDW-SD); relative distribution width of red blood cells by volume, coefficient of variation (RDW-CV) and mean platelet volume (MPV) (Price *et al.*, 2004).

Haematology POCT, in particular the measurement of haemoglobin, may be useful in primary care, A&E and intensive care settings.

#### 2.4 Patient satisfaction with POCT

The opinion of the patient is becoming increasingly more important as the new NHS reforms come into place, with investigations into patient satisfaction in healthcare on the rise from the late 1960s (Sitzia and Wood, 1997).

POCT can offer a more convenient testing service to the patient, with less call for follow up and hospital appointments, without the need for phlebotomy. There is sometimes a reduced cost to the patient also through negating the need to travel to different sites and appointments.

A large multicentre, randomised, controlled trial conducted by (Laurence *et al.*, 2010) aimed to determine if patients were more satisfied with POCT than standard laboratory testing. In the study Laurence *et al.* (2010) included patients who visited their GP for diabetes, hyperlipidaemia and/or anticoagulant therapy. This trial was part of a larger study funded by the Australian government which aimed to determine the safety, clinical effectiveness, cost-effectiveness and satisfaction of POCT in general practice. A total of 3,010 participants in the

intervention group had their samples taken and analysed in practice using POCT devices. Participants in the control group (n=1,958) had their samples either taken in practice, at a collection centre or at the local laboratory and their samples were then analysed at the laboratory. A total of 4,573 participants were requested to complete a questionnaire in which they rated how strongly they agreed/disagreed to several statements relating to their satisfaction with the sample collection process, their confidence in the process and the result, the cost, their convenience and the management of their disease. On analysis of the data returned, Laurence *et al.* (2010) found that the POCT group generally showed higher levels of satisfaction with the sampling process and a higher level of agreement with the statement 'I would rather have blood taken by a finger prick than a needle in my arm' than seen in the control group ( $p < 0.001$ ). The intervention group also reported higher satisfaction in not having to travel to a different site ( $p = 0.009$ ). However results also showed that participants in the control group were seen to have more confidence in the hygiene of a laboratory compared to any site of POCT.

Shephard (2006) details the results of a questionnaire used to assess the acceptance of national Quality Assurance for Aboriginal Medical Services (QAAMS) HbA1c POCT service by doctors, POCT operators and diabetic patients (Shephard, 2006). 41 doctors, 65 POCT operators and 161 patients with diabetes completed the questionnaire. >97% of patients were 'very satisfied' with the convenience of POCT and thought the finger prick sample to be less painful than venepuncture. Over 90% also reported their visit to the doctor to be 'more useful' as a result of the POCT, with more than 95% stating that they wanted POCT to continue as part of their diabetes management.

However, not all studies on patient satisfaction with POCT have reported favourable results. A study conducted by Stone *et al.* (2007) aimed to assess the acceptability of and satisfaction of patients and health professionals with POCT for glycosylated haemoglobin (HbA1c) in primary care (Stone *et al.*, 2007). A questionnaire was used to assess satisfaction with diabetes care in two groups: intervention/POCT and control group/usual laboratory test. Stone *et al.* (2010) found that the 344 patients (n=184 intervention, 160 control) that were assessed

using the questionnaire had similar overall scores for diabetes care ( $P = 0.507$ ). There was also no statistically significant difference between groups for questions relating to information about results ( $P = 0.698$ ) and arrangements for giving blood samples ( $P = 0.886$ ).

Some anecdotal evidence arising from semi-structured interviews include:

*“Well normally you are waiting and wondering, you know, waiting for 10 days or a fortnight, wondering if it's gone up or down”* – an intervention group patient

*“Yes, I do think it does make a difference, because you can instigate changes in treatment there and then and discuss it with the patient and discuss what options are available to them. Sometimes it's a complete surprise, you're expecting it to be quite good and in fact it comes back a bit too high and you've got, you've got a chance to do it there and then rather than waiting”* – opinion of a practice nurse

A study comparing POCT to laboratory International Normalised Ratio (INR) analysis for anticoagulant therapy monitoring (Shiach *et al.*, 2002) found, using pre and post intervention of POCT questionnaires, that there was no significant difference in satisfaction between POCT and laboratory services, participants were generally satisfied with both the POCT and laboratory based services. Shiach *et al.* (2002) also investigated the turnaround time between the two different testing processes. For the hospital laboratory based service, patients, on average, spend 33 minutes in the car commuting and had a 33-minute wait to be seen. For the POCT based service, the average time to commute was 13 minutes with only a 9-minute wait to be seen.

Many of the studies that assess patient satisfaction use surveys and questionnaires to collect data. This method of data gathering may have some drawbacks as discovered in a study by Cohen *et al.* (1996) which examined the consistency of survey estimates of patient satisfaction in a healthcare

environment and found that the wording of a question can have a marked difference on the response. For example, they found that greater patient satisfaction is conveyed when asking the patient if they agree with a negative description of their experience compared to when they are asked if they agree with a positive (Cohen *et al.*, 1996).

Unfortunately, there is no 'gold-standard' method of assessing patient satisfaction. Two administrations of a questionnaire may yield different results for different reasons or a combination of reasons e.g. the patient's views on their healthcare has changed and/or the questionnaire has evoked a different response (Fitzpatrick, 1991).

## 2.5 Patient management of condition

It is thought that POCT could facilitate greater patient self-management of conditions through motivating patients to learn more about their illness and how to manage it. This is achieved through the availability of immediate results during medical consultation and/or the ability for patients to test themselves at home.

Laurence *et al.* (2010) found that participants in the POCT group showed higher levels of agreement than the control group with the following statements: 'I have confidence in the information given by my GP regarding my pathology test result', 'having immediate feedback of the test result was important as it allowed/would allow me to discuss the management of my condition with my GP' and 'I am/would be more motivated to look after my condition because of regular POCT testing'.

Shepherd (2006) found that over 90% of patients reported that their self-motivation to control their diabetes increased as a result of the POCT (Shepherd, 2006)

It is thought that increased patient motivation to manage chronic conditions should be reflected in better therapeutic control, and that therefore better therapeutic control would be seen in those using POCT. However, research has

provided different results in this area, with some studies finding POCT to be more effective than normal care (Muchmore *et al.*, 1994; Guerci *et al.*, 2003; Martin *et al.*, 2005) and others finding little difference (Allen *et al.*, 1990; Farmer *et al.*, 2007) to regular pathology testing.

Therapeutic control is often measured by how long patients can stay within target ranges for their condition. For example the target international normalised ratio (INR) range for a patient with a venous thromboembolism such as deep vein thrombosis (DVT) is 2.0 to 3.0 for two consecutive days (Hyers *et al.*, 2001). Cleas *et al.* (2005) conducted a randomised clinical trial in which 66 GP practices were separated into 4 groups. Each group received education on oral anticoagulation, anticoagulation files, and patient information booklets; the second group additionally received feedback every 2 months on their anticoagulation performance; the third group used POCT devices to determine their INR in the doctor's office or at the patient's home; and the fourth group received Dawn AC computer assisted advice for adapting oral anticoagulation. Dawn AC is a software package designed to help healthcare professionals monitor patients taking potentially dangerous drugs, such as warfarin. Therapeutic control was measured by the time spent in target INR range and adverse events relating to anticoagulant therapy were recorded, both of these factors were then compared to baseline data. A significant increase was seen in percentage of time within 0.5 INR from target, from 49.5% at baseline to 60% after intervention in all groups. However, no specific group had more improved results than another. From this it is possible to conclude that the use of a POCT device was no more effective than providing the patient with educational materials relating to oral anticoagulation (Cleas *et al.*, 2005).

A study by Shiach *et al.* (2002) had similar findings. A randomised group of patients had their INR investigated using POCT and was compared to a different randomised group that had their INRs checked using a mainline laboratory analyser. Shiach *et al.* found that the mean percentage of time within the target range was almost identical for both groups ( $P = 0.2$ ).

Other studies have reported similar findings when assessing POCT for other parameters. O'Kane *et al.* (2008) did not find any significant difference between a POCT self-monitoring group and a control group on HbA<sub>1c</sub> results in patients with newly diagnosed type 2 diabetes mellitus (O'Kane *et al.*, 2008).

It is difficult to determine the cause of the changes in these studies as they adopt differing methodologies and factors such as patient behaviour and therapy adherence are not accounted for. A systematic review of the evidence conducted by Welschen *et al.* (2005), however, concludes that POCT for self-monitoring of blood glucose provides a statistically and clinically significant decrease in HbA<sub>1c</sub> compared with control (Welschen *et al.*, 2005).

## 2.6 Impact of POCT on healthcare professionals

It is also important to consider the impact that the implementation of POCT may have on healthcare professionals.

A study assessing the thoughts and opinions of healthcare staff before and after implementation of POCT found that satisfaction rates more than doubled after POCT was introduced. Over 95% of doctors assessed using a questionnaire agreed that POCT provided a convenient service for them and >90% stated having immediate results contributed positively to patient care and they would be comfortable in continuing with a POCT service (Shephard, 2006). The doctors were seen to report that the programme was 'more effective and impressive to the patient', that it is 'positive on patient outcomes' and that it is beneficial to have the results available at the time of consultation as many of their patients do not return for follow up appointments. Healthcare professionals participating in this study thought that the HbA<sub>1c</sub> POCT aided community awareness of diabetes. An increased awareness of disease could lead to better management of disease.

POCT is particularly useful for clinicians in ruling out suspected acute conditions, such as DVT. POCT D-dimer tests can be conducted in primary care or

outpatient clinics for patients with suspected DVT. Studies have shown that this can reduce the need for referral to secondary care of almost 50% (Büller *et al.*, 2009; Geersing *et al.*, 2009), which inevitably saves the NHS money, especially if the patient would have otherwise been referred onto a consultant led DVT clinic.

### 2.6.1 Prescribing

In recent years, the prescription of antibiotics has come under close scrutiny due to the growing problem of antibiotic resistance. In 2015, new NICE guidance was published on antimicrobial stewardship, with threat of being presented before the General Medical Council (GMC) if not adhered to by clinicians (NICE, 2015).

Patients suspected of lower respiratory tract infections can be tested using POCT for C-reactive protein (CRP) in primary care. CRP is an acute-phase protein, which increases in serum during infection and tissue damage (Black *et al.*, 2004). As respiratory tract infections account for between 80 and 90% of all prescribed antibiotics in primary care (Van Bijnen *et al.*, 2014), ruling out suspected respiratory tract infections could reduce this number, causing a substantial effect on the overall number of antibiotic prescriptions.

A study conducted by Cals *et al.* (2009) compared the use of POCT to traditional laboratory testing for C-reactive protein (CRP). The results showed a reduction in the number of prescriptions for antibiotics in patients being assessed for lower respiratory tract infections (Cals *et al.*, 2009). In this study, general practitioners in the POCT CRP group prescribed antibiotics to 31% of patients compared with 53% in the control group ( $P=0.02$ ).

## 2.7 Considerations relating to POCT

Although POCT has many advantages over laboratory testing, there are some issues that may need addressing in order for POCT to be used more confidently and in greater frequency.

### 2.7.1 Analytical performance and quality of POCT

Pathology test results generated by mainline laboratory analysers are seen as the 'gold standard' for production of reliable results. POCT tests may be more prone to error than their laboratory equivalents.

It has been proposed that these errors may arise from operator-related errors. A major concern is that, even with adequate training, POCT is susceptible to error due to the fact that many users are not laboratory based staff, they are mostly clinicians working in busy environments whose main concern is patient care and not analysis of samples (O'Kane *et al.*, 2011).

#### Errors

Although the requirement of fewer steps in the testing process for POCT could mean that there is less chance of error when compared with laboratory testing, POCT has created new challenges and sources of potential errors (Plebani, 2009). The definition of error in laboratory testing has been defined as: *"a defect occurring at any part of the laboratory cycle, from ordering tests to reporting results and appropriately interpreting and reacting to these"* (Bonini *et al.*, 2002).

There is little published literature on errors in POCT. One seminal paper by Meier and Jones (2005), however, identifies three main sources of POCT errors: operator incompetence, non-adherence to procedures, and the use of uncontrolled reagent/equipment (Meier and Jones, 2005). The paper also considers three amplifiers of POCT error: inconsistent regulation, rapid result availability and immediate therapeutic implications.

As highlighted in section 2.7.2, training is of paramount importance to ensure quality and accuracy in POCT. A 2000-2001 study of waived POCT found that 19% of testing personnel had been neither trained nor evaluated in the performance of the assays that they carried out (Hassan *et al.*, 2003). The same study discovered that 25% of test operators failed to follow manufacturer's directions, and 7% of operators did not perform required calibrations. With regards to use of reagents, 32% failed to perform quality control (QC), and 20% ignored manufacturer directions by physically separating internal QC test fields



from patient test fields in card format tests and 6% used expired reagents and kits (Hassan *et al.*, 2003).

Although rapid availability of results is generally seen as a positive, there is also potential for medical errors to be made on the basis of erroneous results. In a study of stat (immediately or without delay) test errors published in 1997, of 189 clinician-discovered errors, 70% of the errors had no effect on patient care, 19.6% stimulated further inappropriate investigation, and 6.3% led to inappropriate initiation or modification of therapy (Plebani and Carraro, 1997).

In 2003, Gerald Kost proposed a classification system of error classification for POCT (Kost, 2003). Kost (2003) divided the POCT process into pre-analytic, analytic, and post-analytic phases.

#### Pre-analytical errors

Excessive ordering and mistiming of tests can cause error. Test interpreters can become overwhelmed by the plethora of laboratory results when too many tests have been ordered. A mistimed test, in which test results become out of sync with therapeutic interventions, can result in interpreters reacting to transient or recent pathophysiologic states, rather than to a patient's current pathophysiologic status.

Although POCT is often performed near to the patient, misidentification of the patient can still occur. For example, emergency department staff asked to perform POCT on a patient in a specific location, e.g. bed 8, who, in such a challenging and fast-paced environment, actually turns out to be a different patient on whose encounter sheet the test results are written.

In some outpatient settings, test specimens are batch processed e.g. urine tests. If containers or swabs are not labelled on collection, examples of consequent errors tend to result in patients receiving prognoses for other patients and potentially receiving therapy for a condition that they do not have and conversely, the patient who actually has the condition does not receive treatment.

Misidentification of patients and/or absence of patient results can also cause error when uploading on to patient records where results fail to reach the permanent record or reach the wrong record.

Specimen collection for POCT can be erroneous, specifically when inappropriate or inconsistent specimen type or volumes are collected and are applied to the device's testing surface or reaction chamber.

Error detection schemes such as delta checking are not often used in POCT (Kazmierczak, 2011) as automatic availability of both to previous results and the automated statistical analysis, and so erroneous results could be generated and go unidentified. Delta checking is a quality control method that compares present and previous test results and detects whether the difference between the two results exceeds pre-defined criteria. If the difference is smaller than the pre-defined criteria, the result is automatically reported; however, if the difference exceeds the pre-defined criteria, the result requires manual confirmation by laboratory personnel (Sheiner *et al.*, 1979; Ladenson, 1975).

It is difficult for the operator to assess specimen quality, e.g. checking for clotting, in the small sample volumes required by POCT and the reaction sites of POCT are often opaque, meaning that the operator cannot quality asses the reaction. Both of these attributes are not assessed by the POCT device itself and so this could result in error (Kost, 2003; Meier and Jones, 2005).

### Analytical errors

Some POCT devices require calibration. Opportunities for error at this stage include missing out this calibration step and misreporting of the calibration data. This could lead to the developments of defects in specimen/reagent interactions. Errors in these interactions include: patient-related native interferences (for example non-specific agglutinins in precipitation slide tests), specimen-related non-target influences (e.g. drugs causing spurious results in electrolyte channels of handheld chemistry POCT devices), or specimen-reagent, combination-related matrix effects. However, it is impossible to separate native, non-target,

and matrix sources of error inside the closed design of POCT devices (Meier and Jones, 2005).

Errors may also occur at result generation. For example, results that are generated outside a POCT method's validated range may not be reliable. Lack of QC in waived POCT, operator failure to recognise out-of-control QC, and the absence of other performance-control monitors can all lead to uncontrolled acceptance of invalid results.

#### Post-analytical errors

*Errors may still occur post-result. Defects* can occur during formatting of reports, value reporting and report management. Report management includes report verification, preservation, storage, and retrieval. If report generated uses incorrect units of measure, for example, misinterpretation of results could occur, potentially leading to inappropriate clinical management decisions. In addition to this, as POCT generally reports results on a small screen, human error can occur and results can be misread.

In some circumstances, results are not recorded in an appropriate manner, with some POCT results disappearing from the patient record due to human forgetfulness (Salka and Kiechle, 2003).

Report management is an important final step, which can also go wrong. Failure to correlate initially generated results with subsequently preserved reports leaves users unaware of discrepancies e.g. there could be differences between a POCT output and the patient record (Meier and Jones, 2005).

#### Quality error rates

There is little published information on POCT quality error rate (Plebani, 2009). Information on the quality error rate can help inform risk-benefit appraisal of POCT introduction and can inform preventative measures to reduce quality error rates (O'Kane *et al.*, 2011). Although true quality error rates are difficult to assess in any testing system due to potential lack of recognition of errors and discrepancies in recording said errors, a study conducted by O'Kane *et al.* (2011) aimed to investigate the POCT quality error rate in a secondary care setting. Two

of the hospitals used in this study had 24 hour a day pathology laboratory access, whilst the other hospital that took part had 9 am – 5 pm pathology laboratory access and so used POCT in the remaining hours. O’Kane *et al.* (2011) found 225 quality query reports logged against 407,704 POCT tests in a 14 month period. The rate of reports varied between tests with 0.65% of HbA1c tests warranting a quality query report and 0% blood ketones warranting a quality query report. Each report was scored on the basis of the actual effect of the defect on patient care and the worst-case potential outcome that might arise from the defect. Results suggested that the actual effect of the defect tended to have minimal or no impact on patient care. However, the potential effect was scored much higher with 41% at significant adverse outcome level. Compared to laboratory testing, the potential effect score for POCT is lower on average (O’Kane *et al.*, 2008). It was reported that the majority of errors occurred in the analytical stage of testing.

Other studies on this topic adopted alternative methodologies and therefore cannot be directly compared. However, the POCT quality error rate in the O’Kane *et al.* (2011) study is comparatively higher than studies that have assessed quality error rates in laboratories (which vary between 0.012% and 0.6%) (Plebani and Carraro, 1997; Carraro and Plebani, 2007; Bonini *et al.*, 2002; Sirota, 2005; O’Kane *et al.*, 2008). There is reasonable potential for the error rate to be higher than reported as, in some instances, the POCT user may not always log an error report because, for example, they are too busy. Nevertheless, the data presented by O’Kane *et al.* (2011) provides a good insight into the trends of quality error reporting. For instance, clinicians may be more tolerant of quality errors for tests that they do not deem to be as critical as others, like initial urine dipsticks where patients will often proceed to have many more definitive blood tests. This study also highlights the difference in nature of the POCT and laboratory errors; POCT errors tend to be analytical e.g. lack of barcodes, whereas laboratory tends to be pre and post-analytical e.g. misidentification of patients, sampling, preparation and packaging of samples. The kind of POCT errors may be overcome in the future by improvements in POCT management and training.

## Analytical performance

In order to be safe to use and appropriate to base clinical management decisions on, POCT should produce results that are agreeable with the reference standard results produced in the laboratory. As well as manufacturer assessment, there have been numerous independent studies assessing the analytical performance of a range of POCT devices. There appears to be conflicting evidence for the accuracy and reliability of POCT (Murata *et al.*, 2015; Shiach *et al.*, 2002; Clerico *et al.*, 2005; Panz *et al.*, 2004; Storti *et al.*, 2004; Carey, 2006).

A randomised cross-over trial conducted by Shiach *et al.* (2002) compared POCT to laboratory results for INR testing (Shiach *et al.*, 2002). The study investigated 39 patients on long-term warfarin treatment that had received anticoagulant treatment at the hospital anticoagulant clinic before transfer to the community clinic. Each patient was randomly assigned to one of two groups, group 1 (n=19) using POCT monitoring in the first phase and moving on to laboratory monitoring in the second phase and group 2 (n=20) using laboratory monitoring in the first phase and POCT monitoring in the second phase. Each phase lasted 6 months with tests being run on both systems in each group for comparison only, dosage was based on the named phase i.e. in phase 1, group 1 had their INRs tested with both POCT and laboratory analyser but it was only the POCT result taken into account for prescribing.

Using INR results (n=465) from both POCT and laboratory analysis Shiach *et al.* (2002) found that the difference between the two methods increased as the average INR increased, as illustrated in the Bland-Altman plot below in Figure 2.7.

Mean relative deviation was used to assess the level of agreement between the INR results. The mean relative deviation was less than 10% for INR below 4.0, yet for INR results above 4.0 it was 12.6%, this is less satisfactory. However, as there were few INR results >4.0, this disagreement in results is unlikely to be clinically significant.

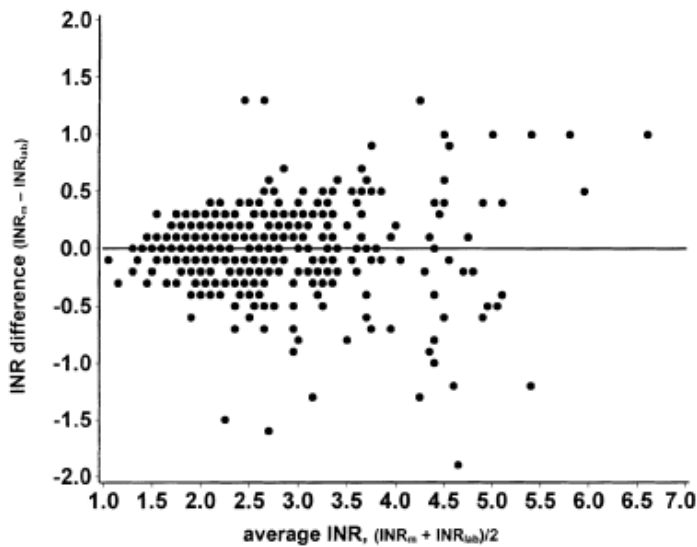


Figure 2.7 Bland-Altman illustrating the difference between POCT and laboratory INR results, indicating proportional bias, from (Shiach *et al.*, 2002).

A study by Murata *et al.* (2015) assessed the performance of POCT vs. laboratory analysis in the measurement of a metabolic panel. The study concluded that most POCT results showed agreement with laboratory results, with the exception of sodium, carbon dioxide, AST and bilirubin (Murata *et al.*, 2015).

Clerico *et al.* (2005) compared five POCT assays for B-type Natriuretic Peptide (BNP) and found that the POCT devices could differentiate between healthy patients and severe heart disease patients but did not differentiate between healthy patients and those with mild cardiac problems (Clerico *et al.*, 2005). A study by Storti *et al.* (2004) showed that POCT had similar analytical performance but different clinical results to laboratory for BNP (Storti *et al.*, 2004).

Panz *et al.* (2004) compared two POCT testing devices with laboratory analysis for cholesterol testing. Whilst the findings of this study suggest that the POCT devices were in close agreement with the reference values ( $p < 0.0001$ ), there was also an underreporting of total cholesterol and LDL cholesterol, placing some of the results in incorrect risk categories (Panz *et al.*, 2004). In a similar study, Carey *et al.* (2006) compared a POCT device with laboratory testing for cholesterol. This study concluded that the POCT was safe and appropriate to use in clinical practice, with no significant differences between POCT and laboratory. There was, however, some overestimation of triglycerides and underestimation of HDL cholesterol (Carey *et al.*, 2006).

It would appear that the analytical performance of POCT varies depending on a number of factors including sample type and parameter tested. Chapter Six assesses the analytical performance of cholesterol and glucose POCT in the community setting.

### 2.7.2 Training in POCT

As stated in the Royal College of Pathologists guidelines on the use of POCT, the user must be formally trained in the use of the devices to ensure a good quality of results and an understanding of their clinical significance (Cramb, 2004).

In contrast to the laboratory setting where there is a greater time between results obtained and reporting of results, POCT provides almost immediate results which can be dangerous to the patient if those results are erroneous and clinical management decisions are made on the basis of them (O'Kane *et al.*, 2011). Erroneous results could arise from simple procedural errors, a lack of training or a lack of understanding in the bioscience underlying POCT (Kyriacos *et al.*, 2005). This is why training of the POCT users is paramount, as it should reduce the likelihood of generating erroneous results.

Although POCT is often accessible to a wide variety of users, in the clinical setting it is usually carried out by a range of healthcare professionals, for example healthcare assistants, nurses and physicians, who possess a range of qualifications and have differing levels of understanding (Liikanen and Lehto,

2013).

Although training is highly recommended to ensure accurate results (Goodwin, 2008; Montagnana *et al.*, 2009) it is not specified how this training should be delivered.

Belsey *et al.* (1987) investigated glucose POCT training of 2100 nurses in an inpatient setting. The training intervention in this study consisted of a self-learning videotape, demonstration technique, tests and option of re-training by the diabetes nurse-educator (Belsey *et al.*, 1987). Results suggested that the training improved the reliability the glucose POCT test results.

A randomised controlled trial conducted by Hansen (1998) compared the quality of training by laboratory staff to that of nursing staff in urine dipstick POCT. 262 nurses in an inpatient setting were trained in this investigation. It was seen that the nurses performed urine dipsticks and quality controls significantly better when trained by laboratory educators, compared to nursing staff (Hansen, 1998).

As training can be time consuming and expensive, studies have been conducted to assess whether alternatives to face-to-face training are appropriate and effective. Knapp *et al.* (2011) compared the efficacy for two different kinds of training of rapid POCT HIV testing on 36 nurses in an outpatient setting. One group received in-person training, consisting of activation kits, lectures and webcam with a health science researcher. The other group received online training consisting of activation kits; Internet learning and live meeting supported by webcam technology. This study concluded that not only is online distant learning more cost effective than in-person training but is also just as effective in transferring knowledge (Knapp *et al.*, 2011).

An interactive two-step training and management model was assessed by (Lehto *et al.*, 2011) for POCT glucose testing in secondary care. A POCT coordinator was designated along with a contact person from each clinical department. In a quiet and fit for purpose environment, the POCT coordinator trained contact persons from each department, spending 60–90 minutes on training each



contact person. The training involved: factors contributing to test results; error sources; uncertainty of measurements and the consequences of false results. The POCT coordinator also included some department specific factors, for example, in the Intensive Care Unit (ICU), for patients with poor peripheral circulation, it was essential to pay attention to skin puncture specimens. Once the contact person felt confident in the use of POCT for glucose testing, they then went on to train other nurses in their unit this is known as cascade training. If competence in the procedure was obtained, a “driving license” for POCT glucose testing certificate was signed by both the contact person and the trained nurse, 49 nurses achieved this in the space of 5 months. POCT glucose results were later reviewed together with the patients’ other laboratory results. Upon assessment Lehto *et al.* (2011) discovered that after training, clinical staff achieved an analytical precision comparable to that of the laboratory personnel and were able to maintain this standard. Imprecision within all personnel groups was low, indicating a similar quality of glucose measurements. Staff trained in this study were also asked to complete a questionnaire, which revealed that the nurses were very satisfied with the clinical contact persons’ prerequisites for training. 96% of the nurses thought that the contact persons had adequate knowledge of sample collection and the POCT device. In the opinion of the respondents, the quality of their glucose measurements was improved. The majority of nurses agreed that understanding the significance of quality control was the most valuable item of training. However, 39% of the nurses trained said that they did not feel sufficiently trained in the maintenance of the equipment and 32% were not motivated by the training to do glucose testing (Lehto *et al.*, 2011).

In countries where POCT is more frequently used, such as Australia, programmes such as the national Quality Assurance for Aboriginal Medical Services (QAAMS) have been set up, providing continuing education; training; competency assessment and support services for all health workers using POCT equipment (Shephard, 2006). Although the UK does have these services available, they tend to come from different sources, which all have different agendas, e.g. industry. It is possible that training, quality assurance and support

would be more effective if provided by one body.

### 2.7.3 Cost of POCT

The cost of POCT not only includes the cost of the devices and reagents but the cost of maintenance, training and local laboratory support meaning that POCT is more expensive than central laboratory testing.

On the other hand, to the NHS as a whole, the implementation of POCT could actually save money as explained in the 2008 report of the review of the NHS pathology services in England, chaired by Lord Carter of Coles because £2.5 billion spent per year on pathology testing is accounted for by the workforce (Coles, 2008) and so even though POCT may seem more expensive than a laboratory on a test for test basis, this may not be the case as the cost of employing the pathology staff is not taken into account.

In a study by Cals *et al.* (2011) concentrating on C-reactive protein (CRP) for investigation of lower respiratory tract infections the total mean cost per patient in 4 groups: group one, patients receiving normal care (non-POCT); group two, patients receiving care with POCT; group three, patients receiving care with GPs who had been given enhanced communication training and group four, patients receiving care using POCT from GPs who had been given enhanced communication training was calculated. The results showed the mean total cost of a patient in group one, receiving normal care (non-POCT) was €35.96, the total mean cost of a patient in group two, receiving care with POCT was €37.58, the total mean cost of a patient in group three was €25.61 and the total mean cost of a patient in group four was €37.78. Cost calculations included medication (both prescribed and over the counter), physician visits (including GP appointments, out of hours GP consultation and hospital outpatients/emergency department), diagnostics tests, testing costs (reagents and time of the healthcare professional) and training costs.

Even though these findings show that using POCT for CRP equated to being €1.62 more expensive than the laboratory, other cost savings were made through using POCT as less prescriptions were given to patients, thereby reducing prescribing costs.

A follow-on study from the Belgian improvement study on oral anticoagulant therapy by had a primary aim of studying the cost effectiveness of interventions (Claes *et al.*, 2006). The intervention groups consisted of:

Group A: Oral anticoagulation education and patient information booklets

Group B: Oral anticoagulation education and patient information booklets and bimonthly performance feedback

Group C: Oral anticoagulation education and patient information booklets and use of INR POCT

Group D: Oral anticoagulation education and patient information booklets and computer assisted advice for adapting treatment.

This study used activity-based costing techniques in the medium of questionnaires to assess the costs per patient per month in the different intervention groups. Cost-effectiveness was expressed as cost per additional day within a 0.5 range from INR target. Costs included the dispensing and explaining of the information booklets and filling in the anticoagulation files for all the intervention groups at the patient level. In group B and D supplementary costs are generated at the study level e.g. creating of a patient file for group B or setting-up, collecting, and introducing patient information in the computer assistance programme for group D. For group C costs at the GP level are related to the usage of the POCT device and test strips.

Results of this study suggest that POCT is less expensive than normal care, saving €17.05 per patient per month.

#### Limitations of this review

This paper considered and included research from across the world. This is not ideal as other countries adopt different healthcare systems and have different geographies and demographics. POCT could have generated more positive results in other countries, for example Shepherd (2006) found that over 95% of POCT operators found POCT to be more convenient than the existing lab service. This study was conducted in Australian aboriginal communities where there is little or no laboratory provision (Shephard, 2006).

There was wide variation in the methodologies of the papers considered, many conducting different study types, using different interventions, assessing different populations, using different follow-up periods and measuring different outcomes. This variation in methodologies of the studies, along with gaps in the research is the reason an effective meta-analysis could not be conducted.

## 2.8 Conclusion

A vast number of laboratory tests are available as POCT. This availability allows for testing to be performed in a number of settings, providing rapid results, without the need for qualifications in medical diagnostics. The introduction of POCT, however, should be considered on a case-by-case basis, as it may not be appropriate in all settings, for example where laboratory testing provides results in an appropriate timeframe and is comparatively inexpensive.

Occurrences of error and/or poor analytical performance of POCT may be offsetting to those using POCT or those looking to adopt it. Still, strategies for error prevention involving checking, testing and monitoring have been proposed to overcome some of these issues (Meier and Jones, 2005).

The benefits of using POCT in emergency and remote setting have long been established. Nevertheless, the future of POCT in the UK is likely to be decided by the way in which the NHS and other healthcare providers evolve to meet current and future challenges. Pressure to provide more healthcare outside of hospitals is just one of the current challenges; POCT could be instrumental in the provision of community-based care.

### Gaps in the literature

Other than some papers which suggested that there is insufficient evidence to support the introduction of POCT into primary care (Gialamas *et al.*, 2009), there was a paucity of research that concentrated on the extent of adoption of POCT in primary care. The aim of the next chapter, Chapter Three, is to answer which POCT tests are conducted within UK primary care, which staff perform the tests, the training they received and general thoughts and opinions on its use.

Excluding papers that assessed the efficacy of patient self-testing using POCT, there was very little evidence for the use of POCT in the community. Chapter Four of this thesis aims to determine the impact of Health Checks using POCT in the community setting on CVD risk factors, as well as assessing patient well-being, health behaviours and evaluating the participant satisfaction with the Health Check service, in relation to POCT in particular.

Chapter Five of this thesis aims to qualitatively analyse the effect of community Health Checks on health behaviours as well as discover participant opinion of the NHS Health Check programme, with particular focus of the use of POCT.

Chapter Six of this thesis assesses the quality of the POCT results generated by the POCT used in the community Health Checks.

## Abstract

### Introduction

With a general shift toward a more patient-centred approach to healthcare, where emphasis is placed on avoiding hospital admissions and use of community and primary care is encouraged, it could be that POCT becomes more widely adopted outside of the hospital setting. Little is known about what POCT is done within general practice (GP) in England. This research aimed to identify how well established POCT is within primary care in England.

### Methods

Online surveys and telephone interviews were designed and conducted with UK primary care staff. The survey consisted of 9 main questions which assessed the POCT undertaken; the POCT operators; their training; quality considerations and general attitudes towards POCT. Results of the surveys were collated and reported in this chapter.

### Results

A total of 136 participants completed the survey. The majority of respondents (80%) were aware of POCT and most reported conducting some tests as POCT in their practice (86%). POCT was mostly performed by nurses and the majority had received device specific training (72%). 20% of practices that used POCT were members of external quality assessment (EQA) schemes. Attitudes towards some of the features of POCT were generally positive and 39% were open to the idea of their practice adopting POCT in the future.

### Conclusion

Results of this survey confirm that POCT is performed within primary care and that it is viewed as a positive tool in the care of patients. However, without a full, physical audit it is impossible to uncover its true status. It appears that the cost of adopting POCT in primary care was the most discouraging factor as funding for devices and reagents; maintenance, training and local laboratory support would have to be allocated.

### 3.1 Introduction

Over the past 20 years there has been a general, world-wide shift in healthcare delivery toward a system which provides a patient-centric approach, with emphasis on the use of primary care and avoiding hospital admissions where possible (Seddon *et al.*, 2001). The 2010 – 2015 coalition between Conservative and Liberal Democrat governments in England brought about many changes, one of the most significant being the reforms made to the NHS which will affect all healthcare professionals as well as the patients that they treat (BMJ, 2011). The NHS reforms aim to create a focus on quality and improving outcomes whilst increasing the accountability of the NHS, strengthen clinical leadership, shift responsibility and decision making for public health to local authorities, promote outsourcing some services and create a competitive market place (Department of Health, 2012; National Health Service, 2013).

After a review of the NHS pathology services, Lord Carter of Coles (2008) suggested that pathology services in England be consolidated. There are currently 240 full-service pathology laboratories in the United Kingdom, it has been suggested that they could be reduced to 60 in a ten year period (Illman, 2013), this may also increase the need for POCT.

The NHS reforms aim to create a focus on quality and improving outcomes whilst increasing the accountability of the NHS, strengthen clinical leadership, shift responsibility and decision making for public health to local authorities, promote outsourcing some services and create a competitive market place (Department of Health, 2012; National Health Service, 2013).

The Health and Social Care Act (2012) highlights “*Evolving clinical practice and technology means that some services that previously could only be provided in an acute hospital can now be provided in a local health centre, GP surgery or even the patient’s own home*” (Department of Health, 2012). This clinical practice now includes some complex tests such as cardiac markers, which thanks to POCT can be done in a variety of locations. POCT has been well established in

community care for over a decade in other countries such as North America and Australia (Francis and Martin, 2010).

Currently, little is known about what POCT is done within general practice (GP) in England. As highlighted in section 1.3.2 of Chapter One, innovative technologies, along with more community and primary based care are being promoted within the NHS. It is important to understand how technologies such as POCT will integrate with current systems and how healthcare staff might receive its introduction. This research aimed to identify how well established POCT is within primary care in England. This paper reports the results of a questionnaire survey involving health care professionals. The objectives of the survey were to identify the POCT undertaken; the POCT operators; their training; quality considerations and general attitudes towards POCT.

Research ethical approval for the study was granted through the Manchester Metropolitan University.



## 3.2 Method

To establish data on current POCT usage in primary care, a questionnaire was designed as an online survey, using Bristol Online Surveys (BOS). The questions focused on which tests are done as POCT, who performs these tests in primary care, user training, quality issues, consideration of POCT in the future and thoughts and attitudes toward POCT. The target audience was general practitioners, nurses, healthcare assistants and practice managers. The survey can be seen in Appendix 3.2. In addition, the survey questions were also used in telephone surveys of primary care practices.

### 3.2.1 Designing the questionnaire

Since the 1980s there have been vast changes in the way in which surveys are designed due to cognitive psychology research on questionnaire design (Bradburn *et al.*, 2004). Computer-assisted survey information collection (CASIC) systems, such as BOS, have also helped to transform the methodology of surveys, allowing quick and accurate display of results. This display of results formed part of the reason for choosing to perform the survey in BOS. Questions were designed to be as unambiguous and clear as possible, whilst avoiding 'loaded questions' and other questions that could potentially bias responses.

When designing a questionnaire it is important to consider wording in order to try and obtain results that are as accurate as possible and affected less by bias. The wording of a questionnaire is important from both the respondent and researcher perspective, '*The precise wording of a question plays a vital role in determining the answers given by respondents*' (Bradburn *et al.*, 2004). Language and context can be ambiguous. A good questionnaire will not include any ambiguity so that the meaning of questions and answers can be easily understood (Bradburn *et al.*, 2004).

As well as ambiguity it is important to avoid politically charged terms as they can elicit very different responses. For example an American social survey

conducted by Davies *et al.* (2007) questioned the public about their views on welfare spend. For around half of the participants the term 'welfare' was used (n=1,317) and for the other half, the term 'assistance to the poor' was used (n=1,390). Responses were much kinder when the term 'assistance to the poor' was used, with 62% reporting that 'too little' was spent on 'assistance to the poor' compared to just 17% believing that 'too little' was spent on 'welfare' (Davis *et al.*, 2007). This is likely to be due to the pejorative connotations associated with the term 'welfare'.

For this reason, questions were designed to be as clear as possible so that they lacked in ambiguity.

### *3.2.2 Piloting the questionnaire*

The questionnaire was piloted on NHS primary care contacts as well as university staff to ensure all questions were clear and made good sense, n=12. Amendments to the questionnaire, as detailed in the results section, were made in accordance with the comments and suggestions made by the pilot contacts.

### *3.2.3 Questionnaire Launch*

Contact details for all Greater Manchester GP practices were collated into an Excel spreadsheet. This data was primarily taken from the NHS Choices website which held information for practices in the 12 Greater Manchester Clinical Commissioning Groups (CCGs). Information for a total of 90 postcodes, containing 528 GP practices, 1647 GPs and 2,682,056 registered patients were included from the region of Greater Manchester. GP practices which provided an email address on the NHS choices website had an email with the link to the online questionnaire was sent to them.

In addition, paper copies were distributed at conferences such as 'Management in Practice' for practice managers.

### 3.2.4 Telephone survey

Telephone surveys were chosen as a means of making contact with the GP practices in Greater Manchester as telephone numbers, unlike email addresses, are available to the public for each practice and telephone calls are also less likely to be ignored or forgotten in comparison to emails. It was decided that 2 GP practices from each of the 90 postcodes would be the target for the telephone surveys. In each postcode, the GP practices were assigned a number in the spreadsheet. An online random number generator ([numbgenerator.org](http://numbgenerator.org)) was then used to select 2 numbers at random from each postcode.

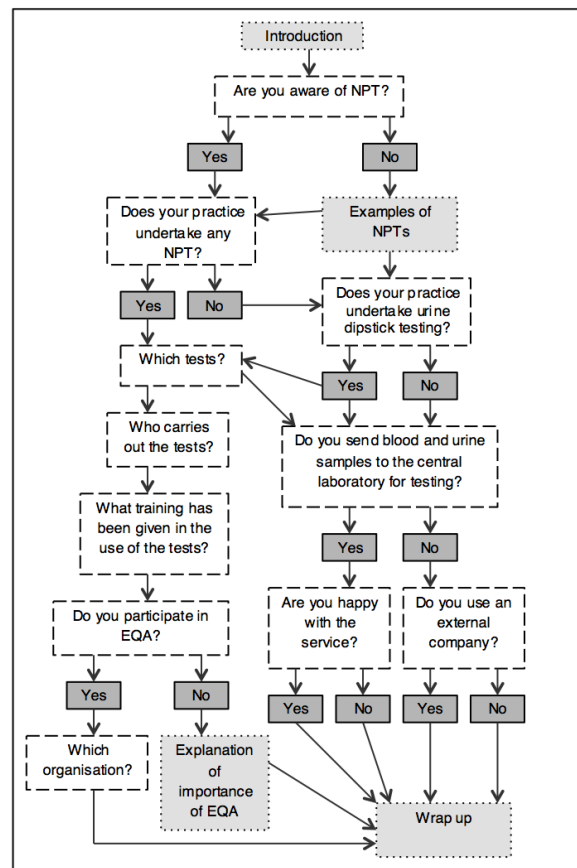


Figure 3.1: flowchart of POCT in primary care telephone survey questions

The telephone survey was scripted and formatted into a flowchart, Figure 3.1. The questions were taken from the online questionnaire. The flowchart aimed to guide the researcher through the questions whilst allowing for different participant responses. The script closed with thanks for participation, opportunity for participant to give comments and explanation of how their responses will aid research after the questions.

### 3.3 Results

#### *3.3.1 amendments arising from the pilot*

No major suggestions for amendments were made as a result of the pilot. Slight wording changes were made, the most common being the suggestion that the term 'Near Patient Testing' (NPT) be used in place of POCT, as this NPT is the terminology used by primary care staff.

#### *3.3.2 Participant characteristics*

A total of 136 participants completed the survey, either as a questionnaire or as a telephone survey. 44 respondents stated that they were nurses (33%), 39 practice managers (30%), 32 GPs (24%), 7 nurse practitioners (5%), 3 practice receptionists (2%), 1 healthcare assistant, 1 public health specialist, 1 community midwife, 1 retired nurse, 1 phlebotomist, 1 chemical pathologist and 1 consultant.

Raw results from both the online and telephone survey were collated and can be seen in Appendix 3.3.

#### *3.3.3 Awareness of POCT*

Participants were asked to state whether they were aware of the existence of POCT. 80% stated that they know what POCT was and 20% stated that they were not aware of it (n=84).

#### *3.3.4 POCT tests used in primary care*

The second question addresses which parameters are tested as POCT in primary care. As illustrated in Figure 3.2, the most common parameter to be tested by POCT in primary care was urinalysis (78%, n=93), followed by pregnancy testing (56%, n=73) and blood glucose (50%, n=66). 27% of practices reportedly measured INR using POCT (n=35), 15% performed POCT cholesterol testing (n=20), 13% POCT HbA1c (n=17), 11% POCT full blood count (n=14), 11% POCT sexual health (n=14), 9% POCT haemoglobin (n=12) and 6% reported testing cardiac markers using POCT (n=6). 8% of respondents reported

that none of their tests were conducted using POCT (n=9) and 6% did not know if any tests were performed using POCT (n=5).

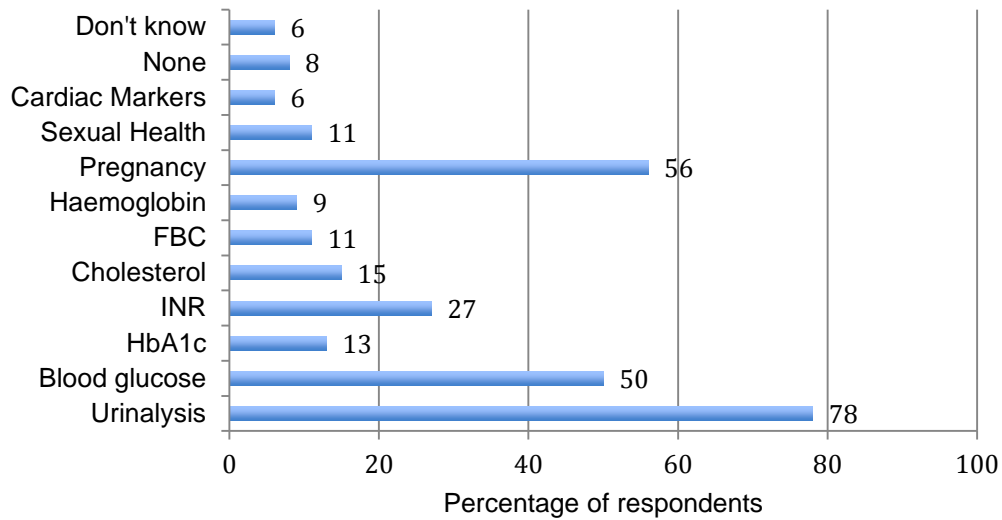


Figure 3.2 Column chart illustrating the percentage of primary care participants that reported performing POCT for a variety of parameters (n=131)

### 3.3.5 POCT operators

Participants were asked who normally performs the POCT tests in their practice. As illustrated in Figure 3.3, nurses undertake the majority of POCT within primary care (69%, n=71). 26% reported that GPs undertake POCT (n=27), 23% reported that healthcare assistants use POCT (n=24), 14% reported that nurse practitioners use POCT (n=14) and 1% reported that an external company is used to perform POCT within the practice (n=1).

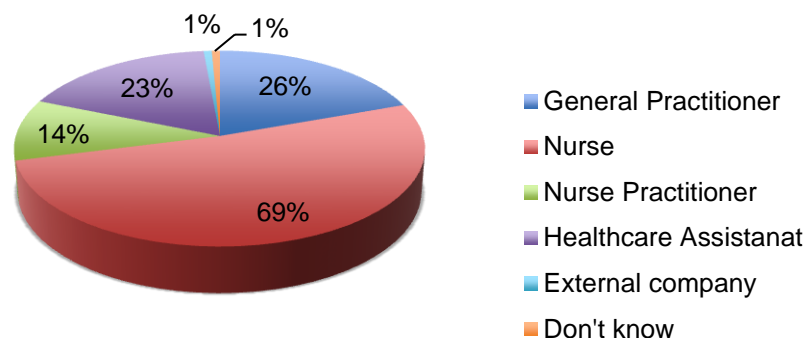


Figure 3.3 Pie chart displaying the results to question 5 of the POCT survey: who usually performs POCT within the practice? (n=103)

### *3.3.6 Training in POCT*

Question 6 of the survey asked the participants who reported that POCT takes place in their practice to state whether the POCT operator had received device training (n=107). 72% reported that the POCT operator had been trained (n=77), 10% stated that the operator had not been trained (n=11) and 18% did not know whether the POCT operator had been trained or not (n=19).

### *3.3.7 Consideration of quality*

As an indicator of quality consideration, participants were asked whether their practice were members of an any EQA services for the POCT that they utilised. 20% of respondents indicated that their practice did participate in an EQA scheme (n=24), 48% stated that their practice did not participate in an EQA scheme (n=56) and 32% stated that they did not know.

### *3.3.8 Attitudes towards the use and adoption of POCT*

Participants were asked to rate nine factors associated with POCT as an advantage, a disadvantage or neutral. 88% reported that it was an advantage that POCT uses small devices, which are often portable (n=74), 12% were neutral to this (n=10) and 0 participants thought that this was a disadvantage. 93% stated that POCT providing rapid results was an advantage (n=78), 6% were neutral to this factor (n=5) and 1% saw this as a disadvantage (n=1). 85% of participants thought that POCT requirement of small, capillary samples was an advantage (n=71), 15% were neutral to this fact (n=13) and 0 saw this as a disadvantage.

46% thought that the requirement of training to use POCT was an advantage (n=39), 38% were indifferent (n=32) and 15% saw this as a disadvantage (n=13). 56% of respondents viewed the statement that test for test, POCT could be more expensive than laboratory testing as negative (n=47), 36% were neutral to this (n=30) and 8% saw it as an advantage (n=7).

73% thought that the use of POCT resulting in fewer appointments was an advantage (n=61), 25% were neutral to this (n=21) and 1% saw this as a disadvantage (n=1).

73% of respondents thought that POCT providing test results on screen was an advantage (n=61), 27% were neutral to this (n=23) and 0 participants saw this as a disadvantage.

63% of respondents thought that the ability for patients to test themselves using POCT was an advantage (n=53), 31% were neutral to this (n=26) and 6% thought that this was a disadvantage (n=5).

56% of participants thought that earning quality outcomes framework (QOF) points using POCT was an advantage (n=47), 36% were neutral to this (n=30) and 8% thought that this was a disadvantage (n=7).

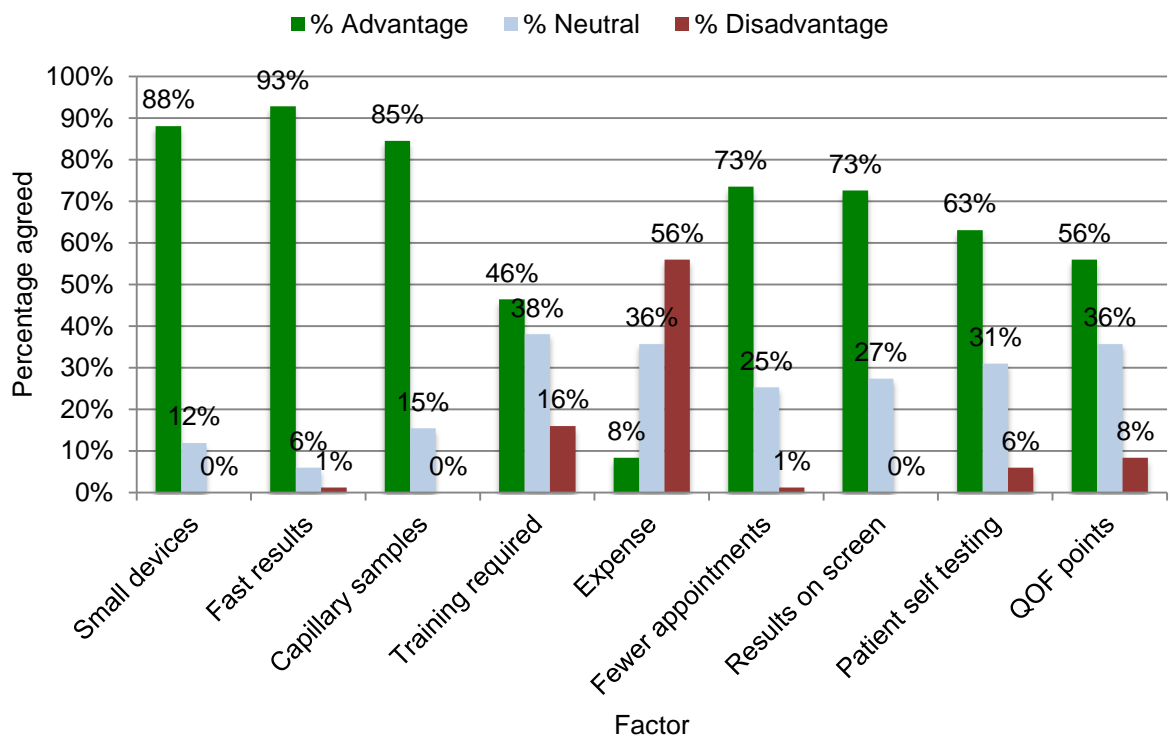


Figure 3.4 Column chart displaying respondent views of nine factors associated with POCT (n=84). Question 8 of the POCT in primary care survey.

### 3.3.9 Future use of POCT in primary care

The final question of the survey asked if the participant would consider their practice using POCT in the future. Of the 103 that responded to this question, 39% stated that the practice staff may adopt POCT in the future (n=40), 4% stated that their practice may consider using an external company to conduct their POCT (n=4), 12% stated that they would not consider using POCT in their

practice (n=13) and 45% did not know whether they will use POCT in the future (n=46).

### *3.3.10 Anecdotal evidence*

Some of the GPs that were emailed with a link to the questionnaire also replied via email giving general thoughts and comments. One GP stated: “[POCT is an] Interesting area. Big move towards doing stuff in primary care- better for patients. Look at INR for example. HbA 1c ideal BUT we found it too expensive to get equipment looked after. Also worth realising on other side that less delays from hospital labs now all connected via links”

Another GP stated: “We do NPT urine and lab tests for different indications. NPT is done either because it’s cheap (urinalysis) and useful but not necessarily urgent. NPT also done when urgent and needed for a decision, e.g. questioning an ectopic pregnancy. Otherwise it’s too much trouble - there is a need for quality control (we always re-check NPT blood glucose) which costs, NPT is always more expensive than the central lab (INR and HbA1c are good examples) and GPs do not get NPT costs fully re-imbursed (the NPT for DMARDs/warfarin is a good example of this). Most GPs are well aware of the costs/benefits and problems, if there was profit to be made or quality to improve we would already be doing it”.



### 3.4 Discussion

Results indicate that there is an awareness of POCT within UK primary care, yet the uptake appears to be slow: tests which have become available as POCT in recent years are seldom used whereas the more historically used tests are still utilised, Figure 3.2. The survey found that the majority of POCT is operated by nurses, GPs and healthcare assistants, of which the majority (72%) had been trained, this leaves 10-28% potentially untrained, a figure that is unacceptable according to Royal College of Pathologists guidelines (Cramb, 2004). Only 20% of those performing POCT were registered with an EQA scheme. This could indicate that the quality and reliability of tests are being overlooked, which could potentially lead to erroneous results and undesired clinical outcomes.

Overall, there were mixed messages in relation to respondents attitudes towards POCT: Figure 3.4 indicated that respondents appreciated positive attributes that POCT could provide, whilst the response to undertaking more POCT in the future was undecided and 100% of respondents found current laboratory services acceptable – these results are not indicative of change to the current pathology testing processes within primary care. Seemingly, the largest concern in adopting POCT in primary care was the potential expense incurred. Cost of devices; reagents; maintenance; training and local laboratory support must all be considered, the sum of which could preclude POCT testing by an individual practice. Cost has been identified as a disadvantage and reason to not adopt POCT in primary care in other studies (Butler *et al.*, 2008). However, both the financial and human cost to the patient pathway could be reduced by the introduction of POCT due to increased patient comfort and reduced transport requirements.

#### 3.4.1 Strengths and limitations

The target audience of the questionnaire was reached effectively, with nurses, practice managers and GPs being the majority of respondents.

The questionnaire relied upon self-reporting and therefore the results must be analysed and interpreted with caution, results are limited to what the respondent thought their practice did or did not undertake.

Although care was taken in the design of the survey questions, as described in the methods section, interpretation can still differ and therefore affect responses. For example, question 4 (Appendix 3.2) refers to POCT currently undertaken, anecdotal evidence suggests that some thought that this question referred to any test provided by the practice and so included samples sent to laboratories, for example 11% reported conducting full blood count (FBC) as POCT, this is highly unlikely as POCT devices that conduct FBCs are larger, bench-top analysers which tend to be expensive and require extensive training to operate. However, the use of questionnaires in primary care research is well established: even though historically response rates are poor in this sector, questionnaires are still seen as a valid method of attaining both qualitative and quantitative data (McAvoy and Kaner, 1996).

Misinterpretation was less of an issue during telephone interviews as the researcher was able to interrogate the answers and ensure that the participant fully understood the question.

The overall response rate to the survey was low: the questionnaire may have gone unnoticed when sent via email, the email may have gone unopened or simply deleted and therefore the potential respondent has not come into contact with the questionnaire. Engaging primary care practitioners via surveys is a known challenge (Cartwright, 1978; Bowling *et al.*, 1991) for a variety of reasons, such as concerned over confidentiality (Cartwright *et al.*, 1976) or not having the time to participate (Silagy and Carson, 1989).

With the consistent poor response rate from GPs and the paucity of evidence on the use of POCT currently done within primary care in the UK considered, the knowledge gained by conducting the questionnaire is valuable.

### 3.5 Conclusion

Results of this survey confirm that POCT is performed within primary care and that it is viewed as a positive tool in the care of patients. However, without a full, physical audit it is impossible to uncover its true status.

100% of respondents stated that they are happy with the service that they currently receive from their local pathology laboratory, however, 39% reported they would consider using POCT in the future.

Although the participants of this study appeared to appreciate the benefits of POCT, there appeared to be little incentive for POCT to be introduced to primary care in any significant way in the near future. The cost of adopting POCT in primary care could be discouraging as funding for devices and reagents; maintenance, training and local laboratory support would have to be allocated. However, the cost of employing pathology staff is not often taken into account and so implementation of POCT could be cheaper to the NHS as a whole (Carter, 2008). It could be that POCT is better suited to locations that do not have links to laboratory provisions, i.e. in the community. Initiatives such as the NHS Health Checks are an avenue in which more POCT could be used as cholesterol and glucose tests are integral to the check and can be performed using POCT equipment and can therefore be done in a variety of settings, which is important as patients often struggle to find time to visit their GPs. These factors could help increase the numbers of checks done: the uptake of the NHS Health Checks is currently below target (Price, 2013).

### Abstract

#### Introduction

Point-of-care Testing (POCT) is frequently used to deliver cholesterol and glucose results as a part of the NHS Health Check (NHS HC) scheme. NHS HCs were introduced in 2009 to screen 40-74 year olds for risk factors of cardiovascular disease (CVD) with an aim of preventing future disease and reducing related risk factors. Recently, the NHS HC scheme has come under criticism for not being cost-effective and causing patients to worry. This study aimed to assess whether receiving a Health Check in the community reduces patient risk of CVD.

#### Methods

Participants were recruited in the community before receiving a Health Check and completed a questionnaire that assessed well-being, diet, exercise, intentions and experience of the health check. Follow-up Health Checks were conducted at three months, where another questionnaire was completed. Results were compared and analysed statistically using SPSS and Stata.

#### Results

122 participants were recruited at baseline and 91 attended follow-up. No change was observed in CVD risk score from baseline to follow-up, with the exception of the participants who were referred for further testing and additionally intended to make lifestyle changes, where a significant decrease occurred ( $P < 0.0001$ ). Two new diagnoses of hypertension and diabetes were confirmed. There were no statistically significant changes in other parameters tested, however, fewer participants were in risk categories at follow-up for BMI, waist circumference, total cholesterol and QRisk2 score compared with baseline. All participants were satisfied with the service received and preferred POCT to traditional pathology testing.

#### Conclusion

Health Checks conducted in the community setting using POCT were well received and may have captured some patients who would not normally visit

their GP to have one. Little effect was seen on CVD risk over a three-month period.

#### 4.1 Introduction

As well as in the traditional primary and secondary healthcare setting as discussed in chapters one, two and three, Point-of-Care Testing (POCT) has applications in the community setting.

##### *4.1.1 Public Health & the NHS Health Check*

In 2009, the NHS Health Check (NHSHC) programme was implemented in the UK. The programme screens for risk factors of cardiovascular disease (CVD), diabetes, kidney disease and some forms dementia in 40-74 year olds. Patients are provided with tailored advice for reducing risk scores with the aim of preventing these diseases. The programme was initiated as a response to the difficulties that the UK faces with these diseases: In 2011, CVD was responsible for nearly 30% of all deaths and is the greatest cause of disability (Department of Health, 2013b).

The NHSHC involves questions around lifestyle and family medical history; assessment of alcohol intake; measurement of glucose and cholesterol levels; height, weight and waist circumference; blood pressure assessment; pulse reading and calculation of CVD risk score. When a Health Check is performed in the community setting, POCT can be used for the measurement of glucose and cholesterol.

It is estimated that the NHSHC programme could prevent over 4,000 people from developing Type 2 diabetes per annum and detect at least 20,000 new cases of diabetes or kidney disease each year (Department of Health, 2008). Disease prevention is extremely valuable both to patients and the NHS; it is estimated that diabetes costs the NHS around £1.5m an hour, equating to 10% of the entire NHS budget for England and Wales and is projected to rise to around 17% by 2035 (Hex *et al.*, 2012).

As well as saving money, disease prevention has a positive impact on Patient quality of life. A study of 9,385 patients found that patients with chronic conditions have decreased scores for factors such as: physical ability, social satisfaction, mental health, health perceptions and body pain, compared with those who do not have long-term conditions (Stewart *et al.*, 1989).

Current research tends to focus on the uptake of the NHS Health Checks in the general population. In the year 2014/2015 15,449,660 patients were eligible for an NHSHC across England. Of those, 3,042,478 (19.7%) were offered an NHSHC and 1,485,339 (48.8% of those offered) took up the opportunity to have one.

In Greater Manchester, 747,670 patients were eligible for an NHS Health Check in the year 2014/2015. 151,661 (20.3%) of these were offered a Health Check and 86,943 (57.3% of those offered) took up the opportunity to have one (NHSHC, 2015), this data is provided by the Health Check service and cannot be verified.

#### *4.1.2 Delivering NHS Health Checks in the community*

In April 2013, local authorities (LAs) became responsible for public health services. Some LAs, such as Salford, provide mobile NHS Health Checks through their health service (Salford Health Improvement Service - SHIS). POCT, in the form of the Cholestech LDX (Alere Inc., San Diego, CA), is used to glucose and cholesterol as part of NHS Health Checks carried out in the community.

The Salford Health Improvement Service employs community health development workers (CHDW) and health improvement project workers (HIPW). Amongst many other services, these staff provide Health Checks to the eligible population. Patients are pre-screened to assess their eligibility for the NHS Health Check, see Appendix 4.1 for the pre-screening form. A patient is not eligible for an NHSHC if they are aged below 40 or above 74 years old or have a pre-existing condition. If a patient is not eligible for a full NHSHC, they are

offered a Mini Health MOT, which involves the same procedure as the NHSHC excluding assessment of alcohol consumption, measurement of glucose and cholesterol levels and CVD risk calculation. The processes for the NHSHC and the Mini Health MOT are illustrated in Figure 4.1.

SHIS staff receive in-house training and/or industry training to ensure their competency in using the Cholestech LDX and in the provision of NHSHCs. The transportable nature of the device allows for NHSHCs to be performed in a range of locations, including in the workplace, community groups and on the 'Heath Bus' (pictured in Figure 4.2).

Although the staff (CHDW and HIPW) performing the Health Checks are not medically trained, they have had extensive, practical training from SHIS and industry in delivering the Health Checks – this training involves a full day session which covers the physiological background, introduction to the equipment, demonstration sessions and hand-on experience of delivering Health Checks. Each trainee provides a Health Check in the session and is assessed on its delivery. If appropriate, areas of improvement are highlighted. Staff are not permitted to provide Health Checks until the trainers and management are satisfied with their performance. When staff are deemed proficient, they are continually assessed during Health Check sessions to ensure the quality of service is maintained at a high level.

The training undertaken by all staff providing the Health Checks places them in a position to give appropriate advice if abnormal results are discovered.

Health Check procedure in the community

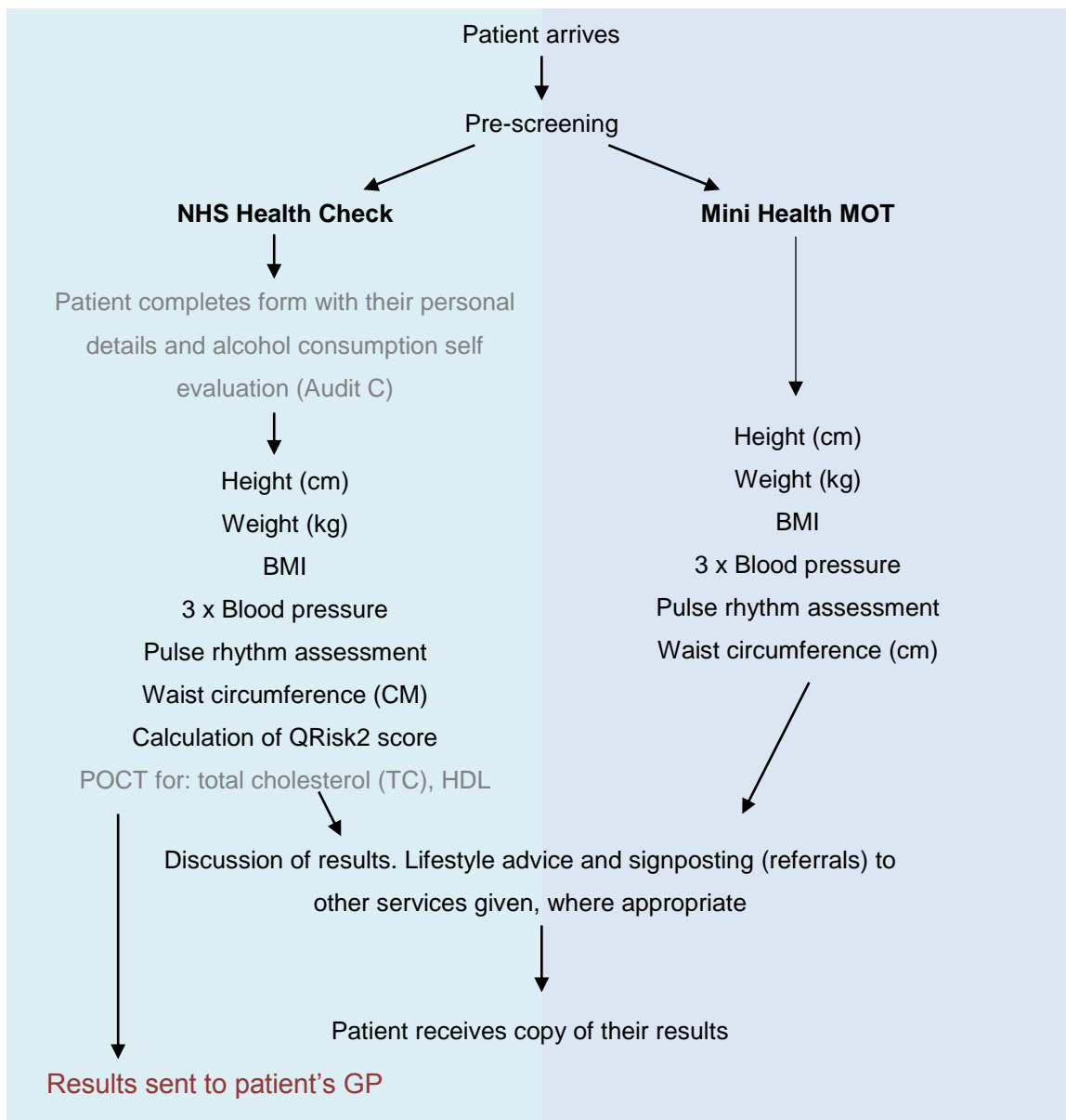


Figure 4.1 Diagram of the testing procedure for the NHS Health Check and Mini Health MOT when provided by the SHIS in the community setting.



#### 4.1.2.1 Cholestech LDX

The Cholestech LDX is a lipid Point-of-Care Testing device. It boasts laboratory-accurate quality as it meets National Cholesterol Education Program (NCEP an American programme managed by the National Heart, Lung and Blood Institute) guidelines and is certified by the Cholesterol Reference Method Laboratory Network (CRMLN).

The device provides rapid results, with results shown on-screen 5 minutes post-testing. It is simple to use, whole-blood capillary samples are applied to single-use test cassettes and do not require any pre-analytical steps. The device is CLIA waived and so operators do not require a clinical or pathology based background.

#### 4.1.2.2 The Health Bus

The Health Bus was specifically developed for providing Health Checks in the community; it has an area at the front where patients are pre-screened to assess if they are eligible for the full NHSHC or the Mini Health MOT, an area for measuring height and weight and three private bays for completion of the patient's Health Check. Each bay has a Cholestech LDX with the assorted consumables required and an automatic blood pressure monitor.



Figure 4.2 Picture of the 'Health Bus' used by the Salford Health Improvement Service to provide HNSHCs in the community

### 4.1.3 Salford Demographics

Salford is a city within Greater Manchester. It has a registered population of 233,900 people living across eight neighbourhoods: Claremont and Weaste; East Salford; Eccles; Irlam and Cadishead; Little Hulton and Walkden; Ordsall and Langworthy; Swinton and Worsley, and Boothstown (ONS, 2012).

#### 4.1.3.1 Deprivation

Although Salford has some affluent areas, it is ranked as one of the most deprived local authority areas in England with life expectancy lower than average in England.

26.8% of children in Salford (n=12,300) live in poverty (PHE, 2015).

#### 4.1.3.2 Life expectancy

Salford men have an average life expectancy 11.5 years lower than the national average and Salford women have an average life expectancy 8.5 years lower than the national average (PHE, 2014).

Vast differences are seen across the city itself, men living in the most deprived areas have over 10.6 years shorter life expectancy than those from the least deprived areas, and there is a difference of 10.3 years amongst women (PHE, 2015).

#### 4.1.3.3 Health inequalities

The number of alcohol-related hospital admissions and premature deaths from heart disease and stroke in Salford are also amongst the worst in England (Salford CCG, 2014). 27% of the adult population were classified as obese in 2012.

As illustrated in Figure 4.3, Salford scores significantly worse than the national average for many indicators of inequality, deprivation and poor health (PHE, 2015).

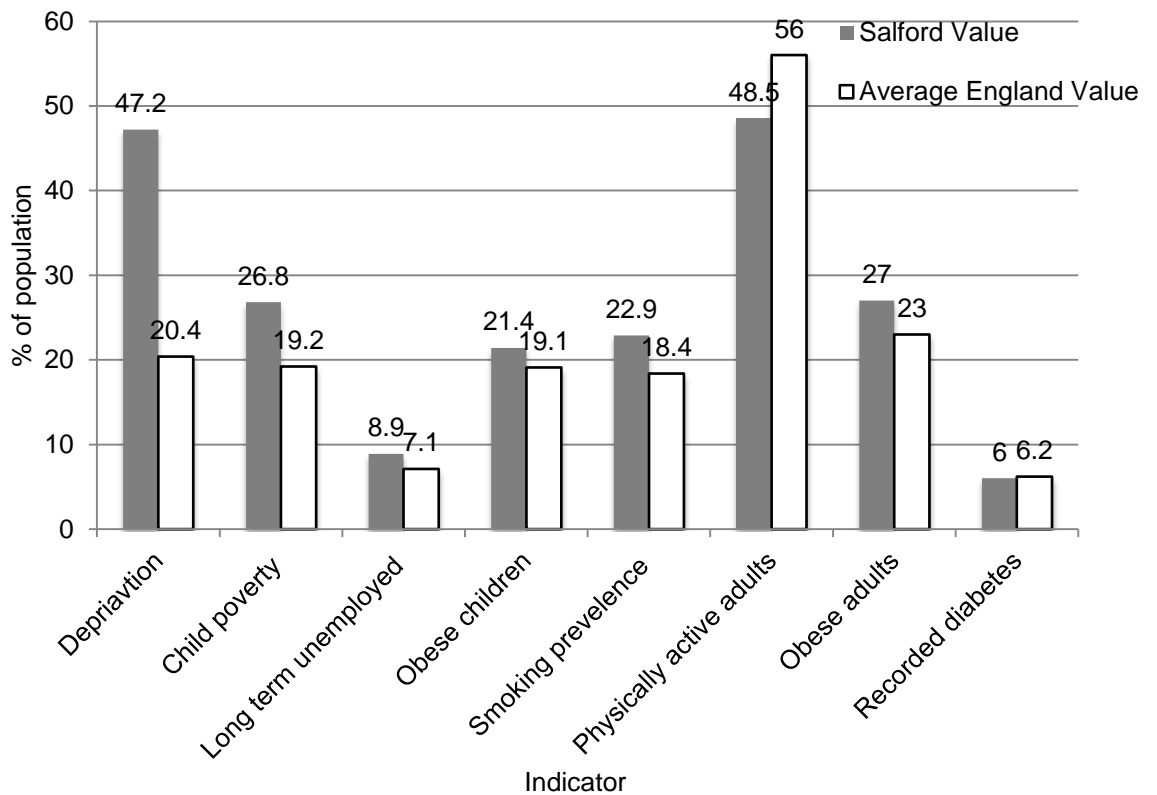


Figure 4.3 Bar chart displaying a comparison of Salford and UK average indicators of poor health and deprivation. Information source: Salford Health Profile 2015 (PHE, 2015).

47.2% of Salford residents live in the 20% most deprived areas in England, this is significantly worse than the England average. 26.8% of children (under 16) live in households that receive means-tested benefits for low income compared England's national average of 19.2%, this is significantly worse. Approximately 8.9% of the Salford population aged 16-64 are have been out of work for 12 months or longer, which is significantly worse than the national average of 7.1%. 21.4% of children aged 10-11 are classified as obese in Salford, which is significantly higher than the 19.4% average in England. A significantly higher portion of Salford's residents smoke compared with the national average (22.9% and 18.4%, respectively). It is reported that 48.5% of people in Salford achieve a minimum of 150 minutes exercise each week, which is significantly lower than the national average of 56% of people.

23% of people are classified as obese in England, in Salford this is significantly higher at 27%.

The only indicator published in the Salford Health Profile 2015 (PHE, 2015) that was significantly better in Salford than the national average is the recorded number of people with diabetes (6% and 6.2%, respectively). However, these figures do not include patients who have undiagnosed diabetes as the information was taken from GP disease registers, therefore it could be that in reality Salford does not have lower rates of diabetes.

The number of hospital stays due to alcohol related abuse in England in 2013/14 was 645 per 100,000 of the population, in Salford this number was 954 per 100,000.

Between 2011-2013 the number of smoking related deaths in England was 288.7 per 100,000, in Salford this number was 415 per 100,000.

There is a significantly higher rate of early deaths from CVD in Salford compared with the national average (PHE, 2015). This evidence provides greater evidence for making the prevention of CVD a priority.

Data on demographics was taken from a non-peer reviewed source as this was the only data available, it therefore cannot be verified.

#### *4.1.4 Published research*

Like many public health schemes, the checks have faced both praise and criticism. There have been many life-saving, success stories reported in association with the scheme but there have also been publications condemning the checks to be a waste of time and money, a cause of unnecessary worry and a task that some healthcare professionals have little interest in performing (Krogsbøll *et al.*, 2012; Capewell *et al.*, 2015). Nevertheless, the World Health Organization (WHO) estimate that better use of existing preventative measures such as Health Checks could reduce the global burden of all diseases by up to 70% (Van Lerberghe, 2008).

Screening for CVD risk factors is seen by many as a part of normal primary care: general practitioners identify risk factors in their patients that are visiting them for other issues and initiate CVD screening (Gøtzsche *et al.*, 2014). There is also potential for Health Checks to produce harmful outcomes, for example, some of the medications used to manage diabetes, which could be prescribed as a result of an NHSHC, have been shown to increase cardiovascular mortality (Nissen, 2012) – the very thing that these checks are aiming to prevent.

Previous research suggests that those who accept the invitation for a Health Check tend to be the ‘worried well’. These people often have a higher socioeconomic status (Attwood *et al.*, 2015), lower cardiovascular risk, less cardiovascular morbidity, and lower mortality than others (Krogsbøll *et al.*, 2012). The impact of screening the ‘worried well’ is less beneficial than screening those who might actually be at a higher risk of CVD e.g. those living in deprived communities (WHO, 2007). Engagement rates in deprived communities are generally lower (Thorogood *et al.*, 1993), suggesting that engaging the target audience for NHSHCs is challenging. The SHIS provide Health Checks in a potentially more appropriate way than traditional primary care based Checks as they bring the Health Checks to the patients. By providing Health Checks in the community, e.g. on the ‘health bus’ or in the work place, this reduces the amount of effort required by the patient in order to receive a Health Check. The patient does not need to contact their GP surgery to make an appointment, they do not need to take time off work or make a special journey to the GP surgery in order to attend the appointment. Additionally, due to the use of POCT, the patient receives the results of their cholesterol and glucose tests whilst in consultation with the SHIS and so they do not need to contact the GP surgery to receive their results. As discussed in Chapter Two there is evidence to suggest that receiving test results during the original consultation can have a more positive effect on the patient and encourage better health outcomes (Laurence *et al.*, 2010).

The overall Health Check experience provided by the SHIS is very convenient for the patient. This, teamed with the fact that the advisors employed by the SHIS are often from the same community as the patients, may encourage those more

hard-to-reach patients who are theoretically at higher risk of CVD to have a Health Check.

#### *4.1.5 Rationale for current study*

Much time and research is spent analysing the uptake of the NHS Health Checks but little has been done to evaluate patient impact.

As all previous research found is based on health screening performed within healthcare organisations, it is important to investigate the impact of screening provided by other organisations, such as Local Authorities, in a variety of settings outside of primary care.

##### *4.1.5.1 Research question*

Does receiving a Health Check in the community setting have a positive effect on patient risk of cardiovascular disease?

#### *4.1.6 Research aims*

This research aimed to:

1. Determine the impact of the Health Check on CVD risk factors over a 3 month period, using Qrisk2 score as a primary outcome
2. Assess the impact of the Health Check on participant reported well-being
3. Assess the impact of the Health Check on the health behaviours behaviours of the participants
4. Evaluate participant satisfaction with Health Check and Health MOT service, in relation to POCT in particular
5. Identify potential areas for service improvement

## 4.2 Methods

This study was designed to have minimal impact on normal patient care. As described in section 4.1.2, in normal circumstances a patient must be aged between 40 and 74 years and without previous diagnosis of heart disease, stroke, diabetes or kidney disease to be eligible for an NHSHC. For the purposes of this research, anybody eligible for a Health Check delivered by the SHIS was also eligible to participate in the study. Therefore including participants that were outside of the target age group when screened in a workplace screening initiative, for example. Workplace screening initiatives conducted by the SHIS are intended for any employee wishing to receive a Health Check, irrespective of age or medical history.

The researcher and SHIS staff conducted Health Checks with recruited participants at baseline and at a 12-week follow-up. All results were recorded and anonymised. At each Health Check, participants completed a 'Health and Lifestyle Questionnaire'. In addition to this, semi-structured interviews were conducted with a selection of participants at follow-up, as reported in Chapter 5. The aim of the Semi-structured interviews was to fully saturate the qualitative data collected from the questionnaires.

NHS research ethical approval was sought through and granted by the Berkshire B Health Research Authority (HRA) (Appendix 4.2).

### *4.2.1 Questionnaire design and pilot*

#### 4.2.1.1 Baseline questionnaire

The questionnaire was designed as a two-sided A4 sheet of paper in colour (see Appendix 4.3). The first side had two sections: well-being and health behaviours, this side could be completed either before or after the patient received their Health Check. The second side had just one section, which concentrated on the participant's experience of the Health Check they had received; this side had to be completed after their Health Check.

The questionnaire had an introductory paragraph which thanked the participant for taking part, explained the purpose of the questionnaire, asked them to take their time and consider their answers, reminded them that they could ask questions if necessary and that all answers were confidential. Additionally, each section was introduced with a short paragraph explaining the theme of the questions that were to follow.

To protect participant confidentiality, the questionnaire provided space for the participant to input their name at the end. This was removed from the questionnaire once the participant has been assigned an ID number.

### *Section 1 (questions 1-5)*

The first section utilised the WHO-5 well-being index. This index was developed by the World Health Organisation (WHO) during the 1980s and is frequently used for assessing subjective psychological well-being (Topp, 2015).

The index has been validated both clinically and psychometrically in several studies (Wu, 2014; Löwe *et al.*, 2004; Henkel *et al.*, 2003; Hajos *et al.*, 2013).

The WHO-5 well-being index is concise and asks 5 positively phrased questions regarding the participant's everyday life e.g. 'over the past 2 weeks I have felt cheerful and in good spirits' to provide a self-reported measure of emotional well-being. The index can be used to track changes in well-being over time (Löwe *et al.*, 2004).

Assessing the participant's well-being is an important factor whilst conducting any health research, all too often mental health issues are overlooked in routine-care and so go undiagnosed and effect the patient's quality of life (Pouwer *et al.*, 2006). Evidence suggests that mental health issues, like depression, have a two-fold risk of occurring in patients with chronic conditions like diabetes, compared with the general population (Barnard *et al.*, 2006). The aim behind conducting the well-being section of the questionnaire was to identify patients with possible mental health issues and assess whether these change in correlation with improved or deteriorated general health. The data collected on well-being will be assessed against participant activity levels as previous research has suggested



that there is a strong correlation between physical activity and quality of life in the general population (Bize *et al.*, 2007).

### *Section 2 (questions 6-11)*

The second section focused on the participant's health behaviours and perceptions of themselves. Questions 6 and 7 aimed to record if the participant routinely exercises and if so, which activities they tend to do. Question 8 aimed to record how often the participant consumes fresh fruit and vegetables.

Questions 9 and 10 assessed the participant's perception of their own health. Question 11 gave the participant opportunity to record any ill-health that they regularly suffered from e.g. shortness of breath.

The information from baseline and follow-up questionnaires was compared and used to examine changes in Health Check results.

### *Section 3 (questions 12–16)*

The last section probed the participant's experience of the Health Check that day.

Question 12 assessed whether the participant has understood their Health Check results and what level of explanation from the advisor was required. In the case of this study, 'advisor' refers to either a member of SHIS staff or the researcher. Longitudinal studies have shown a link between educational advantages and improved health, therefore, in theory, participants with a higher level of education should be healthier (Walsemann *et al.*, 2008), this was assessed by Qrisk2 score in relation to employment level status.

Question 13 provided the participant with the opportunity to record any intended lifestyle changes that they wish to make.

Question 14 asked if the participant preferred receiving their Health Check in the community setting compared to seeing their GP and allows space for them to explain their answer. Patient preference and satisfaction is high on the NHS agenda and so it is pertinent to establish how they prefer to receive treatment and care.

Question 15 asked the participant to rate their overall experience of their Health Check from unacceptable to excellent and provided space for them to explain their answer.

The final question, question 16, examined the participant's attitude towards the use of POCT over traditional pathology testing for the measurement of their glucose and cholesterol levels.

The questionnaire was designed to be easy to read and complete, taking a maximum of 5 minutes. The sans-serif font 'Calibri' was used as it is acknowledged that sans-serif fonts significantly increase the reading performance of individuals with dyslexia (Rello and Baeza-Yates, 2013). Font size 13 was used to make the questionnaire easy to read for most people. However, a copy of the questionnaire in size 16 font was also available for those who had difficulty reading size 13.

The questionnaire was piloted on a cohort of 10 individuals that fit within the eligibility criteria for an NHS Health Check.

Study participants were asked to complete the questionnaire in private on completion of their baseline Health Check.

#### 4.2.1.2 Follow-up questionnaire

Sections 1 and 2 of the follow-up questionnaire (Appendix 4.4) remained the same as baseline. Section 3 of the questionnaire aimed to collect some information about what the participant had done in the time between baseline and follow-up.

Question 11 asked 'Have you been to visit your doctor as a result of your last Health Check?' and allows a simple 'yes' or 'no' answer. Followed by question 12, which asks 'If yes to question 11, have you been diagnosed or are you being treated for any new conditions?' Again, the respondent had the option of yes/no tick boxes and a space to add extra information e.g. 'Yes – I have been diagnosed with diabetes'.

Question 13 aimed to follow-up on the participant's stated lifestyle change intentions from the baseline questionnaire, it asked 'Since your last Health Check, have you made any lifestyle changes?' If the respondent answered 'yes', they also have space to explain what they have changed.

Question 13 had 2 successive questions. Question 14 asked 'If 'yes' to question 13, why have you made those changes?' Respondents had the options of: 'Because of the results and/or advice from the previous Health Check', 'Had already planned to make the changes' and 'Other' with the addition of a free-text answer to further explain their motivations.

Question 15 asked 'If 'no' to question 13, has anything stopped you from making lifestyle changes?', with response options of: 'No – I did not plan on making any lifestyle changes', 'Yes – I have not had the time', 'Yes – I do not know which lifestyle changes to make', 'Yes – I have not been motivated enough to make any changes' and 'Other' with a free-text space for further information.

The final question, much like question 15 of the baseline questionnaire was based on the NHS 'friends and family test', it asked: 'would you recommend having a Health Check to family and friends?' with yes/no tick boxes for response and free-text space to explain their answer. Questions like these provide useful information to the service providers.

The questionnaire was piloted on a cohort of 10 individuals that fit within the eligibility criteria for an NHS Health Check.

Study participants were asked to complete the questionnaire in private on completion of their follow-up health Check.

#### *4.2.2 Recruitment and follow-up*

Participants were recruited on site as they arrive for their Health Check, where they had the study explained to them and asked if they would like to participate. Potential participants received a participant information sheet (Appendix 4.5) and

were given approximately five minutes to read through it and a further two minutes to ask any questions. Individuals who were interested in participating were given a consent form (Appendix 4.6) to read and sign. Both the participant and the person taking consent were required to sign the consent form in order for the individual to participate. Copies of all documents were available in larger text for participants with difficulty reading.

Follow-up health checks were arranged depending on where the participant originally received their Health Check: the human resources manager was contacted and follow-up appointments were made for participants seen in the workplace, participants recruited on the Health Bus or in a community group, were contacted via letter and later by phone to arrange their attendance to a 'Health Check day'. The 'Health Check day' was conducted in a room hired by the SHIS in a community building.

#### *4.2.3 Conducting Health Checks and collecting data*

As described in more detail in Chapter One, each participant received an NHSHC or mini health MOT at baseline and again at follow-up, which was a minimum of twelve weeks later.

Once the participants had been 'pre-screened' to determine the test that they would receive, full NHS Health Check or mini Health MOT, the testing process began. For a full NHS Health Check, the participant had to fit the eligibility criteria: aged between 40 and 74, registered with a Salford GP, not already be diagnosed with the conditions that the Health Check screens for and not have had a previous Health Check in the last 12 months. The participants did not have to fit the criteria to receive an NHSHC in the workplace setting.

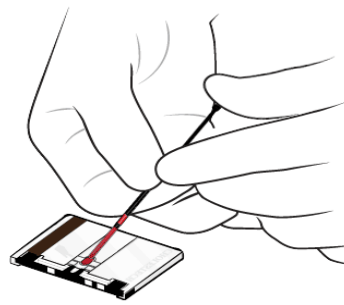
##### *4.2.3.1 Testing process*

At the start of each Health Check, the participant provided some basic information such as name, DOB, address, contact number, ethnicity, gender, GP/practice name and socio-economic classification by completing the first side of the 'patient assessment form' (Appendix 4.7). Once they had done this, the

participant completed the Audit C questionnaire (Appendix 4.8), which assesses how much alcohol they normally consume.

Participants had their height measured in centimeters using a Leicester Height Measure (Seca, Hamburg, Germany) and were weighed in kilograms using a calibrated scale. Body Mass Index (BMI) was calculated using these results. Waist circumference was measured in centimeters using a retractable tape. Seated, the participant was asked to remain calm, silent and breathe normally with their legs uncrossed whilst three blood pressure and pulse readings were taken using an electronic blood pressure meter (sphygmomanometer). Additionally, an assessment of the participant's pulse rhythm is conducted using the pulse in their wrist. The assessor looked for regular, strong, equally spaced beats. If the pulse felt weak and/or erratic, it was recorded as irregular.

For those who were eligible for a full NHSHC, non-fasting cholesterol and glucose was measured. For this test, their finger was cleansed using an alcohol wipe (Sterets skin cleansing swab, 70% isopropyl alcohol) and a 40 $\mu$ L capillary blood sample was taken from the fingertip using a 21 gauge lancet with a 2.00mm depth (Unistik 3 extra). The first drop of blood was wiped away with a gauze swab and the rest was collected using a capillary tube (Fig. 4.4), the capillary tube only allows a 40 $\mu$ L sample to be collected. The sample was transferred onto the appropriate lipid panel cassette (TC – HDL – GLU) (Fig. 4.5) and then inserted into the Cholestech LDX POCT device (Fig. 4.6).



Figures 4.4 to 4.6 Pictures illustrating the POCT process used for the assessment of cholesterol and glucose levels during the NHS Health Check performed by the SHIS.

Once all Health Check results had been recorded, the advisor used the online QRisk2 2015 calculator ([www.qrisk.org](http://www.qrisk.org)) to calculate the participant's 10-year risk of CVD. The information required for the calculations consists of: age, sex, ethnicity, postcode, smoking status, diabetes status, medical history, TC/HDL ratio, systolic blood pressure, height and weight.

The QRisk2 score provided an indication of an individual's risk of having a myocardial infarction or cerebrovascular accident (stroke) over the next ten years. The QRisk2 calculation uses an algorithm that has been developed by UK NHS physicians and academics using data collected routinely from thousands of general practitioners from all over the UK.

At the end of the Health Check, the advisor discussed the results with the participant, highlighting any areas that may require attention. The advisor discussed the patient's lifestyle and provide healthy living advice, where necessary.

If the participant had any results that require further attention, the advisor had opportunity to refer the participant on to appropriate services.

At this point, the participant had time to complete their questionnaire.

A copy of each participant's Health Check results were recorded on to an encrypted, password protected laptop. These results were pseudo-anonymised using participant identification (ID) numbers in place of identifiable data. The participant ID numbers were stored on a separate, encrypted file on the laptop. Participant contact details were stored on another separate, encrypted file on the password-protected laptop using ID numbers in place of names.

Completed questionnaires, in their paper-based form, had their participant's ID number assigned to them and any identifiable data removed from them. These were taken off-site, along with the laptop and stored securely in a locked cupboard in a locked room.

All results were analysed statistically using SPSS, Minitab, stata and Excel.

### 4.3 Results

A total of 122 participants were recruited to the study. 13 of these were recruited through community groups, 16 were recruited on the Health Bus and 93 were recruited in the workplace (4 from one workplace and 89 from another).

#### 4.3.1 Participant characteristics

108 of the participants received full Health Checks and 14 received Mini Health MOTs.

Patient characteristics are reported in Table 4.1, these results were self-reported on the patient assessment form.

<b>Characteristic</b>	<b>Results</b>
Gender	78% male (n=95), 22% female (n=27)
Age	Range: 17-71 years old, mean: 42.6, mode: 46, median: 43 and a standard deviation of 11.74 years
Ethnicity	White British (n=94), Other White Background (n=11), Chinese (n=2), Other South Asian (n=1), African (n=1), Indian/Pakistani (n=1), Irish (n=1) and 11 did not disclose their ethnic background
Employment status	39 in managerial/professional role, 35 in routine and manual role, 22 in an intermediate role, 4 retired, 2 unemployed and 20 did not state their employment status
Smoking status	80 non-smokers, 16 ex-smokers, 6 light smokers (<10/day), 2 moderate smokers (10-19/day), 3 heavy smokers (>20/day) and 15 did not state their smoking status

Table 4.1 Table containing self-reported characteristics of the Health Check participants at baseline. This data was provided by the participant and therefore cannot be verified.

*The information contained in the above table (Table 4.1) was not required for the Mini Health MOT.*

#### 4.3.1.1 Alcohol consumption

A total of 103 participants completed an Audit C alcohol consumption assessment questionnaire. This information is not required as part of the Mini Health MOT. Of those that completed it, 14 scored 0, meaning that they did not regularly drink alcohol or did not drink alcohol at all. 52 scored 1-5 which places them in a low risk category for problem drinking. 37 scored 5+, places them in a higher risk category for problem drinking.



### 4.3.2 Baseline Health Check Results

The results of the mean blood pressure (n=122), weight (n=122), height (n=122), BMI (122), waist circumference (n=118), total cholesterol (n=108), HDL cholesterol (n=108), total cholesterol/HDL cholesterol ratio (n=107), blood glucose (n=108) and Qrisk2 (n=112) measurements are show in Table 4.2.

Measurement	Mean	Mode	Median	Standard Deviation	Range
Systolic blood pressure (mmHg) (average of 3)	131.63	122	132	15.36	99-182
Diastolic blood pressure (mmHg) (average of 3)	78.18	75	77	10.39	47-112
Weight – Male (kg)	83.1	56.3	80.9	18.48	56.3-180.1
Weight – Female (kg)	68.5	N/A	66.5	13.46	49.4-97.8
Height -Male (cm)	175.91	178	176	7.71	152-198
Height –Female (cm)	163.4	164	162.5	0.08	152 – 182
BMI	26.5	25.5	25.5	5.03	18.8 – 54.3
Waist circumference – Male (cm)	92.93	84	91	12.17	71 – 139
Waist circumference – Female (cm)	86.94	86	86	9.61	71 – 107
Total Cholesterol (mmol/L)	4.96	4.32	4.86	0.98	2.77 – 7.83
HDL– Male (mmol/L)	1.21	1.13	1.15	0.34	0.47 – 2.39
HDL – Female* (mmol/L)	1.48	1.28	1.4	0.42	0.84 - >2.59
HDL/TC ratio	4.23	3.3	3.8	1.4	1.9 – 9.7
Blood glucose (mmol/L)	5.69	5.17	5.31	1.52	4.28 – 16.4
QRisk2 Score (%)	4.42	0.3	2.6	5.24	0.1 – 22.5

Table 4.2 Participant Health Check result data recorded at baseline (n=122)

#### 4.3.2.1 Baseline risk categories

Participants were organised into risk categories for blood pressure (NICE, 2006a), total cholesterol (NICE, 2008a), blood glucose (NICE, 2008c), BMI (WHO, 2000), waist circumference (NICE, 2006b) and QRisk2 score (NICE, 2008b) based on their results in relation to NICE guidelines and WHO publications for each parameter.

0 participants had a systolic blood pressure (BP) that indicated hypotension (<90mmHg). 91 participants had ideal systolic BP (90-140 mmHg). 30 participants had an average systolic BP reading that indicated pre-hypertension (141-179 mmHg), the guidance for which is to recommend they see GP within 1 month. 1 participant had an average systolic BP that indicated hypertension requiring a GP appointment within 1 week (180-219 mmHg). None of the participants had an average systolic BP ( $\geq 220$  mmHg) that required urgent attention and referral to A&E.

1 participant had a diastolic blood pressure that indicated hypotension (<50mmHg). 108 participants had ideal diastolic BP (50-90 mmHg). 12 participants had an average diastolic BP reading that indicated pre-hypertension (91-109 mmHg), the guidance for which is to recommend they see GP within 1 month. 1 participant had an average diastolic BP that indicated hypertension (110-120 mmHg), requiring a GP appointment within 1 week. None of the participants required urgent attention and referral to A&E due to their diastolic BP (>120 mmHg).

0 participants had a BMI that indicated that they were underweight (<18.5), 46 were of ideal weight (18.5-<25), 58 were classified as overweight (25-<30) and 18 were classified as obese ( $\geq 30$ ). Of the participants in the obese category, 11 were classified as grade 1 obese (30-<35), 3 were grade 2 obese (35-<40) and 4 were grade 3 obese (40+). Proportionally, more males than females were classified as overweight or obese (51% vs. 37% and 16% vs. 11% respectively).

The results placed the majority of male participants, 64.1%, in a low risk waist circumference (<94 cm) category (n=59), 20.7% in a high-risk category (94 – 102 cm) (n=19) and 15.2% in the very high-risk category (>102 cm) (n=14).

By contrast, just 26.9% of female participants fell in the low risk category for waist circumference (<80 cm) (n=7), 30.8% were classified as high risk (80 – 88 cm) (n=8) and 42.3% classified as very high risk (>88cm) (n=11).

Total cholesterol (TC) risk categories were grouped in association with Qrisk2 scores. 101 participants had a total cholesterol of <7.5 mmol/L with a Qrisk2 of <20%, these participants are considered to be low risk and do not require follow-up. 0 participants had a total cholesterol of <7.5 mmol/L with a Qrisk2 of >20%, which would have placed them in a higher risk category where they would be advised to make a GP appointment within one month and given healthy lifestyle reinforcement. 3 participants had a total cholesterol of >7.5 mmol/L, these participants were advised to arrange a GP appointment for a familial hypercholesterolemia screening within one month, regardless of their Qrisk2 score. 4 participants had a TC of <7.5 mmol/L but did not have a calculated Qrisk2 score and so they do not fit in to any of these risk categories, the assumption is that they were low risk as their TCs were all less than 5mmol/L (2.77 - 4.98mmol/L).

There are no risk categories used for HDL cholesterol. Females tend to have greater levels of HDL compared to males (Singh, 2014) One participant had a HDL reading of '>2.59 mmol/L' and so 2.6 mmol/L was used in its place for the purpose of analysis.

The balance between cholesterol relates to the overall balance between atherogenic lipoproteins and antiatherogenic lipoproteins and therefore risk of cardiovascular disease (Sniderman *et al.*, 2006).

TC/HDL ratio is a clinical indicator of coronary heart disease (CHD). According to the American Heart Association, men with a TC/HDL of 5 are at average risk of CHD and men with TC/HDL of 9.6 are at double that risk. Similarly for women, a TC/HDL of 4.4 indicates average risk and TC/HDL of 7 indicates that those

women are at twice the risk of CHD. The American Heart Association states that TC/HDL ratio should ideally be around 3.5 for both men and women. 43

participants (40.2%) achieved a TC/HDL of 3.5 or lower. 37 participants (34.6%) had a TC/HDL of less than 5. The remaining 27 participants (25.2%) had a TC/HDL of over 5.

87 participants (80.5%) had a random blood glucose result that falls within the 'normal' category of  $\leq 6.0$  mmol/L. 20 participants (18.5%) had a random blood glucose result between 6.1 – 11.0 mmol/L, these participants were referred to their GP for a fasting blood glucose or HbA1c test within one month.

1 participant had a random blood glucose result between 11.1 – 17.9 mmol/L, they were referred to their GP for a fasting blood glucose or HbA1c test within one week. 0 participants had a random blood glucose result which required urgent emergency attention ( $>18$  mmol/L).

103 Qrisk2 scores were calculated from full result data sets. 8 Qrisk2 Scores were calculated from partial result data sets, for example, where a participant's smoking status or family medical history was not known, non-smoking status and no medical history were used in the calculator in these cases. 11 participants did not have a Qrisk2 score calculated for them as they either were under the age of 25 (n=4), no age was recorded (n=6) or their BMI was too high for the calculator to provide an accurate score (n=1).

Of the 111 calculated, 9 participants had a QRisk2 score between 15 and 19%, placing them in a moderate risk category and one participant had a QRisk2 score  $>20\%$ , placing them in a high risk category.

#### 4.3.2.2 Baseline referrals

It was recorded that 31 participants were advised to seek further testing or advice as a result of their health check. 6 participants were referred to see their GP for more than one reason. 18 participants were advised to see their GP to recheck their blood pressure, the QRisk2 Score of these participants ranged from 0.6 – 18.7%, with an average of 6.5%. 9 were advised to have a fasting cholesterol checks, the QRisk2 score of these participants ranged from 0.9 – 15.6%, with an average of 6.3%. 5 participants were advised to have a fasting

glucose check; these had QRisk2 scores ranging from 5.9 – 15.6% with an average of 9.1%. 4 participants with QRisk2 scores ranging from 2.8 – 19.7% and an average of 11.3% were referred to the smoking cessation service. One participant with a QRisk2 score of 14.9% was referred to their GP for symptoms unrelated to the Health Check.

#### 4.3.3 Follow-up Health Check results

A total of 91 of the original 122 participants received a follow-up Health Check, achieving a follow-up rate of 75%. 74 were male, 17 female.

As shown in the consort diagram, Figure 4.7, participants that received their Health Check on the Health Bus or in a community group at baseline received their follow-up Health Check on a follow-up Health Check day held in a community location, achieving a follow-up rate of 48%. Participants that received their baseline Health Check at their workplace received their follow-up Health Check in their workplace, achieving a follow-up rate of 83%.

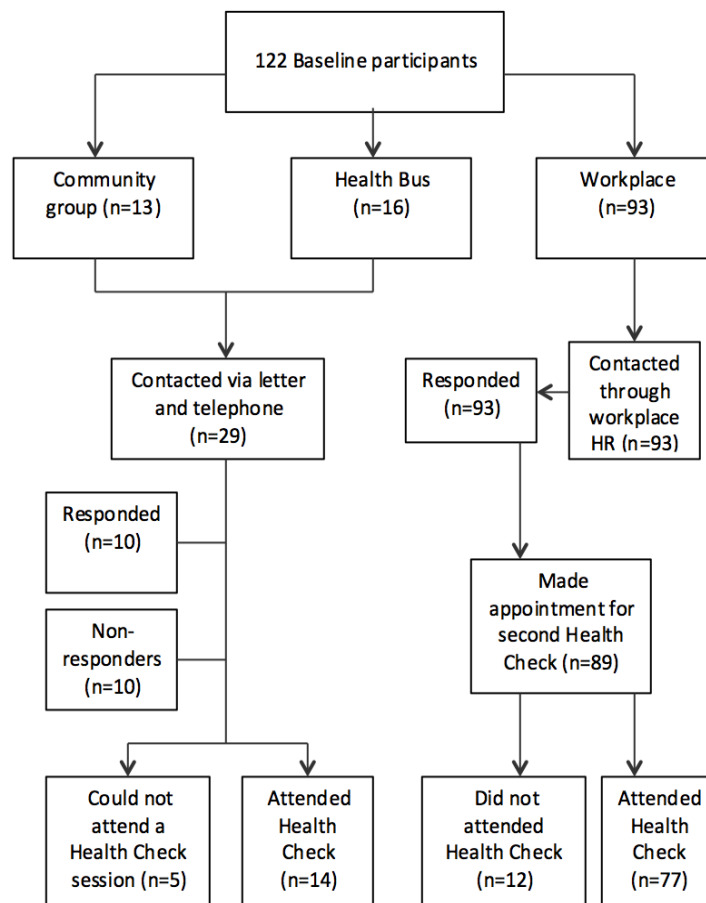


Figure 4.7 Consort diagram illustrating the attendance of the community and workplace Health Check study population from baseline to follow-up

The results of the mean blood pressure (n=91), weight (n=91), height (n=91), BMI (n=91), waist circumference (n=89), total cholesterol (n=85), HDL cholesterol (n=85), total cholesterol/HDL cholesterol ratio (n=83), blood glucose (n=85) and Qrisk2 (n=88) measurements are shown in Table 4.3.

Measurement	Mean	Mode	Median	Standard Deviation	Range
<b>Systolic blood pressure (mmHg) (average of 3)</b>	134.77	139	135	16.19	108-196
<b>Diastolic blood pressure (mmHg) (average of 3)</b>	81.08	74	80	11.18	60-120
<b>Weight – Male (kg)</b>	81.04	65.6	79.5	14.31	57.9-146.5
<b>Weight – Female (kg)</b>	67.91	N/A	66.8	12.62	46.7-85.5
<b>Height -Male (cm)</b>	176.04	178	177	7.86	157.5-198
<b>Height –Female (cm)</b>	164.8	164	163	7.49	155 – 182.5
<b>BMI</b>	25.9	26	25.6	3.76	19.4-41
<b>Waist circumference – Male (cm)</b>	91.6	91	91	9.24	75 – 124
<b>Waist circumference – Female (cm)</b>	83.03	84	84	6.83	69-94
<b>Total Cholesterol (mmol/L)</b>	4.88	4.18	4.65	0.9	2.58 – 8.03
<b>HDL– Male (mmol/L)</b>	1.24	1.16	1.16	0.34	0.71 – 2.12
<b>HDL – Female* (mmol/L)</b>	1.54	1.58	1.58	0.43	0.94 - >2.59
<b>HDL/TC ratio</b>	4.03	4.8	3.9	1.14	2.2 – 7.2
<b>Blood glucose (mmol/L)</b>	5.58	5.16	5.36	1.08	3.95 – 10.6
<b>QRisk2 Score (%)</b>	4.15	0.2	2.3	5.05	0.1 – 26.4

Table 4.3 Participant Health Check result data recorded at follow-up (n=91)

#### 4.3.3.1 follow-up risk categories

0 participants had a systolic blood pressure (BP) that indicated hypotension (<90mmHg). 64 participants had ideal systolic BP (90-140 mmHg). 25 participants had an average systolic BP reading that indicated pre-hypertension (141-179 mmHg). 2 participants had an average systolic BP that indicated hypertension (180-219 mmHg). None of the participants had an average systolic BP ( $\geq 220$  mmHg) requiring emergency attention.

0 participants had a diastolic blood pressure that indicated hypotension (<50mmHg). 75 participants had ideal diastolic BP (50-90 mmHg). 14 participants had an average diastolic BP reading that indicated pre-hypertension (91-109 mmHg). 2 participants had an average diastolic BP that indicated hypertension (110-120 mmHg). None of the participants required urgent attention and referral to A&E due to their diastolic BP (>120 mmHg).

0 participants had a BMI that indicated that they were underweight (<18.5), 38 were of ideal weight (18.5-<25), 43 were classified as overweight (25-<30) and 9 were classified as obese ( $\geq 30$ ). Of the participants in the obese category, 6 were classified as grade 1 obese (30-<35), 2 were grade 2 obese (35-<40) and 1 was grade 3 obese (40+).

The results placed the majority of male participants, 65%, in a low risk waist circumference (<94 cm) category (n=47), 25% in a high-risk category (94 – 102 cm) (n=18) and 10% in the very high-risk category (>102 cm) (n=7).

At follow-up, 24% of female participants fell in the low risk category for waist circumference (n=4), 52% were classified as high risk (80 – 88 cm) (n=9) and 24% classified as very high risk (>88cm) (n=4).

Total cholesterol (TC) risk categories were grouped in association with Qrisk2 scores. 81 participants had a total cholesterol of <7.5 mmol/L with a Qrisk2 of <20%, these participants are considered to be low risk. 1 participant had a total cholesterol of <7.5 mmol/L with a Qrisk2 of >20%, which placed them in a higher risk category. 1 participant had a total cholesterol of >7.5 mmol/L.

30 participants achieved the target ratio of 3.5 or lower for TC/HDL, 39 participants had a TC/HDL between 3.6 and 5 and 14 participants had a TC/HDL of over 5.

63 participants had a random blood glucose result that falls within the 'normal' category of  $\leq 6.0$ mmol/L. 22 participants had a random blood glucose result between 6.1 – 11.0 mmol/L, 0 participants had blood glucose levels higher than this.

Of the 88 calculated QRisk2 Scores, 4 were between 15 and 19%, placing them in a moderate risk category and 1 was >20%, placing that participant in a high risk category.

#### 4.3.3.2 Comparison of baseline and follow-up Health Check results

Table 4.4 shows the percentage of participants falling within risk categories for the parameters assessed at baseline and follow-up. Although there was a slight decrease in the percentage of participants in moderate and high QRisk2 score categories from baseline to follow-up (8% and 6%, respectively), there was an increase seen in other risk categories such as high blood pressure and blood glucose.

	Systolic blood pressure	Diastolic blood pressure	BMI	Waist circumference	Total cholesterol	Blood glucose	QRisk2 score (>15%)
Baseline	25%	11%	62%	44%	3%	19%	8%
Follow-up	30%	18%	57%	43%	2%	26%	6%

Table 4.4 comparison of participants falling within risk categories from baseline to follow-up. Categories are based on SHIS referrals guide (Appendix 4.9) and NICE guidance. Risk categories include any patient that would have been referred for further testing. Percentages calculated from 122 participants at baseline and 91 at follow-up.



The change in individual participant results from baseline to follow-up is shown in the statistical analysis, section 4.3.6.1.

#### 4.3.3.3 Referral attendance

Of the 31 participants that were signposted to see their GP as a result of their baseline Health Check, 21 were seen again at follow-up. Of those 21, 5 reported that they saw their GP between baseline and follow-up and the remaining 16 reported that they did not seek further medical attention or testing.

As a result of those 5 participants seeking further testing, there was 1 new diagnosis of diabetes, 1 new diagnosis of high blood pressure and 1 patient awaiting further investigation for suspected high blood pressure.

#### 4.3.4 Questionnaire results

The Health and Lifestyle Questionnaire, version 4, (27/11/14) (Appendix 4.3) was generally well received at pilot. All respondents said that they understood all the questions and found the questionnaire easy to complete in a short amount of time. Small word changes were suggested with the addition of an extra line for participants to enter more free text responses for question 13. The questionnaire was amended in accordance with the suggestions made.

All 122 study participants completed the questionnaire at baseline. 90 of the 91 participants completed the questionnaire at follow-up, 1 did not as they did not wish to answer questions on their current well-being due to a recent bereavement.

##### 4.3.4.1 Well-being assessment

The baseline and follow-up responses to questions 1 to 5, the WHO-5 Well-being Index, are shown in tables 4.5 To 4.7.

The results of this section were reasonably positive overall, with the majority of participants selecting the second most agreeable answer, 'most of the time' for each question, both at baseline and follow-up. Question 4, pertaining to the feeling of being 'refreshed and rested' after sleep received the largest spread of

responses and a higher frequency of less agreeable responses compared with the other questions.

There appeared to be a general shift toward the selection of more positive responses for all five questions on the follow-up questionnaire. This may suggest some improvement in the well-being of the participants in this study after the three month follow-up period.

**Question 1. In the last two weeks, I have felt cheerful and in good spirits**

Response	% of participants at baseline	% of participants at follow-up
All of the time	13	12
Most of the time	52	61
More than half of the time	24	19
Less than half of the time	4	6
Some of the time	6	2
At no time	1	0

Table 4.5 Participant answer selection to question 1 of the health and lifestyle questionnaire, n=122 at baseline and 90 at follow-up

**Question 2. Over the last two weeks, I have felt calm and relaxed**

Response	% of participants at baseline	% of participants at follow-up
All of the time	15	9
Most of the time	43	57
More than half of the time	22	23
Less than half of the time	13	8
Some of the time	6	2
At no time	1	1

Table 4.6 Participant answer selection to question 2 of the health and lifestyle questionnaire, n=122 at baseline and 90 at follow-up

Question 3. Over the last two weeks, I have felt active and energetic

Response	% of participants at baseline	% of participants at follow-up
All of the time	14	10
Most of the time	36	53
More than half of the time	30	26
Less than half of the time	10	8
Some of the time	8	3
At no time	2	0

Table 4.7 Participant answer selection to question 3 of the health and lifestyle questionnaire, n=122 at baseline and 90 at follow-up

Question 4. Over the last two weeks, I have woke up feeling refreshed and rested

Response	% of participants at baseline	% of participants at follow-up
All of the time	8	4
Most of the time	28	37
More than half of the time	25	30
Less than half of the time	27	20
Some of the time	10	9
At no time	2	0

Table 4.8 Participant answer selection to question 4 of the health and lifestyle questionnaire, n=122 at baseline and 90 at follow-up

Question 5. Over the last two weeks, my daily life has been filled with things that interest me

Response	% of participants at baseline	% of participants at follow-up
All of the time	9	13
Most of the time	48	51
More than half of the time	26	21
Less than half of the time	9	11
Some of the time	7	3
At no time	1	1

Table 4.9 Participant answer selection to question 5 of the health and lifestyle questionnaire, n=122 at baseline and 90 at follow-up

Each participant's raw WHO-5 well-being scores were multiplied by four to give a percentage score out of 100. At baseline, the average WHO-5 score was 67.4%, rising to 69.5% by follow-up, an increase of 2.1%. 15% of participants had no change in their WHO-5 score from baseline to follow-up (n=15). 48% of participants had well-being scores that increased by follow-up (n=43) and 37% of participants' wellbeing scores declined from baseline to follow-up (n=33).

#### 4.3.4.2 Lifestyle assessment

Questions 6 to 11 of the Health and Lifestyle questionnaire assessed the participant's current exercise and diet choices.

Question 6 asked the respondent to state which kind of physical exercises they undertake, if any. As shown in Figure 4.8, the most popular form of exercise at baseline amongst these respondents was walking, with over 61% of the participants (n=74) reporting that they regularly walk. 34% of respondents (n=41) reported that they regularly cycled, 33% regularly ran (n=40), 22% lifted weights (n=27), 17% played team sports such as football (n=21), 15% attended fitness classes (n=18) and 11% swam regularly (n=14). A further 11% (n=13) selected the 'other' box. These respondents further reported using exercise DVDs, attending the gym, gardening, yoga, skiing, kayaking, home workouts, shadow boxing, boxing, karate and rock climbing. 7% of participants (n=9) reported undertaking no regular exercise.

The responses at follow-up for question 6 produced similar results to baseline. The most popular form of exercise, again, was walking, 58% of the participants (n=52) reporting that they regularly walk. As with baseline, running, cycling and weightlifting were amongst the more popular activities at follow-up (38%, 31% and 24% respectively reporting undertaking those activities). 19% reported playing team sports such as football (n=17), 14% attended fitness classes (n=13) and 13% swam regularly (n=12). A further 17% (n=15) selected the 'other' box. These respondents further reported using exercise DVDs, attending the gym, gardening, yoga, skiing, kayaking, home workouts, shadow boxing, boxing,

karate, rock climbing and playing golf. The percentage of participants undertaking no regular exercise fell from 7% at baseline to 4% (n=4) by follow-up.

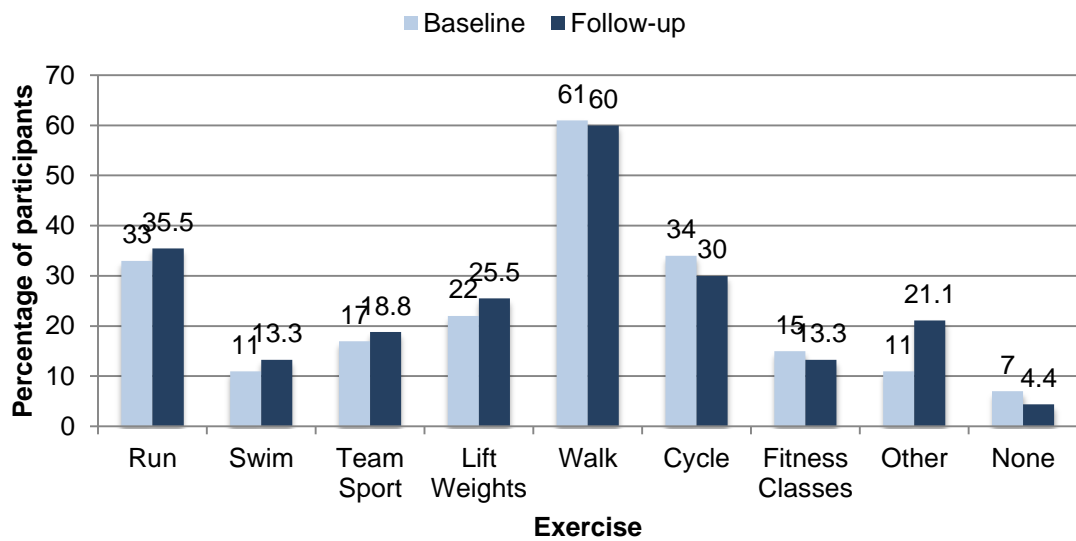


Figure 4.8 Exercise activities reportedly undertaken by the study participants at baseline and follow-up, data collected from the Health and Lifestyle Questionnaire, question 6.

The number of activities that each participant performed was also recorded. As Figure 4.9 illustrates, there was a tendency for fewer people take up multiple physical activities at baseline, with only 9% (n=11) undertaking three or more activities regularly. By follow-up, the majority of respondents, 37%, reported that they undertook 3 or more physical activities regularly (n=33). 28% performed two physical activities regularly (n=25) and 31% performed only one physical activity regularly (n=28). 4% stated that they undertook no regular physical activities (n=4). When these individual results were compared with the baseline results, it would appear that there was a split between those participants whose exercise habits had become healthier (n=4) i.e. they had taken up exercise from previously not doing any and those participants whose habits had become less healthy (n=2), i.e. they partook in fewer exercise activities at follow-up compared with baseline.

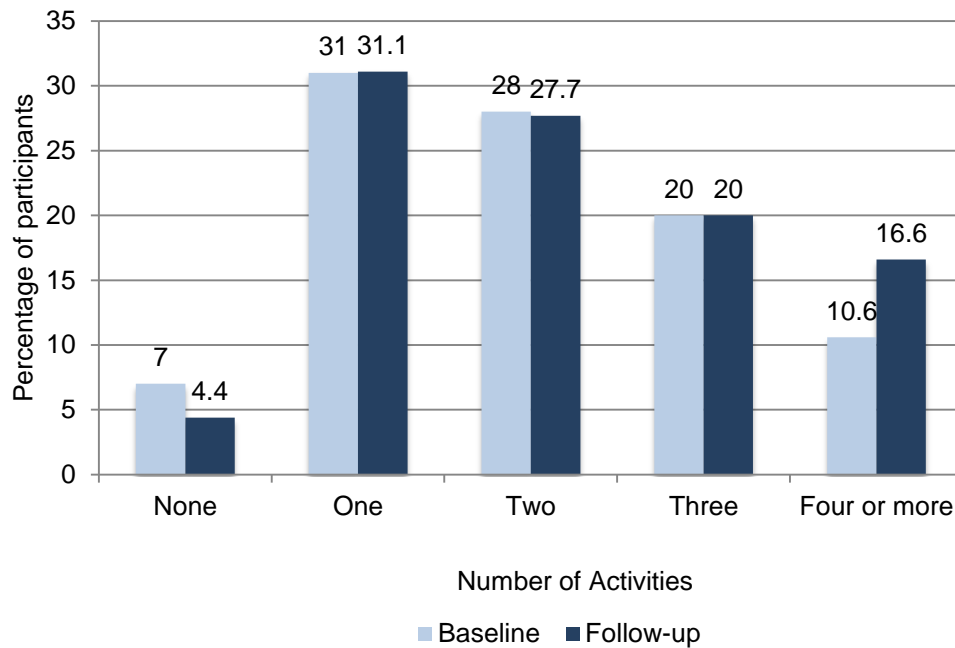


Figure 4.9 Number of physical activities reportedly undertaken by the study participants at baseline and follow-up, data collected from the Health and Lifestyle Questionnaire, question 6.

Question 7 of the Health and Lifestyle Questionnaire aimed to assess how many hours per week each participant spends exercising. As illustrated by Figure 4.10, 47% (n=58) reported exercising 3 hours or more each week, rising to 50% (n=45) by follow-up. 29% (n=35) exercised 1-3 hours/week at baseline, rising to 40% (n=36) at follow-up. There was a decrease in the number of participants reporting less than 1 hour of exercise per week from 14% (n=17) at baseline to 4% (n=4) by follow-up. At baseline, 10% (n=12) reported never exercising, this decreased to 6% (n=5) at follow-up.

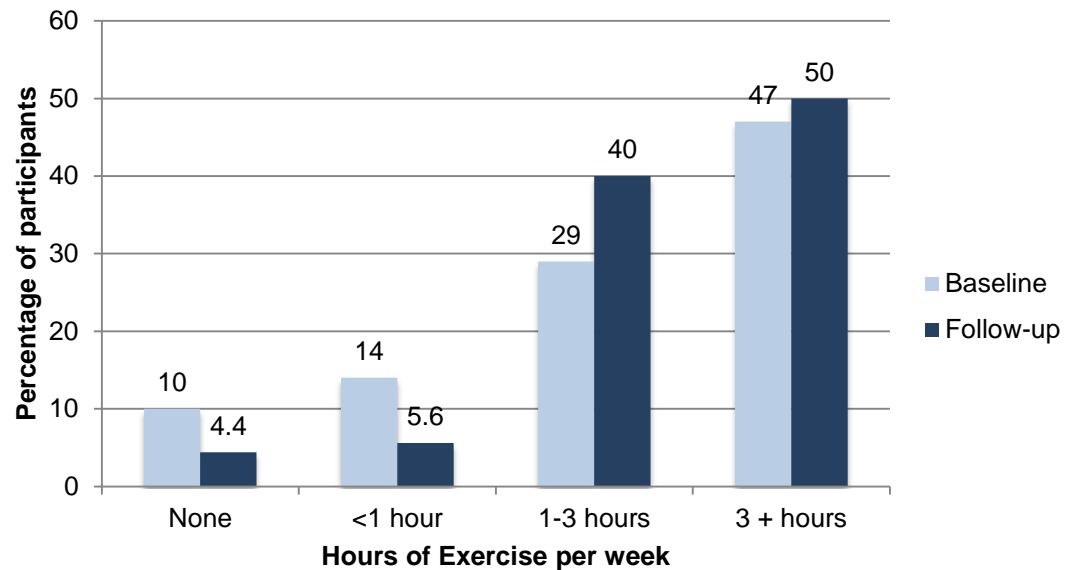


Figure 4.10 Number of hours reportedly spent performing physical activities by the study participants at baseline and follow-up, data collected from the Health and Lifestyle Questionnaire, question 7.

Question 8 aimed to ascertain the frequency in which the participants consumed fresh fruit and vegetables. At baseline 40% (n=49) reported eating fresh fruit and vegetables ‘everyday’, rising to 47% (n=42) at follow-up. 44% (n=54) reported eating fresh fruit and vegetables ‘most days’ at baseline, decreasing to 40% (n=36) by follow-up. A similar percentage of participants reported eating fresh fruit and vegetables ‘every now and then’ at baseline as at follow-up (11 and 10%, respectively). A similar percentage selected ‘hardly ever’ at baseline and follow-up (4% and 3%, respectively). At baseline, 1 participant reported that they never consumed fresh fruit and vegetables, 0 participants reported this at follow-up.

Question 9 aimed to ascertain the participant’s perception of their own body weight. At baseline, 5% believed that they were ‘underweight’ (n=6), decreasing to 1% (n=1) at follow-up. At baseline 50% believed that they were ‘just right’ (n=61), this increased to 56% (n=50) by follow-up. At baseline and follow-up, a similar percentage believed that they were overweight (43%, n=53 and 42%, n=38, respectively).

Question 10 pertained to the participant's perception of their own health. At baseline, 70% of participants reported that they thought of themselves as 'reasonably healthy' (n=86), rising slightly to 74% at follow-up (n=67). Similar percentages reported feeling 'slightly unhealthy' at baseline and follow-up (15%, n=18 and 16%, n=14, respectively), 10% reported feeling 'very healthy' (n=12) at baseline, with a similar percentage reporting the same (9%, n=9) at follow-up. A decrease was seen in the percentage of participants feeling 'very unhealthy' from baseline to follow-up (5% decreasing to 1%).

#### 4.3.4.2.1 Responses to baseline specific questions

Question 11 of the baseline Health and Lifestyle questionnaire asked the participant to report any regular symptoms of ill health that they suffered with. 7 participants reported 'shortness of breath', 4 reported arthritic pain, 3 reported asthma, 3 reported back pain and 2 reported chest pain.

In response to question 12 of the baseline questionnaire, the majority of participants, 61%, reported that they understood their Health Check results after they had received explanation from the advisor (74%). 33% reported that they understood their results without explanation, one participant reported having 'some idea' of the meaning of their results after explanation and 0 participants reported having no idea of what their results meant. 6% did not answer this question (n=7).

Question 13 asked the participants to record whether they intended to make any health or lifestyle changes and which changes they intended to make. 71% of participants recorded that they intended to make lifestyle changes (n=87), 25% stated that they did not intend to make any changes (n=31) and 4 did not answer this question.

Of those that stated they intended to make lifestyle changes, 50 cited that they would like to increase exercise levels, 28 stated that they intend to improve their diet, 12 said that they wanted to either quit or cut down on smoking and 12 stated that they intended to reduce alcohol consumption.



In response to question 14, 70% of participants (n=81) stated that they preferred receiving their Health Check in the community setting compared to having one at their GP practice. 30% reported that it makes no difference where they receive their Health Check (n=34). No participants reported preference to receiving health Checks in primary care.

Question 15 of the baseline questionnaire aimed to evaluate the participant experience the Health Check. Of the 117 participants that answered, 81% rated the experience of their baseline Health Check as 'excellent' (n=95) and 19% rated it as 'good' (n=22).

The final question of the baseline questionnaire was intended for participants that had received a full NHS Health Check only, as it refers to their experience of the POCT. 67% of the 108 participants that received a full NHS Health Check stated that the POCT procedure was 'painless' (n=72), 18% reported that it was 'slightly uncomfortable' but better than providing a venous blood sample (n=19) and 1 participant stated that it was 'more painful' than giving a venous blood sample. 17% also stated that the process was 'convenient' (n=18). 4 participants did not answer this question.

#### 4.3.4.2.2 Responses to follow-up specific questions

Questions 11 to 15 of the follow-up Health and Lifestyle questionnaire were used to record what changes, if any, the participant had achieved since their first Health Check and the reasoning behind them.

By follow-up, 12% of participants reported that they had been to see their GP (n=11), 85% reported that they had not (n=76) and 3% did not answer the question (n=3). Of the 11 that visited their GP, 2 were diagnosed with a new condition, one diagnosis of high blood pressure and one diagnosis of type 2 diabetes. The remaining 9 had no new diagnoses at the time of follow-up, however, one participant was awaiting further testing for high blood pressure.

Question 13 of the follow-up questionnaire asked the participants if they made any lifestyle changes after their initial Health Check. 53% stated that they did not make any changes (n=48), 45% stated that they did make lifestyle changes (n=40) and the remaining 2% did not answer (n=2). Of the 40 participants that reported making lifestyle changes, 50% (n=20) stated that they had already intended to make the changes, 35% stated they made the changes because of the results of their previous Health Check (n=14), 13% stated other reasons such as changes in the seasons and having a baby (n=5) and 1 participant did not answer.

Of the participants that did not make lifestyle changes 57% stated that this was because they had not intended to (n=28), 23% stated that they did not have enough time to make changes (n=11), 14% stated that they had no motivation (n=7) and 6% stated that they did not know which changes to make (n=3).

The final question of the follow-up questionnaire asked if the participant would recommend having a Health Check to their family and friends, of those that answered the question 100% answered 'yes' (n=86). 4 participants did not answer the question.

#### *4.3.5 Results of participants aged 40+ subgroup*

In this study participants ranged in age from 17 to 71 years. Normally to be eligible for an NHSHC, a patient must be aged 40 to 74 years. 69 of the 122 baseline participants and 53 of the 91 participants seen at follow-up were aged 40 to 74, achieving a follow-up rate of 76.8%. This section reports the results of the participants who were aged 40 years and over, ergo the participants who would normally be eligible for an NHSHC, only.

##### *4.3.5.1 Lifestyle change intentions (40+)*

Of the participants that were aged 40+ and completed the full study, 77% stated that they intended to make some sort of lifestyle change (n=41) and the remaining 23% stated that they did not intend to make any changes (n=12).

There was an equal split between participants that reported achieving their intended lifestyle changes by follow-up and those that did not (n=19 for both). Reasons given for making lifestyle changes included: because of the results of initial Health Check (n=11), because they had already intended to make changes (n=7) and 1 participant stated 'other reasons'.

Reasons given for not making intended changes included: lack of time (n=5), lack of motivation (n=3) and not knowing which changes to make (n=1). 9 participants that stated they intended to make lifestyle changes at baseline later stated at follow-up that they had not made those plans.

##### *4.3.5.2 Change in 10-year cardiovascular risk (40+)*

At baseline, QRisk2 scores ranged from 0.6 to 22.5% in the participants that were aged 40+. The average QRisk2 score was 6.47%, with a mode of 5%, median of 4.59 and standard deviation of 5.57 (n=67).

By follow-up, the QRisk2 scores ranged from 0.9 to 26.4% and the average dropped to 6.3%.

At follow-up, 100% of the QRisk2 scores  $\geq 5\%$  belonged to participants in the 40+ years age category (n=23).

#### 4.3.5.3 Change in other risk categories (40+)

For the participants that were 40+, there was little change between baseline and follow-up in the numbers falling within the risk categories for the measurements taken, as shown in Table 4.10.

A greater number of participants were in a high-risk category due to their systolic BP being higher than 140 mmHg at follow-up than at baseline (n=17 and 16 respectively).

Exactly the same numbers of participants were classified as 'overweight' (n=34) and 'obese' (n=5) at baseline as they were at follow-up.

There was a reduction in the number of participants classified as having high cholesterol levels from baseline (n=2) to follow-up (n=0).

From baseline to follow-up, there was an increase seen in the number of participants entering risk categories for blood glucose (n=13 at baseline and n=15 at follow-up).

The number of participants in a 'high' risk category for waist circumference remained the same (n=19), however the number in a 'very high' risk category decreased from baseline (n=8) to follow-up (n=7).

Measurement	% of participants in risk category at baseline	% of participants in risk category at follow-up
Blood pressure	30	32
BMI	74	74
Cholesterol	4	0
Glucose	25	28
Waist circumference	51	49

Table 4.10 Percentage of participants falling in Health Check risk at baseline and follow-up, for participants aged 40+

#### 4.3.5.4 Referrals to GP

Of the 53 participants that we aged 40+, 21 were advised to seek further testing through their GP. 17 of the 21 were advised to get one parameter re-checked, 3 were advised to get 2 parameters re-checked and one participant was advised to get 3 parameters re-checked.

The most frequent referral was due to raised blood pressure (n=17). 8 participant were advised to have a fasting cholesterol test carried out, 5 were advised to have a fasting blood glucose or HbA1c test conducted and one participant was referred to GP for symptoms unrelated to the Health Check.

Recorded referrals for blood pressure agree with the number of participants in a high-risk category for blood pressure (n=17). However, there were more referrals for cholesterol (n=8) than there were participants in a high-risk category for that parameter (n=2). This could be as a result of advisors referring from the cholesterol ratio, rather than the total cholesterol guidelines.

Worryingly, there were fewer referrals for blood glucose (n=5) than participants in the high-risk category for that parameter (n=13). Analysis of the written notes suggests that this under-referral could be down to the advisor deciding that the raised glucose results are due to the participant having recently eaten or having a sugary drink.

#### 4.3.6 Statistical analysis (all participants)

##### 4.3.6.1 Change in 10-year cardiovascular risk

88 participants had a Qrisk2 score calculated at baseline and follow-up.

To eliminate effect of age increase, the Qrisk2 scores were re-calculated for any participants that had a birthday between baseline and follow-up so that the same age was used in both calculations for that individual. This is a method that has been adopted in previous research (Richardson *et al.*, 2011). If all other variables remain constant, an increase in age results in increased Qrisk2 scores.

As detailed in tables 4.2 and 4.3, the mean QRisk2 score decreased from 4.42% at baseline to 4.15% at follow-up. A Kolmogorov-Smirnov test was performed on the difference between the QRisk2 data at baseline and follow-up, this confirmed that it was not normally distributed and was positively skewed ( $p=0.000$ ).

However, because it was evenly distributed around the mean, parametric testing was used.

As the primary outcome of this study, the null hypothesis was that there is no difference between zero and the mean change in Qrisk2 (difference).

To compare the individual participants results at both time points, a paired t-test was performed resulting in a p value of 0.684. This value does not indicate statistical significance in the difference from baseline to follow-up Qrisk2 scores, therefore, the null hypothesis cannot be rejected.

##### 4.3.6.2 Change in blood pressure

All 91 participants that were seen at baseline and follow-up had their blood pressure measured three times, the average of which was recorded and analysed.

Systolic blood pressure increased from baseline to follow-up. As shown in tables 4.2 and 4.8, the mean systolic blood pressure increased from 131.63 mmHg to 134.77 mmHg.

The data was normally distributed according to a Kolmogorov-Smirnov test ( $p=0.200$ ). A paired t-test confirmed that there was significant increase between baseline and follow-up results ( $p=0.046$ ).

#### 4.3.6.3 Change in BMI

All 91 participants that were seen at baseline and follow-up had their BMI measured. As shown in tables 4.2 and 4.8, the average BMI decreased from 26.5 at baseline to 25.9 at follow-up. As this data was not normally distributed, it was transformed using Log10. A paired t-test was performed on the transformed data to confirm that the decrease seen was not statistically significant ( $p=0.501$ ).

#### 4.3.6.4 Change in total cholesterol

83 participants had their total cholesterol measured at baseline and follow-up. On average, there was a decrease seen from baseline to follow-up, 4.96 mmol/L to 4.88 mmol/L. A Kolmogorov-Smirnov test confirmed that the difference was normally distributed and so a paired t-test was performed. The t-test indicated that there was no statistically significant change in total cholesterol between the two time points ( $p=0.097$ ).

#### 4.3.6.5 Change in blood glucose

Average blood glucose levels decreased from 5.69 mmol/L at baseline to 5.58 mmol/L at follow-up.

A Kolmogorov-Smirnov test performed on the difference between the baseline and follow-up data confirmed that it was not normally distributed and was positively skewed ( $p=0.015$ ). However, because it was evenly distributed around the mean, parametric testing was used. A paired t test indicated that the decrease seen was not statistically significant,  $p=0.379$ .

#### 4.3.6.6 Change waist circumference

Across all participants, the average waist circumference was 90.7 cm at baseline, this decreased to 90.1 cm at follow-up. A Kolmogorov-Smirnov test confirmed that the difference was normally distributed ( $p=0.200$ ) and so a paired t-test was performed. The t-test indicated that the observed decrease was not statistically significant,  $p=0.248$ .

#### 4.3.6.7 Referrals and change in QRisk2 score

The graph shown in Figure 4.11 and Table 4.11 illustrate the results of an analysis of covariance, ANCOVA, test of the effect of referral for further testing and/or intention to make lifestyle changes on the change in QRisk2 score.

No real change was seen in CVD risk scores from baseline to follow-up in all groups, with the exception of the group that intended to change and were referred for further testing (orange line). The CVD risk score in the group which were referred for further testing and intended to make lifestyle changes decrease significantly from baseline to follow-up,  $P<0.0001$ .

These results suggest that participants experiencing both referral for further testing and intention to make lifestyle changes have the greatest chance of decreasing their CVD risk score in the short-term.



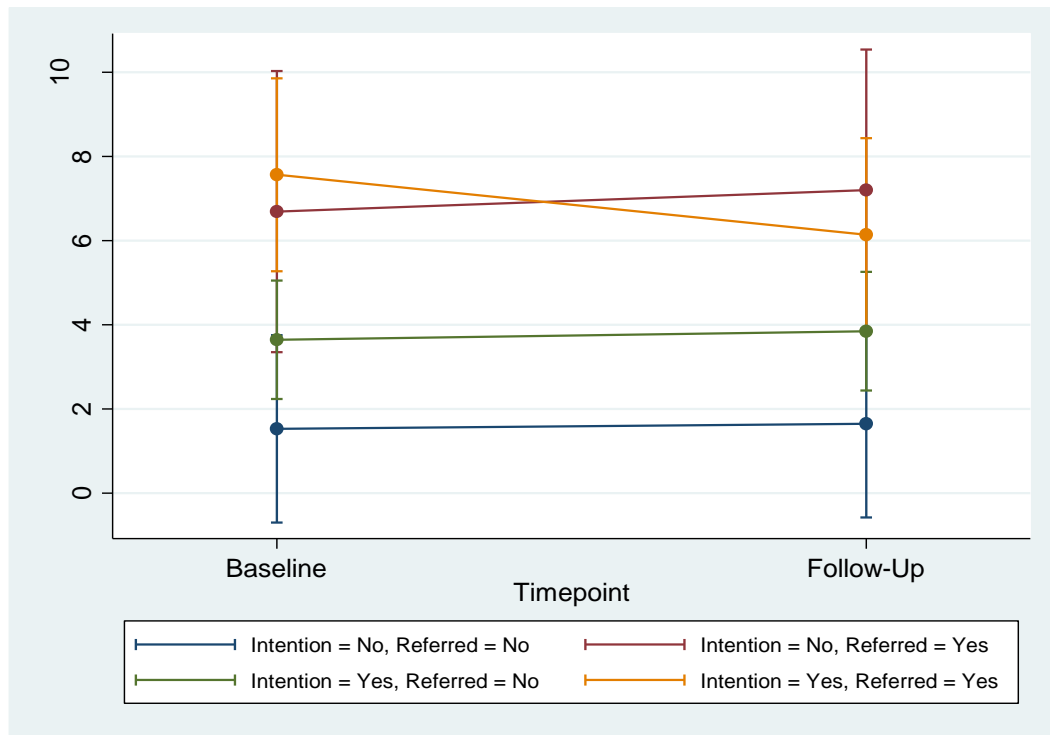


Figure 4.11 Graph illustrating the ANCOVA analysis of the mean CVD risk change in four groups of participants: those not intending to make lifestyle changes and not being referred for further testing (blue line), those intending to make lifestyle changes and not being referred for further testing (green line), those not intending to make lifestyle changes and being referred for further testing (red line) and those intending to make lifestyle changes and being referred for further testing (orange line).

Group	Mean baseline QRisk2	Mean Follow-up QRisk2	Mean change	p-value	95% Confidence Interval	
					Lower	Upper
No intention to change + no referral	1.5278	1.65	0.122	0.678	-0.455	0.699
No intention to change + referral	6.6875	7.2	0.5125	0.246	-0.353	1.378
Intention to change + no referral	3.642	3.8489	0.2067	0.267	-0.158	0.572
Intention to change + referral	7.5647	6.1412	-1.4235	<0.0001	-2.018	-0.829

Table 4.11 Change in QRisk2 from baseline to follow-up in four participant groups: those not intending to make lifestyle changes and not being referred for further testing, those intending to make lifestyle changes and not being referred for further testing, those not intending to make lifestyle changes and being referred for further testing and those intending to make lifestyle changes and being referred for further testing.

#### 4.3.7 Statistical analysis (participants aged 40+)

##### 4.3.7.1 Change in 10-year cardiovascular risk (40+)

53 participants of the participants that were seen at both time points were aged 40 years or older and were eligible for a full NHS Health Check by normal standards. As described in section 4.3.5.2, the mean baseline QRisk2 score was 6.47% decreasing to 6.3% at follow-up.

A Kolmogorov-Smirnov test was performed on the difference between the QRisk2 data at baseline and follow-up, this confirmed that it was not normally distributed and was positively skewed ( $p=0.000$ ). However, because it was evenly distributed around the mean, parametric testing was used. A paired t test indicated that the observed decrease in QRisk2 score was not statistically significant,  $p=0.716$ .

##### 4.3.7.2 Change in blood pressure (40+)

*On average, the systolic blood pressure of the 53 participants aged 40+ increased from baseline to follow-up (134.42 and 135.83 mmHg respectively).*

*The difference in the data was normally distributed according to a Kolmogorov-Smirnov test ( $p=0.200$ ). A paired t-test indicates that the increase was not significant ( $p=0.326$ ).*

#### 4.3.7.3 Change in BMI (40+)

*The average BMI decreased from 26.28 to 26.08 baseline to follow-up ( $n=53$ ). A Kolmogorov-Smirnov test confirmed that the difference in the data was not normally distributed, however, it was evenly distributed across the mean. A paired t test confirmed that the decrease was not statistically significant ( $p=0.297$ ).*

#### 4.3.7.4 Change in total cholesterol (40+)

On average, there was a decrease seen from baseline to follow-up, 5.16 mmol/L to 4.97 mmol/L. A Kolmogorov-Smirnov test confirmed that the difference in the data was not normally distributed, however, it was evenly distributed across the mean. The t-test indicated that there was almost a statistically significant change in total cholesterol from baseline to follow-up ( $p=0.052$ ).

#### 4.3.7.5 Change in blood glucose (40+)

*The average blood glucose decreased from 5.81 to 5.73 mmol/L in the participants aged 40+. A Kolmogorov-Smirnov test confirmed that the difference in the data was not normally distributed, however, it was evenly distributed across the mean. A paired t test confirmed that the decrease was not statistically significant,  $p=0.742$ .*

#### 4.3.7.6 Change waist circumference (40+)

*The average waist circumference in the participants aged 40+ was 91.42 cm at baseline, this decreased to 90.68 cm at follow-up. A Kolmogorov-Smirnov test confirmed that the difference was normally distributed and so a paired t-test was performed. The t-test indicated that the observed decrease was not statistically significant,  $p=0.297$ .*

#### 4.4 Discussion

It is not possible to determine the similarity of the study participants to the general Salford population. It would appear that the participants of this study were healthier than the general population in England and the population of Salford. 18.4% of adults in England and 22.9% of adults in Salford smoke, whereas the prevalence of smokers in this study was 10%. 23% of adults in England and 27% of adults in Salford are obese, whereas only 15% of the study participants were obese. 56% of adults in England and 48.5% of adults in Salford achieve one hour or more of exercise each week, 76% of participants in this study achieve the same goal. However, this data cannot be validated. The population data is derived from one source (PHE, 2015), some of the data is self-reported and not all participants in this study disclosed their smoking status (n=15). It could be that the study participants are more similar in nature to the Salford and England demographics than they first appear. For example, the percentage of overweight and obese adults in this study (62%) more closely matches that of England (63.8%) and Salford (63.3%).

Of the 88 participants that had a QRisk2 score calculated at each time point, a greater percentage, 43% (n=38), saw a decrease in CVD risk from baseline to follow-up, compared with those participants that had an increased CVD risk at follow-up compared with their baseline result, 40% (n=35). Reductions in QRisk2 score ranged from -0.1% to -5% and increases ranged from 0.1% to 3.9%. 17% of participants saw no change in their CVD risk (n=15).

Although this is a positive outcome, no statistically significant changes were seen from baseline to follow-up in the CVD risk score of the study participants as a population. This finding agrees with other studies that have assessed the impact of dietary change on CVD risk. Howard *et al.* (2006) conducted a randomised controlled trial of 48,835 participants over an average of 8 years. This trial found that a dietary intervention that reduced fat intake and increased vegetable, fruit, and grain intake did not significantly reduce the risk of CHD, stroke, or CVD in postmenopausal women and achieved only modest effects on CVD risk factors (Howard *et al.*, 2006). However, other studies assessing the impact of the NHS

Health Check scheme have shown a greater decrease in QRisk2 scores over a longer period of time, 2% over one year (Artac, 2013).

There was a statistically significant increase in blood pressure from baseline to follow-up ( $p=0.046$ ), placing a greater percentage of participants a higher risk category (Table 4.4). There was also an increase in the number of participants that were categorised as higher risk due to their blood glucose measurement at follow-up than there was at baseline. This could indicate that the Health Check has little, or even a detrimental effect on these disease indicators. This could be explained by the potential for health screening to reassure patients in to a false sense of security and thereby prevent the adoption of healthy lifestyle choices (Kinlay and Heller, 1990), discussed in greater detail in Chapter Five. However, it is not possible to determine the cause of this change as blood pressure and random blood glucose readings depend on numerous variables such as physical activity, stress and recent food consumption (Barr, 2010).

Although there were no statistically significant changes in the other parameters tested for by the Health Check, the overall picture is that of slight improvement: fewer participants were in risk categories at follow-up for BMI, waist circumference, total cholesterol and QRisk2 score compared with baseline.

Slight improvements were seen in the well-being of the study group, with a greater percentage of participants achieving increased WHO-5 well-being scores compared with those whose score decreased (48% vs. 37%). Tables 4.5 to 4.9 illustrate the areas in which the scores changed in the group, however, none of the questions produced markedly different results from one time point to another.

There did not appear to be any change in the type of physical activities undertaken from baseline to follow-up, however, the number of activities and the hours spent performing them (Figs 4.9 and 4.10) was increased by follow-up. In addition, some increase was seen in the percentage of participants that reported eating fresh fruit and vegetables on a daily basis, all indicating the adoption of healthier lifestyles. This is supported by the positive change seen in the

participants' perception of their health, with a general shift toward feeling healthier at follow-up.

Just under half of the participants that completed the entire study made healthy lifestyle changes by the follow-up Health Check (n=42). This outcome is contrary to the intentions recorded at baseline, with more participants, 69%, originally stating that they intended to make changes (n=62).

The results of the follow-up questionnaire suggest that the Health Check influenced the decisions of one third (n=14) of the study participants, whereas 48% stated that they had already planned to make the changes.

The majority of the participants preferred receiving their Health Check in the community setting and many stated that they simply would not have had a Health Check in general practice as they do not visit their GP, this is discussed further and evidenced in Chapter Five.

All participants reported a positive Health Check experience and POCT was preferred to the traditional pathology testing process. This suggests that the community is a convenient setting for patients receiving an NHSHC.

Of the 91 participants that were seen at both baseline and follow-up, two received diagnoses of new conditions: one of hypertension and one of diabetes, meaning that there was a new diagnosis as a result of 1.1% of the Checks performed. A recent study of 214,295 patients that received an NHS Health check between 2009 and 2012 was conducted by Robson *et al.* (2016) and found that new diagnoses of hypertension occurred in 3.8% of Checks and new diagnoses of diabetes in 0.9% of Checks (Robson *et al.*, 2016).

If all 31 participants that were referred for further testing at baseline sought consultation with their doctor then the number of new diagnoses could potentially be higher. Only 35% of participants referred for further testing reported visiting their GP post Health Check, the results of this study would be more in line with studies of larger cohorts had there been a greater number of new diagnoses. However, Robson *et al.* (2016) only included at Health Checks performed in

primary care, where patients would not have to take the extra step of arranging a GP appointment for further testing and/or diagnosis as they are already there.

The results of this study would suggest that being referred for further testing as well as having intentions to make healthy lifestyle changes, whether this was actualised or not, had positive impact on the health of the individual. Figure 4.11 illustrates the statistically significant reduction seen in CVD risk of the participants that were referred for further testing and had intentions to change at baseline. This could be because those participants had evidence to suggest that they needed to make changes and therefore started to take their health more seriously as a result of this.

Although the identification of risk factors and diagnosis of related conditions are seen as a positive outcome in that they meet the primary objective of the screening programme, there is evidence to suggest that the treatment that potentially follows can have little benefit or even be detrimental to the patient. A systematic review conducted by Diao *et al.* (2012), concluded that primary prevention of mild hypertension (systolic BP 140-159 mmHg and/or diastolic BP 90-99 mmHg) with hypertensive drugs did not reduce mortality and did not reduce CVD events in 79% of participants (n=7,080). 9% of participants experienced adverse side effects from the drug treatment, causing them to withdraw from the study (n=802) (Diao *et al.*, 2012).

Drugs used to prevent hypercholesterolaemia also face criticism. Currently, the NICE guidance for the primary prevention of hypercholesterolaemia is for patients to be offered statin treatment (20mg atorvastatin) when their 10-year CVD risk score, as calculated by QRisk2, is  $\geq 10\%$  (NICE, 2014a). Although there is a strong evidence base suggesting that statin therapy among individuals with established coronary heart disease (CHD) not only prevents complications related to atherosclerosis but also reduces all-cause mortality, the use of statins in primary prevention has come under debate. A meta-analysis, including 65,229 participants, found that statins had no effect on all-cause mortality when used in a prevention setting i.e. how they would be used for participants flagged with having high cholesterol as part of the NHSCHC (Ray *et al.*, 2010). Abramson *et al.* (2013) highlight that the use of statins can also elicit adverse effects, e.g.

nausea, joint pain, as well as an increased risk of diabetes, again raising questions of the appropriateness of their use on patients without history of CHD (Abramson *et al.*, 2013).

#### *4.4.1 Criticisms of the Health Check procedure*

The Health Check procedure, as described in section 4.2.3.1, *is not without fault. Although BMI is widely accepted as a useful tool in assessing body weight, other measurements, such as waist-to-height ratio, are deemed by some to be a more reliable screening tool for CVD risk factors (Ashwell et al., 2012). A meta-analysis conducted by Ashwell et al. (2012) found robust statistical evidence, assessing more than 300,000 adults, to show waist-to-height is superior to BMI and waist circumference (WC) for detecting CVD risk factors.*

In addition, the position in which the measuring tape is placed on a participant's waist can vary, making the WC measurement highly subjective.

Due to the 'drop-in' nature of the Health Checks provided by the SHIS, the participant does not always have their blood pressure checked in the recommended manner, normally because there is not enough time to provide breaks between the BP measurements. The latest NICE guidelines state that any result of 140/90 mmHg or higher be retaken a few minutes later and that if that is different to the first reading, a third reading should be taken a few minutes after the second, recording the lowest of these readings. NICE also recommends that BP should be measured in both arms in the first instance and if the readings are markedly different, that the measurement be taken in both arms again. If the readings remain markedly different, this should be noted and the arm that provided the highest reading be used for BP measurement in the future (NICE, 2011).

The cholesterol and glucose measurements are non-fasting in these NHSHCs. Although using non-fasting samples for total cholesterol and HDL cholesterol measurements has been deemed appropriate for screening of CVD (Craig *et al.*, 2000), blood sugar levels can vary greatly depending on when the participant last ate, especially if they consumed carbohydrates. This is problematic when



comparing baseline and follow-up glucose results if they were performed at different times of day, i.e. one before a meal and one after a meal.

The use of a CVD risk calculator is necessary for these tests as it is used as a guide for the advisor when making decisions on advice and referrals, they also help provide context for the participant as the QRisk2 calculator additionally provides an average result for an individual of the same age, sex and ethnicity. However, risk calculators have faced criticism for being low in specificity and sensitivity, with most risk calculators missing over one-third of people who subsequently have a heart attack or stroke (Collins and Altman, 2009). A review of the QRisk calculator by Collins and Altman (2009) concluded that the calculator tends to underestimate 10-year CVD risk, yet it is still an improvement on the Framingham risk score. Another review compared the accuracy of the QRisk2 calculator against that of the NICE version of the Framingham and QRisk1. This review concluded that QRisk2 was better at predicting 10 year CVD risk than the NICE version of the Framingham score and marginally better than QRisk1 (Collins and Altman, 2010). Both reviews analysed data sets that had missing data and so the results must be considered with caution.

It is important that the measurements taken as part of the Health Checks be as accurate as possible as they are used to inform decisions that could affect the health of that participant in the future.

As the participants of this study knew that their results were being observed and recorded, it is possible that the Hawthorne effect was elicited, causing participants to modify their behaviours in an unrealistic way. This could have impacted on the Health Check results, as positive health behaviour changes will generally generate healthier results.

#### 4.4.1.1 Suggestions for Health Check procedure improvement

The evidence generated by this study indicates high participant satisfaction with the Health Checks that were performed by the SHIS, however, some changes could be made in order to improve the service provided.

An observation of the height and weight measurement process was that some SHIS staff asked the participants to remove their shoes before stepping on the weighing scales and assessment by the height measure. This produced some variation within the results and also provided inaccurate BMI results in some cases. It is therefore recommended that the service adopts one approach for these measurements, with all staff utilising the same method e.g. shoes removed.

It is also recommended that the SHIS staff refer back to the signposting and referral guidance (Appendix 4.9) when making decisions on whether a patient requires follow-up and/or further testing. Whilst recorded referrals for blood pressure agree with the number of participants in a high-risk category for blood pressure (n=17), more referrals were made for cholesterol (n=8) than there were participants in a high-risk category for that parameter (n=2) and fewer referrals were made for blood glucose (n=5) than participants that were in the high-risk category for that parameter (n=13). It could be that the SHIS staff over-referred participants for cholesterol testing because they were concerned with their TC/HDL ratio rather than their total cholesterol, which the referral guidance is based on. Analysis of the written notes suggests that the under-referral for blood glucose testing could be because the SHIS advisor decided that the raised glucose results are due to the participant having recently eaten a meal or had a sugary drink.

#### *4.4.2 Strengths and weaknesses of the study*

The results of this study are not generalisable as the participants were not representative of the general population due to, for example, the split between male and female participants (78% and 22%, respectively).

While the questionnaire was designed in a manner to reduce ambiguity, as with any questionnaire, the meaning of the questions is susceptible to some variation in interpretation. For example, at baseline 7% did not select any exercise activities that they undertake (question 6), whilst 10% stated that they do not

spend any time exercising when answering question 7 regarding hours spent exercising. This 3% difference could be explained a differing perception of what is classified as exercise i.e. that 3% of participants do not classify walking as a form of exercise.

This study had a relatively short follow-up period of three to four months. Other studies of this nature have adopted longer follow-up periods, for example Artac (2014) looked at CVD Risk change over one year and saw an overall reduction in high risk patients of 2% (Artac, 2013). A randomised controlled trial (RCT) conducted by the OXCHECK study group (1995) found significant decrease in cholesterol and self-reported dietary fat intake over a four year period ( $P < 0.0001$ ) (OXCHECK, 1995). Richardson *et al.* (2011) found significant reductions in blood pressure, anxiety and depression scores over an eighteen month period (all  $P < 0.0001$ ) (Richardson *et al.*, 2011). Perhaps a greater decrease in CVD risk and other associated risk indicators would be seen in this study had the follow-up period been extended.

The actions of the participants may have been influenced by the knowledge that they would be receiving another Health Check in the near future. Participants may have adopted healthier lifestyles in order to improve on their result by follow-up, thereby resulting in better results than they may have been in normal circumstances. However, it is impossible to control for this effect as a control group would still require some form of measurement and it is the measurement, and results of, that are likely to be the cause of the effect.

QRisk2 scores increase when diabetes and/or blood pressure treatment are selected on the calculator. For the participants who received diagnosis of diabetes and hypertension between baseline and follow-up, their QRisk2 scores are increased as a result. This appears to be a negative outcome, when in reality it is positive as it proves that the Health Checks are achieving their aim to detect and prevent those diseases.

The results generated by the Health and Lifestyle Questionnaire were entirely self-reported. This is a weakness, as the data can in no way be verified, potentially leading to unreliable results. However, the semi-structured interviews conducted with 28 of the participants in this study (reported in Chapter Five) go some way in explaining the results of the questionnaires as they concentrate on the influences and barriers to making healthy lifestyle changes.

In this study, the participants with the higher QRisk2 scores and the participants that received new diagnoses of long-term conditions were all over the age of 40 years, this supports the decision to target the 40+ age group as the NHS HC scheme does.

To date, this study is the only research to investigate the effect of local authority delivered Health Checks on patients seen in the community setting. The findings of this research provide some insight into the short-term effects of these particular Health Checks and observations made will be used to help improve the service provided.

## 4.5 Conclusion

This study has shown some slight, but not statistically significant, reduction to the CVD risk of the overall participant population after they received a Health Check, provided by a local authority health team, in the community setting. The only exception to this was the significant CVD risk reduction observed in the participants who intended to make lifestyle changes and were referred for further testing ( $P < 0.0001$ ). Overall, there were high levels of satisfaction with the service and the health of participants improved slightly. Nevertheless, this evidence does not offer any rebuttal to the argument that the scheme is failing to meet its primary objectives of preventing CVD, stroke and dementia whilst helping patients reduce their risk of future disease, nor the argument that the scheme is not cost effective, now costing approximately £450 million per year (Capewell *et al.*, 2015).

As the NHSHC scheme seems to be set to continue, the community setting in an opportune place for the checks to be conducted, facilitated by POCT, as it captures patients who would not normally visit their GP (as evidenced in Chapter Five).

### Abstract

#### Introduction

One of the main objectives of the NHS Health Check programme is to reduce patient risk of cardiovascular disease by providing appropriate health advice. This research focuses on why individuals chose to make health behaviour changes, or not, and the aim of this research was to explore the factors that influence lifestyle choices and assess the role of NHS Health Checks in the workplace, including the impact of POCT use.

#### Methods

32 participants were chosen at random from a pool of participants that had been split in to two groups, intended to make lifestyle changes (Group One) and did not intend to make lifestyle changes (Group Two). Semi-structured interviews lasting approximately 30 minutes were conducted with those participants. Interviews were recorded using Dictaphone and transcribed verbatim. Transcripts were analysed using thematic network analysis.

#### Results

28 of the 32 invited participants completed the interview, 18 from Group One and 10 from Group Two. The main stimuli for health behaviour change were: education, season, challenge, family, standards, availability and enjoyment. The main barriers to health behaviour change were: lack of motivation, commitments, convenience, condition, work, existing health and cost. Participants regarded the NHSHC scheme as important and valuable, appreciating the use of POCT and convenience of having them conducted in the workplace.

#### Conclusion

Participant decision to make healthy lifestyle changes was often made prior to the Health Check, suggesting that having an NHS Health Check did not influence the conscious health behaviours of the study participants. Local authority provided NHSHCs could address more of the barriers and encourage more of the stimuli of health behaviour change than primary care NHSHCs through promotion of other community health initiatives.

The biggest barrier to the adoption of healthier lifestyles was lack of time, which is something that is unlikely to be resolved by a Health Check programme.

## 5.1 Introduction

With advancing healthcare and living conditions in England, children born today can expect to live longer and healthier lives than ever before. Over the last 30 years, average life expectancy has increased from 70.8 to 79.1 years for men and 76.8 to 82.2 years for women (ONS, 2015). However, major health issues still exist, with a third of all deaths occurring before the age of 75. Cancer, heart disease, stroke, respiratory disease and liver disease are the five main causes of premature death in England (Department of Health, 2014).

Cardiovascular disease (CVD) is a general term encompassing diseases of the heart or blood vessels. In 2011, CVD was responsible for nearly 30% of all deaths and is the greatest cause of disability (Department of Health, 2013a).

Many of the risk factors for CVD, such as smoking, high blood pressure, physical inactivity, poor diet and high cholesterol are modifiable through healthy lifestyle choices. This means that it is possible to delay and/or prevent onset of CVD through lifestyle changes.

Another important intention in preventing CVD is screening for known risk factors, high cholesterol and high blood pressure for example, which is the aim of the NHS Health Check scheme.

As previously described, some local authorities now conduct NHS Health Checks (NHSHCs) in workplaces and in the community, for example in supermarkets or at activity groups. The idea behind this is to attract the 'hard-to-reach' individuals who may not visit their GP regularly and so would be less likely to receive a Health Check in primary care.

As well as clinical outcomes, for example change in cholesterol levels, it is important to know the influence that NHS Health Checks have on health behaviours. Screening is used to improve health by early detection of disease and/or risk factors. It may also influence health behaviours either by intention or as a side effect (Deutekom *et al.*, 2010).

Health behaviours are behaviours that may affect an individual's physical health or behaviours that the individual believes will affect their health (Sutton, 2004).

Previous investigations of health behaviour in screening programmes have produced conflicting results.

Miles *et al.* (2003) highlighted that having colorectal cancer screening had positive effect on health behaviours. Miles *et al.* (2003) found that, despite confirmation that they were healthy, improvements were still seen in exercise rates, fruit and vegetable consumption as well as a reduction in smoking (Miles *et al.*, 2003).

Bankhead *et al.* (2003) conducted a systematic review of studies between 1980 and 2000, which investigated behaviour change post-screening. 55 papers were identified, reporting a total of 56 individual studies investigating the effect of cholesterol screening. It was concluded that cholesterol screening had a positive effect on health behaviours with a general move towards the adoption of healthier diets, increased exercise, weight loss and reduction in cholesterol levels (Bankhead *et al.*, 2003).

However, as highlighted by this review, studies in to behaviour change often have methodological issues, for example baseline data was not always recorded. Therefore determination of true cause and effect cannot be made.

Few randomised controlled trials (RCTs) have been conducted on the impact of screening on health behaviours; Deutekom *et al.* (2010) conducted a review of such trials. This review included seven RCTs, four of which investigated the effects of different CVD screening programmes on health behaviours. Three of the trials investigated Health Checks delivered in primary care (OXCHECK, 1995; Wood *et al.*, 1994; Hutchison *et al.*, 1998) and one in the workplace (Strychar *et al.*, 1998). Whilst the four trials of interest included a large sample size, 18,587 participants, there are significant differences in methodologies and outcome measures and so results cannot be pooled to provide an overall outcome. Deutekom *et al.* (2010) concluded that screening for risk factors



provides some positive effect on the health behaviours assessed, namely smoking, diet and exercise assessed (Deutekom *et al.*, 2010).

Conversely, there is some evidence to suggest that risk factor screening may have a negative effect on health behaviours. A study conducted by Kinlay and Heller (1990) found that participants who did not have high cholesterol levels were less likely to respond to population strategies for the reduction of dietary fat intake (Kinlay and Heller, 1990). Barlow (1993) reports that positive screening results for CVD risk factors can have a negative impact on health behaviours such as lowering activity levels as well as a negative impact on mental health due to worry caused (Barlow, 1993).

Screening programmes such as the NHS Health Checks have also been criticised for providing a false sense of security. It has been proposed that patients may think that they can maintain a healthy lifestyle simply by visiting their doctor or receiving Health Checks (Marteau *et al.*, 1996; Stewart-Brown and Farmer, 1997). The 'certificate of health effect' may also be elicited by those who receive normal results from a Health Check; this is where the individual is resistant to health behaviour change because they view their results as confirmation that their existing lifestyle behaviours are healthy (Tymstra and Bieleman, 1987).

Although there is a strong research base on the impact of screening programmes, to date, there has not been any research on the effect of local authority delivered NHS Health Checks on health behaviours.

Whilst Chapter Four concentrates on what happens to the individuals that receive an NHS Health Check, this chapter focuses on why those outcomes may occur. The aim of this research was to explore the factors that influence lifestyle choices and assess the role of NHS Health Checks in the workplace.

Objectives:

1. Explore the stimuli for health behaviour change for patients screened in the workplace

2. Explore the barriers to health behaviour change for patients screened in the workplace
3. Discover the opinion of workplace participants of the workplace screening programme
4. Discover participant's opinion of NHS Health Check programme, with particular focus of the use of POCT

NHS research ethical approval was sought through and granted by the Berkshire B Health Research Authority (HRA).

## 5.2 Methods

### *5.2.1 Design of interview questions and prompts*

Interview questions were designed to assess the participant's reasons for making, or not making, their intended lifestyle changes after their first Health Check. Questions were open-ended in order to avoid bias and to promote full answers. Participants who had intended to make lifestyle changes were grouped into 'Group One' and participants who had not intended to make lifestyle changes were classified as 'Group Two'.

Figure 5.1 illustrates the questions used in the semi-structured interviews. The first question was used to remind the participant of what had happened at their first Health Check and their intentions at that time. Participants from both groups could continue down the left (achieved) side of the flow diagram providing that they completed their original intentions i.e. participants from Group Two who did not intend to make lifestyle changes could achieve this by not making any lifestyle changes and therefore graduate on to the question that asks how they reached that decision.

For participants struggling to answer the question regarding their motivation behind their intention to make lifestyle changes, prompts were used in the form of suggestions e.g. specific results Health Check results, pre-existing intentions, existing sense of health.

For participants who did not achieve their original intentions, the next question tries to ascertain why that may have happened. Example prompts for Group One

participants struggling to answer this include: what issues did you come across? Did anything affect your motivation, and if so, what? Example prompts for Group Two participants struggling to answer this question include: What factors do you think made you change your mind? Was it a conscious decision or do you think it happened due to a change in seasons for example?

In the case of participants who had achieved some original objectives but not others, all four questions in Fig 5.1 were asked.

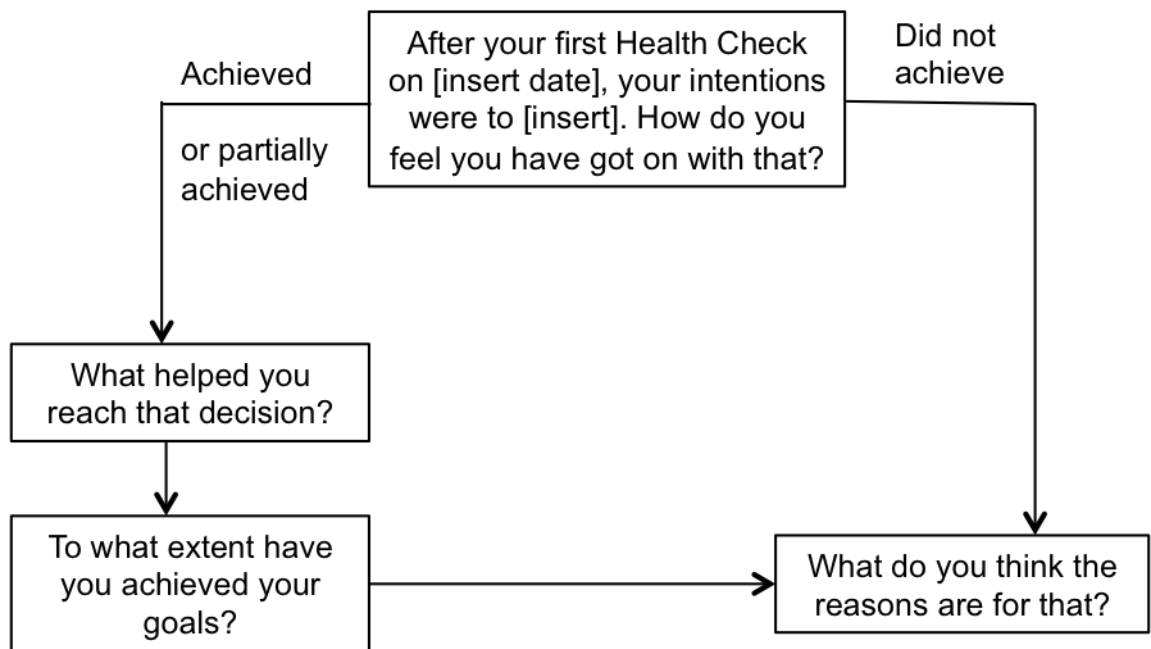


Figure 5.1 Semi-structured interview question flow diagram

Some participants were asked additional questions, as shown in Figure 5.2, which aimed to ascertain their thoughts and opinions on the NHS Health Check scheme as a whole and how it is utilised in the workplace.

For participants struggling to answer the questions concerning the advantages and disadvantages of receiving a Health Check in the workplace as opposed to in a GP practice factors such as time/convenience, safety, testing procedures and staff were used as prompts.

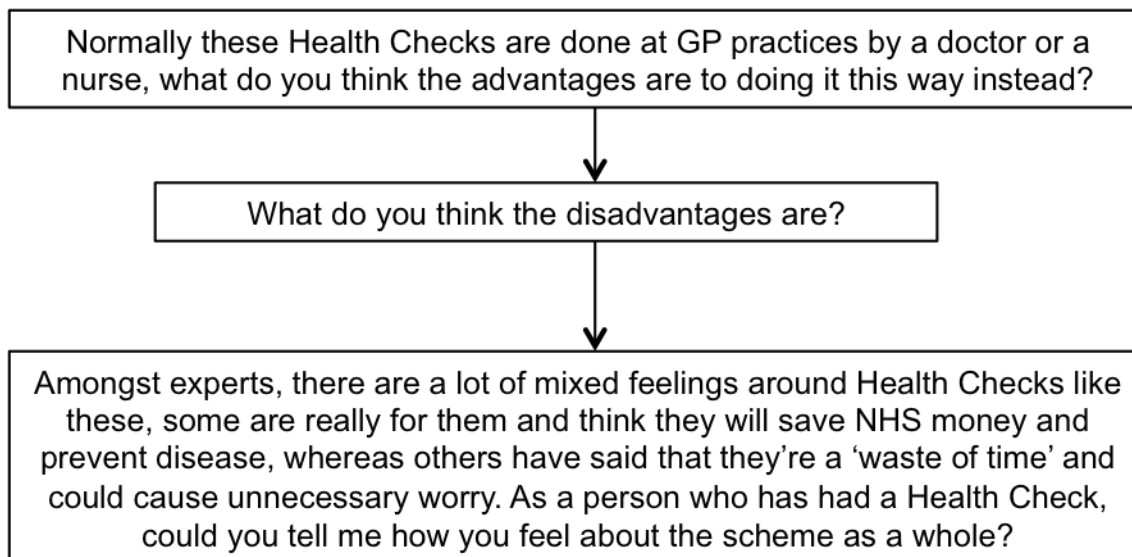


Fig 5.2 A flow chart of additional questions regarding participant opinions on the NHS Health Check

### 5.2.2 Pilot

Interview questions and prompts were piloted on two of the participants that had consented to interview, one from each group. In addition to the predefined questions the pilot participants were also asked if they understood the questions and asked to make suggestions of improvements.

The purpose of piloting the semi-structured interviews was to make sure all questions were appropriate and specific enough to address the objectives of the interview, without excluding the opportunity for the participants to provide extra supporting information.

### 5.2.3 Sampling and data collection

The consent form used for participants recruited to the Health Check study (Chapter Four) additionally asked participants if they would like to participate in a semi-structured interview on completion of their follow-up Health Check. Those who selected 'yes' to this question were recorded as 'consented to interview'. Participants that had their Health Check conducted in the workplace setting (n=89) were divided in to two groups: intended to make lifestyle changes (Group One, n=59) and did not intend to make lifestyle changes (Group Two, n=28) based on information provided in the 'Health and Lifestyle Questionnaire', version 4, (27/11/14) (Appendix 4.9). The workplace was in the manufacturing

sector and employed approximately 300 staff, 72% male, 18% female. Both managerial and manual staff were included.

21 participants from group one and 11 participants from group two were selected at random, using a random number generator, from the pool of ID numbers of participants that had consented to interview. This was done to provide a spread of opinion that was relative to the overall numbers that stated intention to change and those who did not.

Semi-structured interviews were carried out immediately after the participant's follow-up Health Check. Prior to the interview commencing, the participant was reminded that they had consented to be interviewed and for that interview to be audio recorded. At this point, the participant was given the opportunity to withdraw their consent and therefore the interview would not go ahead.

Participants who provided verbal consent at this point were then read a short introduction (Appendix 5.1) that informed them of the aim of the interviews and how the information gained will be used. No participants withdrew consent at this point.

Participants were then asked questions relevant to their original intentions, as described in section 5.2.1, Figure 5.1 and Figure 5.2. At the end of each interview, participants were given the opportunity to ask their own questions and/or provide any additional thoughts, concluding with thanks for their participation. Interviews were audio recorded using a Dictaphone and transcribed verbatim. Once transcribed, audio recordings were deleted. The transcripts were stored using the participant ID numbers, as assigned in Chapter Four (section 4.2.3.1), without identifiable data.

#### *5.2.4 Analysis*

The transcribed interviews were analysed thematically and results were described using thematic networks. As an analytical tool, thematic networks draw on core features that are common in many qualitative research methods (Attride-Stirling, 2001) such as grounded theory (Corbin and Strauss, 1990) and frameworks (Ritchie and Spencer, 1994). Broadly speaking, thematic network analysis is based on argumentation theory (Toulmin, 1958). Argumentation

theory aims to analyse negotiation processes using a structured method, which defines and elaborates the formal elements of arguments. In doing so, argumentation theory explores the connections between explicit statements and implicit meanings found within discourse.

The first stage of thematic analysis was data coding, which involved identifying key words and terms that emerged repeatedly throughout the texts. Themes were extracted from the coded data. A theme should be discrete, yet broad enough to encapsulate a set of ideas (Attride-Stirling, 2001). The initial level of themes identified were classified as 'basic themes'. Basic themes were grouped together in to similar topics, called 'organising themes'. Organising themes were given names that encapsulated all of the basic themes that sat under them. Finally, the main point of the text, which encapsulates the principle metaphor, was deduced, this is known as the 'global theme'. An example of the resulting network can be seen in Figure 5.3.

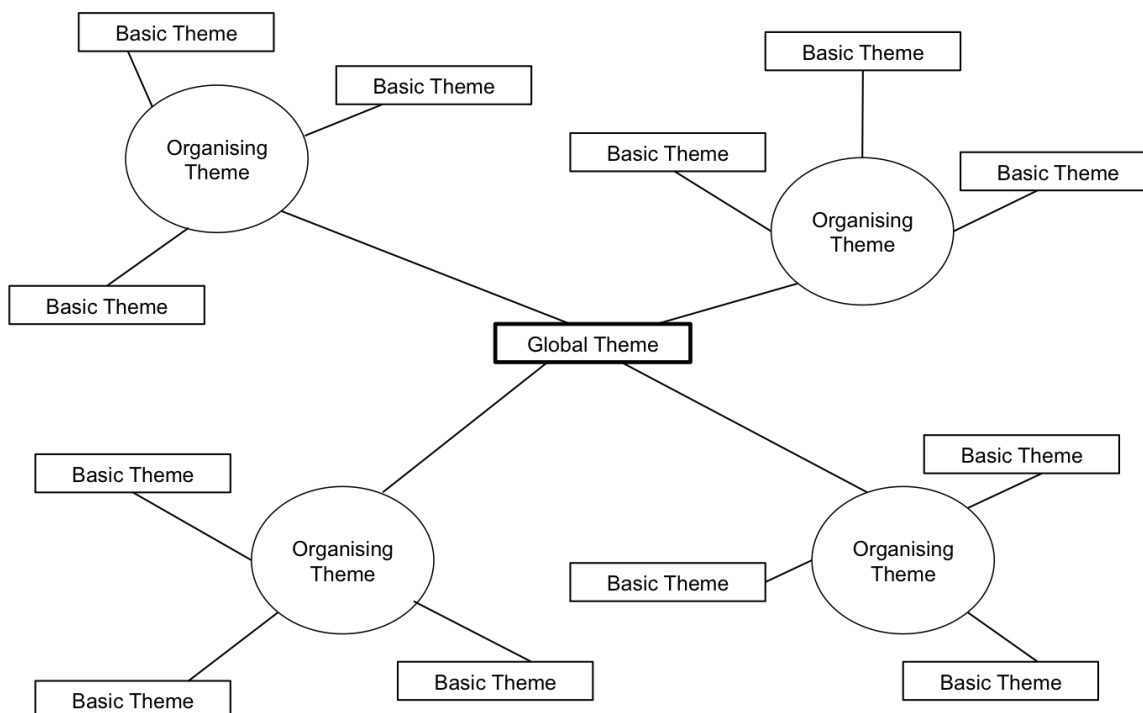


Figure 5.3 Example of a thematic network

## 5.3 Results

### 5.3.1 Result of pilot

The semi-structured interviews were well received by both pilot participants, both reporting that they understood all questions. One participant suggested that more explanation should be added around the final question regarding opinions of the Health Check scheme as a whole. The interview script was amended in accordance with the suggestions made.

### 5.3.2 Uptake and characteristics

As depicted in the consort diagram (Figure 5.4), 28 of the 32 participants that were randomly selected attended the semi-structured interview.

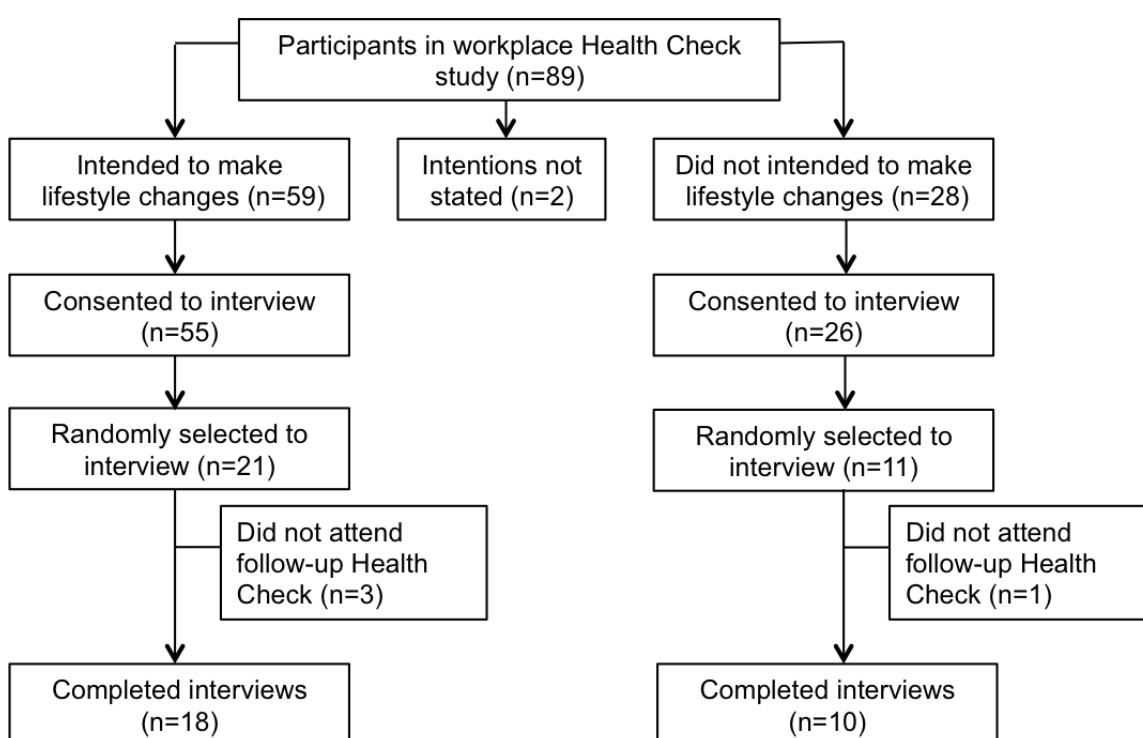


Figure 5.4 Participant selection and uptake

None of the selected participants refused consent on the day of interview.

Table 5.1 shows the participant characteristics for this study. 25 of the participants were male and 3 were female, this was similar to the division of gender at the workplace. All participants were white British. Age ranged from 21-59 with a mode of 42 years. 10 of the participants were aged under the normal inclusion criteria for an NHS Health Check, though the majority of these were 30+ (n=7).

Characteristic	Number
Male	25
Female	3
Aged <40	10
Aged 40+	18
Underweight (BMI <18.5)	0
Ideal weight (BMI 18.5 - 24.9)	10
Overweight (BMI 25 – 30)	14
Obese (BMI 30+)	4
Non-smoker	20
Ex-smoker	6
Light smoker (<10/day)	2

Table 5.1 Semi-structured interview participant characteristics

### *5.3.3 Stimuli of positive health behaviour changes*

Seven main domains were identified from the texts that provided insight into the stimuli for making healthy lifestyle changes, these were: education, season, challenge, family, standards, availability and enjoyment (Figure 5.5).

The age of each participant is provided after each statement along with their participant ID numbers, to be used for reference with the transcripts (Appendices 5.2 and 5.3).



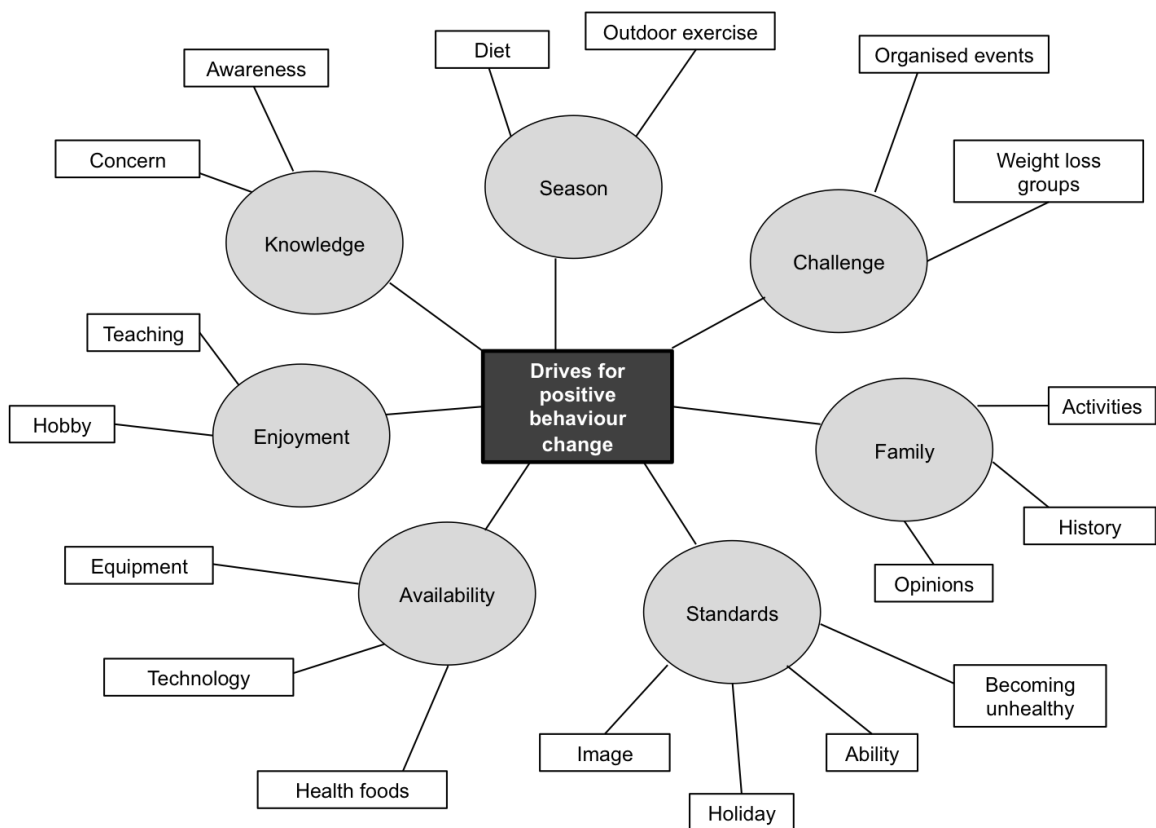


Figure 5.5 Thematic networks displaying the stimuli for positive behaviour change

### 5.3.3.1 Availability

The availability of technologies, equipment and health foods was frequently mentioned as factor that drove and/or aided the participants in making healthy lifestyle choices.

Mobile technologies were mentioned on numerous occasions:

*“I monitor my steps on my phone, you know”* Male, 50 (2448)

*“I’ve actually got an app on my phone now, and well, I’ve got one for me heart rate... one’s called heart rate monitor and it gives you your pulse... And I’ve got another one what’s like keeping an eye on what ya eat”* Male, 59 (1820)

*“I’ve got this thing [shows device], which has been good to me, counting me steps and stuff and, err, it monitors your sleep and stuff like that”* Male, 33 (2307).

Four participants stated that they had blood pressure monitors at home that they used to monitor their blood pressure on a regular basis:

*“Yeah, yeah got one of them monitors”* male, 59 (1947).

Occasionally, a lack of technology was accredited with increasing participant physical activity:

*“my car’s in the garage this week so I’ve been cycling to work”* female, 37 (2349).

Equipment available to some participants also appeared to have positive impact on health behaviours:

*“Got one of those teppanyaki grills”* Male, 57 (1744)

This encouraged the participant to cook healthier meals. Sports equipment had influence on participant choices: one participant intended to start cycling:

*“Get a bike, I keep sayin’ I’ll get a bike so I need to. Go cyclin”* male, 59 (1947),

*“I’ve got roller skates and I go out in the for two or three hours in the nice weather. A gym at home too”* male, 27 (2470)

*“If I bring my trainers. I can have them sitting there staring at me and when I can see them, I think, “oh, well I have to put them on...”* female, 35 (1800).

Smoking cessation aids such as nicotine patches and e-cigarettes were also mentioned as effective when attempting quitting or a reduction in smoking

*“The patches work, they’re the only thing that do...”* male, 43 (1705)

*“Yeah, Yeah went on to the e-cigs about a year or two ago”* male, 39 (1743).

The availability of healthy food was another thing that was quoted as a positive health behaviour:

*“have a handful of nuts every day and a little anti-cholesterol yoghurt”* male, 51 (1758).

### 5.3.3.2 Challenge

The challenge of achieving goals was often stated as a focus that encouraged healthy behaviours, examples of this include:

*“Well, I’ve got a race coming up so I thought it would be a good idea to keep an eye on what I’m eating and stuff”* male, 59 (1820),

*“I did the Manchester 10K... I was the three hundred and twentieth man over fifty” male, 51 (1758)*

For some it was also about proving others wrong:

*“I bought it [Insanity DVD] my wife for Christmas and she said she couldn’t do it, that you needed to be an athlete to do it. I hadn’t ran for two years and I was just about starting up again so I said “well I’ll do it” and I did it” male, 42 (1900).*

For one participant, the new season for American Football was motivation to become fitter:

*“it’s like the new season starts in less than a year so I’ve been given my goal to get ready because I’m gonna go play” male, 32 (2111).*

Some of the participants talked about the progression to meet an objective or challenge, for example participant 1800, female, 35, stated that the Couch to 5K programme continues to help her improve her fitness. Couch to 5K is a free nine-week programme that aims to help anyone, regardless of fitness, run the distance of 5 kilometres.

Another participant talking about how long they had been kickboxing for:

*“Just over ten years I think. Got me back belt in it and then September I’m supposed to be doin’ ma instructor grade” male, 46 (1623).*

Progression and quantifiable achievements encourages the adoption and continuation of a healthier lifestyle.

*Weight loss groups were mentioned by three participants (1800, 1993 and 2307):*

*“tryin’ to follow some of the Slimming World food guidelines... You just don’t realise how much [bread] you eat it until you start cuttin’ it out” female, 35 (1800).*

Weight loss groups are a good way of tracking progress and could even create some friendly competition between attendees.

### 5.3.3.3 Family

The opinion of family and friends was described by some of the participants as something that made them, and others, make positive lifestyle changes. One participant talking about smoking:

*“I gave up last year and I keep telling him that he smells so he has finally given up [laughs]”* female, 31 (1811).

Another participant stated:

*“My boyfriend won’t let me not go”* to the gym, female, 37 (2349).

Another participant suggests that he has taken his wife’s opinion in to account:

*“I just know it’s not good to drink too much. Wife goes on about it too”* male, 48 (1677).

Physical activities arose as another basic theme relating to family:

*“An’ I’ve been goin’ on walks with the dog. Well it’s me daughter’s dog”* male, 59 (1957),  
*“football with the kids and stuff”* male, 39 (1873)  
*“kids keep us active”* male, 50 (2448).

The history of family health appeared to be an influencing factor on participant’s lifestyle choices. When one participant was asked if his father’s “*bland diet*”, lack of exercise and numerous heart attacks had influenced his choice to be more physically active, he said:

*“Erm, yeah it probably has actually. I don’t really think about it like that but I suppose it has done really”* male, 43 (1506).

One participant saw his father as being particularly unhealthy “*overweight, smoked, drank*” as a reason to be more healthy and to get regular health checks:

*“Because of my dad, I’ve got to see my doctor deliberately over the past five to eight years or so, just for cholesterol checks. And then obviously I jump at the opportunity to come here and have it done”* because “*don’t want to turn out like that. So you know, you can’t do anything about the hereditary bit but it may be that his lifestyle was something that played in to it and it was completely different to mine”* Male, 51 (1758).

One participant's parents were both diabetic. She quoted that as being something that had influenced her to have a healthier diet:

*"Yeah, seeing it all happen to my mum and dad is a bit scary...and I don't want to end up like that" and that having a young child provides extra impetus to be healthy* "Especially because of my daughter, you know, I want to be fit and healthy for her" female, 35 (1800).

As well as the history of family health, family traditions also seemed to play a part in participant's current choices:

*"from a drink point of view, my dad didn't really drink...My mum didn't, as such. You know, maybe a glass of wine at New Year or something. So it wasn't really prevalent in the house"* male, 49 (1967).

#### 5.3.3.4 Season

Seasons, or more specifically weather conditions, were a trend that emerged from the texts in relation to physical activity and diet. Some participants quoted warmer weather as having a positive influence on their diets:

*"Few more salads and stuff with it being warmer"* male, 43 (1705).

However, it appeared that warmer, sunnier weather had a bigger influence on the amount and type of outdoor physical activity undertaken:

*"Better weather maybe. I used to do more events in the summer so your trainin' kinda goes up"* male, 48 (1677)

*I started running again now that the weather has got a bit better* male, 39 (1873) *"I already do runnin' and biking already. I suppose I've done more of both since the weather has got a bit better"* male, 42 (2131)

*"do a bit more cyclin' like with the weather bein' nice"* male, 47 (1855).

### 5.3.3.5 Standards

The participant's self-image was theme that emerged from the texts as something that encouraged them to consider their diet and exercise regimen, to attain a goal of how they imagined they should look. When one participant was asked why they wanted to lose weight, they replied:

*"I just want to look better. Fit in my clothes better"*  
female, 31 (1811).

Another participant was encouraged to lose weight when he decided that buying clothes from a retailer that specialises in 'plus size' clothing was below the standards that he had set for himself:

*"I mean, at the moment I can't buy any clothes because I'm mid-sized, so I'm gonna drop again. I'll tell ya how bad it got, and this is what made me go on a diet...Jackamo"* male, 33 (2307)

Going on holiday was another basic theme that emerged from the texts in relation to standards set by the participants. One participant decided to cut down on unhealthy foods because they wanted to look good for their holiday, male, 59 (1947). Another participant decided to restart an intense exercise regimen in preparation for their holiday:

*"So I think I'll start this again before I go on holiday, a few weeks before to get ready"* male, 42 (1900).

It appears as though participants had a clear idea of what they saw as an acceptable body image for themselves whilst on holiday, which inspired them to adopt healthier lifestyle choices in an effort to achieve these standards.

Participants with knowledge of their own ability seem to be spurred on by it, one participant, who is a distance runner, on entering a marathon:

*"I know, someone said "are you mental, at your age?" and I was like "no, I've done 'em before so..."* male, 59 (1820).

Some participants wanted to restore a former physique and fitness that they were happier with, for example, one participant did not originally plan to make lifestyle changes but has become unhealthy due to work commitments, so now feels he needs to make changes to restore his standard, male, 33 (2320).

For some participants it was the standards set by others that motivated them to make lifestyle changes. A participant that had previously made positive health behaviour changes stated:

*“yeah, it was the cholesterol. I had worse cholesterol than people who were much older. Like me dad who was in his sixties”* female, 37 (2349).

#### 5.3.3.6 Knowledge

*Having an NHS Health Check provided participants with information about their health. For some, this knowledge created concern, which in turn instigated some healthy behaviour changes. One example of this is a participant who had previously discussed statins with his GP due to his cholesterol levels and decided to change his diet and increase exercise first before taking statins:*

*“I’m fifty-one...I am aware of my cholesterol bein’ a little high. I had discussed statins with my doctor but I don’t really wanna go down that route just yet”* male, 51 (1758).

For other participants, an awareness of what is, and what is not healthy has provided enough impetus for change:

*“You know, I’m aware that obviously in time, as you get older, you need to change certain things though”* male, 33 (1506)

*“I was always dead skinny growin’ up, right the way through my twenties. But then once I hit thirty, it just started piling on”* female, 37 (2349).

Other participants feel as though if they had previously had more information, they would have made better lifestyle choices at the time:

*“Maybe, maybe I wouldn’t have started smokin’ in the first place is I were to have known how bad it is for you”* male, 43 (1705).

### 5.3.3.7 Enjoyment

Some participants explained that they practiced healthy behaviours because of the enjoyment that they get from doing so.

The enjoyment of physical activity was mentioned on numerous occasions, one participant expresses his enjoyment of riding his bicycle:

*“I enjoy it quite a lot”, which he does “four, five times a week” in all weather, male, 57 (1744).*

For others, regular physical activity is a habit that has lasted twenty-seven years:

*“I cycle in here every day. That’s about three an’ a half miles each way” male, 57 (1777).*

With regards to regular exercise classes one participant, who has been attending kickboxing classes for over ten years, explains that:

*“it makes a big difference if you enjoy it” male, 46 (1623).*



### 5.3.4 Indicators of negative health behaviour changes or no changes

Seven domains that provided insight into reasons for not adopting intended positive behaviour changes (Figure 5.6) these were lack of motivation, commitments, convenience, condition, work, existing health and cost.

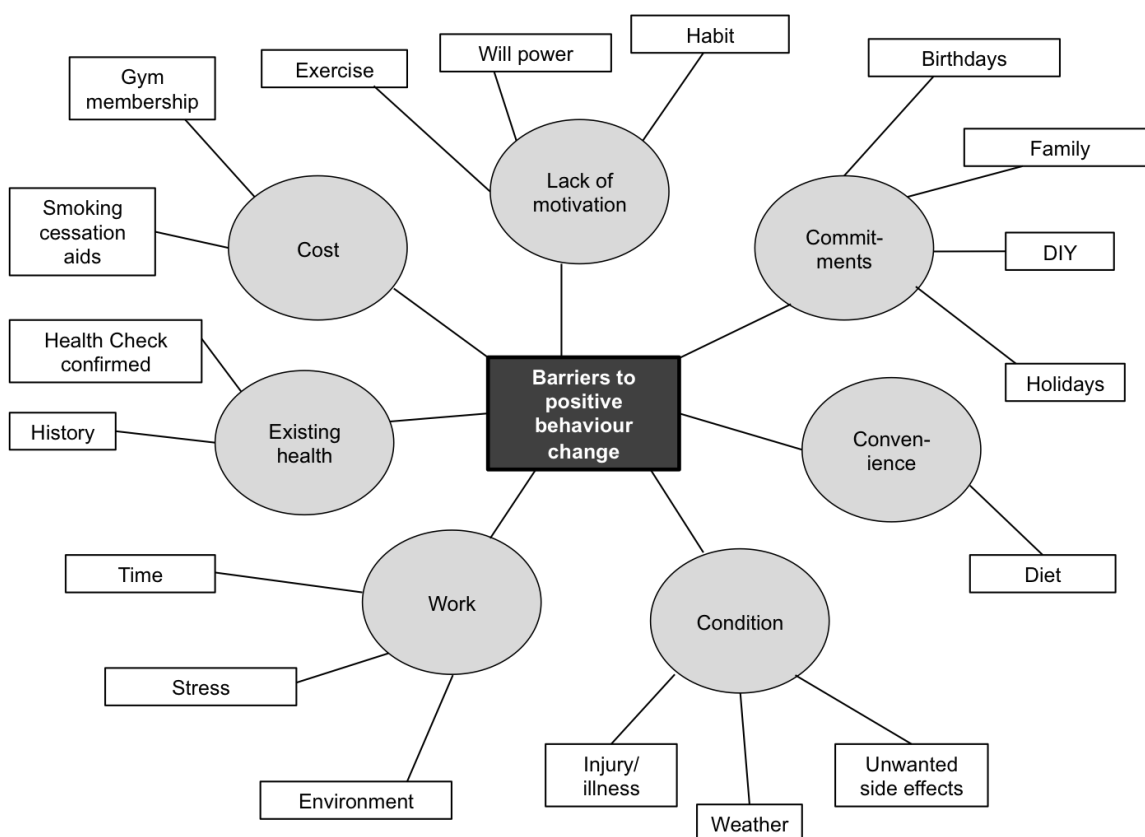


Figure 5.6 Thematic networks displaying the barriers to positive behaviour change

#### 5.3.4.1 Lack of motivation

Lack of motivation was a key organising theme emerging from the text.

Exercise was the most frequently cited factor that the participants of this study wanted to increase, Chapter Four (Chapter Four, section 4.3.3.3), yet it also seemed to be one of the more difficult things to adopt:

*“yeah, so it was like six, seven o’clock when I was having to go”...“And you know, sometimes you just can’t be bothered getting up” female, 37 (2347)*

One participant admitted that their reason for not exercising was often laziness:

*“It’s just being lazy”* male, 27 (2470)

Some participants appeared to lack the will power to pursue their intentions. One participant on the topic of smoking cessation:

*“I was takin’ them [Champix] an’ thinkin’ I’m not actually gonna go the full hog here”* male, 47 (1855)

Another participant who intended to follow Slimming World more rigorously:

*“But sometimes I just think, ah well, what’s the point?”* male, 42 (1993)

Some participants had unhealthy habits that they simply did not want to change, whether they were aware of its consequences or not:

*“this won’t sound good but I get a Subway every morning. But I don’t have sauce” “So like, just beef with salad. And I eat that at like quarter to nine and then I don’t eat here then for the rest of the day”* male, 42 (1993)

*“Still doin’ a mix of tryin’ to eat healthy and then piggin’ out on curries and burgers and stuff “Just what I’ve always done”* male, 46 (1623)

#### 5.3.4.2 Commitments

Other commitments were often obstructive to implementing healthier lifestyle behaviours. The four most often described in this study were family, holidays, birthdays and DIY.

Participants that stated family as being a reason for not implementing healthier behaviours tended to be the parents of young children:

*“I’m just busy, got young children”* male, 44 (2108)

*“Errr, well....not much exercise really. I’ve got four kids, they keep me busy”* male, 39 (1743)

For some, elderly relatives also added to this barrier, for example participant 1993 (male, 42) has four young children and frail parents, all of whom require regular care.

Although holidays were motivators of healthy lifestyle changes for some, they caused delays and setbacks for others:

*“Well, I’ve just been on holiday back home so lots of drinking an’ eating”* male, 27 (2470)

*“we went to Tenby with the granddaughter. So I probably ate a bit too much then”* male, 59 (1820)

Birthdays and parties were another cause of delay or reversal of progress:

*“then I come back off holiday and it was my birthday and you’re thinkin’ and before you know it, that three months has just gone”* male, 43 (1583)

*“Well I’ve been to a lot of parties recently so lots of food and lots of drink”* male, 46 (1623).

Problems around the house and improvement work arose as another basic theme that the participants were committed to, which obstructed their intentions of lifestyle change:

*“I have to do everybody else’s DIY too. Can you just do his trellis? the daughter will be like’ can you do this, can you do that?”* male, 57 (1744)

*“These last...probably last 12 months I been err, renovating me house and it’s err coming to the end now”* male, 59 (1947)

Participating in DIY appeared to be seen as a replacement for exercise in some cases:

*“Only from the fact that I’ve been doing the back garden so I’ve been doin’ a lot of diggin’ and stuff like that”* male, 43 (1583).

#### 5.3.4.3 Convenience

Diet was the main factor affected by convenience, with participants opting to consume food that were readily available. Some were tempted by restaurant and hotel catering as they spent a lot of time in hotels and restaurants because of work:

*“it’s hard to keep the diet on when the food is like right in your face”* female, 31 (1811)

Rather than plan healthy meals or particularly consider the nutritional value of what they ate, some participants tended to eat whatever was available in their house at the time:

*“I tend to be at the whim of what’s in the fridge”* male, 39 (1873)

*“It just tends to be whatever you can get out of the freezer”* male, 59 (1820)

#### 5.3.4.4 Condition

Several participants reported that they had not increased the amount of exercise that they did or that they had to stop exercising due to illness or injury:

*“I had a heavy fall and cracked all my ribs a while ago so couldn’t run for a month”* male, 59 (1820)

*“Well, I actually injured my knee when doin’ Tough Mudder so that’s why I had a break for a few years”* male, 42 (1900)

For some, alternative exercises were not as appealing as their preferred form of exercise, and so they did not do as much exercise:

*“I saw the surgeon a few weeks back and he told me to do cyclin’ but I’d rather do running, I like running”* male, 44 (2108).

For some participants, it was weather conditions that negatively affected their exercise regimen, in wet weather:

*“I managed to do it [run] a couple of times a week for about three weeks but then the weather just go really cold an’ rainy an’ horrible an’ you don’t wanna run in the rain, coming back looking like a drowned rat and having to come back in to work for the rest of the day [laughs]”* female, 35 (1800)

For some, hot weather had a negative impact on exercise:

*“Obviously we’re all tired at some stage, it’s just keeping going. Especially in this weather, ‘cause we’re more winter runners and it’s really hot at the moment”* male, 59 (1820)

More temperate weather influenced other, less healthy lifestyle choices such as smoking:

*“An’ now it’s sunny, it’s easier to go out an’ smoke. I mean you don’t wanna go outside smokin’ in the rain do ya?”* male, 47 (1855)

Several participants stated that potential unwanted side effects were a factor that influenced their decision not to make healthy lifestyle changes. One participant had previously seen marked improvements in weight loss whilst taking a powdered dietary supplement:

*“well that has worked for me before, I lost six and a half...erm, but, err...me hair were fallin’ out, I didn’t feel good ‘n’...yeah, I just came off”* male, 33 (2307)

Other participants were concerned with the adverse side effects from smoking cessation aids:

*“‘cause I’d tried patched before and they, well they’re ok but you end up with throbbin’ in your arms...it’s really weird, can be really painful. You know, you wake up and all the top of your arm is achein”* male, 47 (1855)

*“I mean with those the work, ten out of ten but then you read the leaflet and see some of the side effects like suicide, you know if you’re thinkin’ suicidal then stop immediately”* male, 47 (1855)

#### 5.3.4.5 Work

For some participants in this study, working away from home was a regular occurrence, which impacted on the time that they had to exercise:

*“from Monday to, to Thursday, I am in Leicester so when I come home, I just want to be home”* female, 31 (1811)

*“Well I’m here most days six am to seven pm and in a lot of Saturdays, so it’s just time”* male, 32 (2111)

As well as the time they had to cook healthy meals:

*“we both work so we’re limited as to what we can do”* male, 59 (1820)

Work induced stress was also cited as a reason for adopting less healthy lifestyle choices:

*“I’m in Leicester two weeks out of every three at the minute and at the minute its’ er, it’s very stressful. The management are actually getting involved a lot and stuff like than so I think my alcohol intake has increased”* male, 33 (2320)

Working environment also negatively influenced the choices of some participants; one participant had started to smoke again after quitting:

*“everyone else here smokes so it’s so easy to just go along with that”* male, 27 (2499)

Another participant was subject to drink related peer pressure:

*“Like one day we had a stressful night and my boss’s boss decided to get the Sambuca out and the chilli, chilli vodka. And that was just a Wednesday night”* male, 33 (2320)

#### 5.3.4.6 Existing health

Another key organising theme that emerged from the text was that some participants had a pre-existing sense of health, which lead them to believe that they did not need to make health behaviour changes. For some, this was as a consequence of the Health Check, some participant stated that the pervious Health Check had confirmed their health and helped them decided not to make healthy changes:

*“I mean, I’ve never really had health issues so never worried about it, but it was nice knowing that there was nothing to worry about as a fact sort of thing”* male, 48 (1677)

*“So I thought I could just yeah, relax a little bit. Have that extra whatever...”* male, 49 (1967)

For others, this sense of health came from pervious experience. One participant rarely exercised and found that they did not have to consider their diet:

*“I’ve just always had a...had a really good metabolism”* male, 50 (2448)

#### 5.3.4.7 Cost

There can be a cost associated with adopting some healthier lifestyle behaviours, for example, smoking cessation aids and gym memberships:

*“I was on those Champix weren’t I? But it got too expensive. I’m not payin’ eight pound when everyone else’s was free so...”* male, 47 (1855)

*“Err, I was going to the gym three or four times a week but I’ve cancelled me gym membership because it was getting a bit expensive and I’ve not joined another one yet”* female, 37 (2349)

For these participants, the cost associated with smoking cessation and gym membership contributed to their decision to stop with those particular lifestyle choices.

### 5.3.5 Participant opinion on NHS Health Checks

Six domains provided insight into participant opinion of the NHS Health Check scheme, with particular focus on workplace screening (Figure 5.7), these were knowledge, change, convenience, comfort, value and target.

Participants were asked not only what their experience and thoughts of the HC were but also what they thought HCs do to the bigger picture and other people.

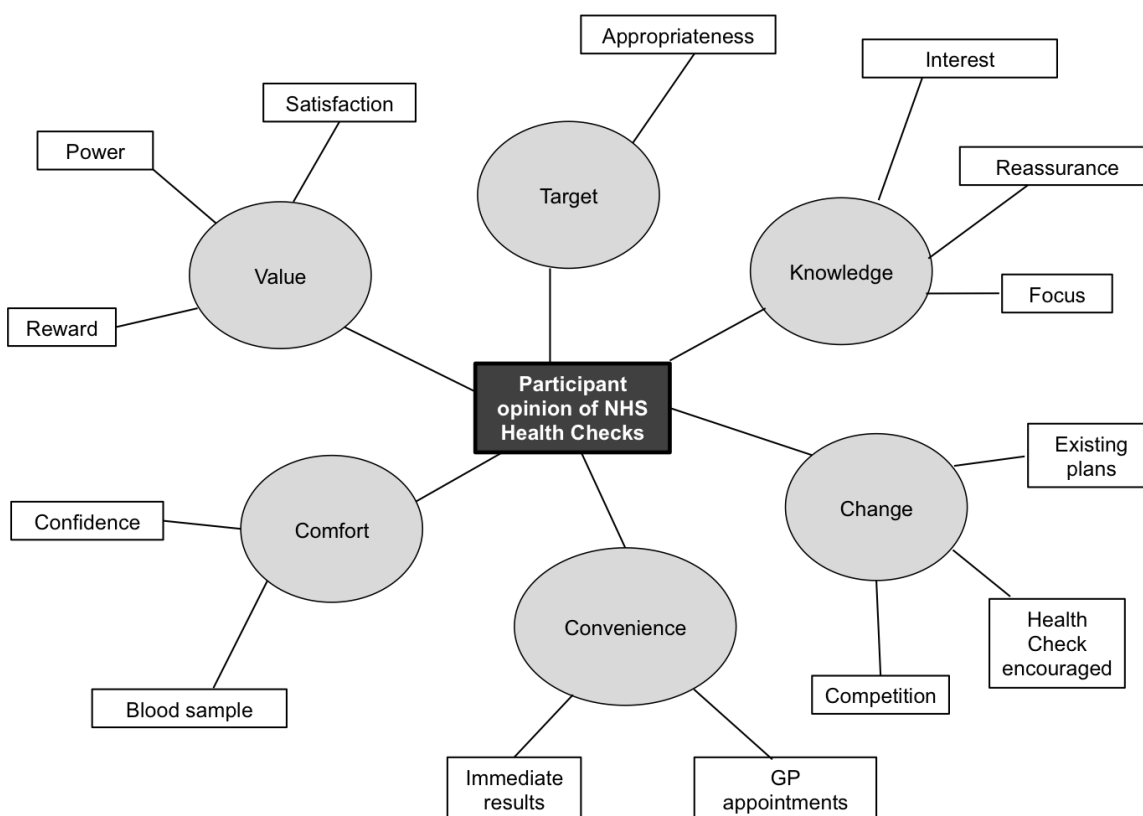


Figure 5.7 Thematic networks displaying participant opinions of the NHS Health Check scheme

#### 5.3.5.1 knowledge

Many participants spoke of the knowledge gained from their health Check as a positive outcome. For most, it seemed to either satisfy an interest, provide focus or provide reassurance that they were healthy:

*“Well, they make me feel happier anyway. And if there was something else wrong, then I’d want to know*



*about it. Comes back to peace of mind again” male, 57 (1777)*

*“it’s just nice knowing that you’re ok. So it can help mentally I suppose. If you’re ok that is” male, 39 (1743)*

*“Err, it’s just interesting. Nice to be healthy, I suppose” male, 21 (2321)*

*“Just good really. Sometimes life takes over and you forget about your health a little bit, this check err, it helps remind you and makes you stop and think a little. Even if your results are ok” female, 31 (1811)*

### 5.3.5.2 Change

When participants were asked what they had based their decision on when they decided to make lifestyle changes, there were mixed opinions. Some stated that they had planned on making the changes for other reasons, before they had a health check:

*“No, obviously I’m fifty-one...I am aware of my cholesterol bein’ a little high. I had discussed statins with my doctor but I don’t really wanna go down that route just yet... definitely, don’t want to turn out like that [father]. So you know, you can’t do anything about the hereditary bit but it may be that his lifestyle was something that played in to it and it was completely different to mine” male, 51(1758)*

Some participants said that they made changes solely because of their Health Check results:

*“It was just seein’ my BMI last time, seeing it in the overweight category” male, 44 (2108)*

And some participants stated that they had previous intentions and that the Health Check reaffirmed them and helped them reach a decision:

*“Err, bit of both really. Always want to do it but then having a check reinforces it” male, 43 (1705)*

*“I think I would ‘ave looked at it [diet] anyways but it was interesting to know that the other results were healthy and that [diet and exercise] was what I needed to focus on*

*without being worried about anything else”* female, 35 (1800).

One participant even reported that their colleagues were comparing heart age results, post-check:

*“Really good. It’s been really interesting. A few of the people in the office have been goin’ round comparing heart ages”* male, 33 (2320)

The competition created by this could have heightened interest and created more impetus for change.

### 5.3.5.3 Convenience

The availability of immediate results during a workplace Health Check was a positive theme emerging from the interviews:

*“this way is just better. I like getting my results quickly. I get nervous if I have to wait for my results”* male, 50 (2448)  
*“it’s nice to not have to wait for results, get it all over an’ done with at once”* male, 57 (1744)

Several participants would be far less likely to receive an NHS Health Check if they were not done in the workplace as booking a GP or nurse appointment appeared to be an issue for some:

*“I don’t go to my GP to be honest, not unless I really have to. It’s just such an arse getting in”* male, 33 (2307)  
*“Not been to my doctor in ages, I’d probably only go if I were dyin’. I’ve just not got the time. Even my wife struggles to get the kids in when she needs to so I’d have no luck”* male, 27 (2499)  
*“Just good to know isn’t it? Havin’ it done here is good because I wouldn’t bother goin’ to the doctors for it to be honest...because I only go to then doctors if there’s something definitely wrong wi’ me. That’s just the way it is”* male, 47 (1855)

However, the point was raised that if a workplace Health Check raised any concerning results, the participant would still have to make an appointment to see their GP, which is less convenient:

*I would say that's a disadvantage but it's still better to know and have to go to a few appointments. I just suppose it's not as good as, err, going to your doctor in the first place"* male, 27 (2470)

*"Suppose if something was properly wrong, I'd still have to make a doctor's appointment wouldn't I?"* male, 43 (1705)

#### 5.3.5.4 Comfort

Many participants spoke of their preference of having a blood sample taken from their finger rather than providing a venous sample:

*"Yeah and I like having them here too...far easier. And I don't like needles either. So these are perfect with the little finger prick things are great"* male, 42 (2131)

*"Err, I'm not a big fan of needles or seeing blood so this way is better than out of my arm"* female, 31 (1811)

Other participants stated that they are interested in all forms of health checks but do not have the confidence to go through with them all, whereas an NHS Health Check was a comfortable concept to them:

*"I'd, I'd love to have the confidence to go for a full men's health kinda of check of things like that...that's what my peers do, sort of every 6 months...yeah, some of them do, the Well Man's Health Clinic. But yeah, I'm not that confident" [laughs]*

Researcher: *"Is it more the testing procedures that you're not comfortable with?"*

Interviewee: *"Err, I'd say so, yeah. Just not comfortable I suppose"* male, 39 (1873).

#### 5.3.5.5 Value

The Health Checks were generally well received by all participants, with many stating that they think the scheme is a good idea:

*"I like things like this. I know I'm young but it's always good to know about your health"* male, 32 (2111)

*I know there are people here who aren't bothered about having it done and I think they're crazy"* male, 51 (1758)

Some participants saw the results of their follow-up Health Check as quite rewarding:

*“I knew I was ok, or I thought I was anyway but having that sort of confirmed has been really pleasing”* male, 44 (2108)  
*Yeah, it shows me that my effort has been working. Feels good”* female, 31 (1811)

However, the power and seriousness of the Health Checks could be questioned when signposting and referrals are not sought. One participant was signposted to their GP for further cholesterol testing, but they did not go, stating:

*“I just didn’t think it was that bad”* male, 43 (1583)

#### 5.3.5.6 Target

Some participants raised a criticism of the NHS Health Check scheme, that it does not target those most at risk of CVD effectively:

*“Like I said, I’m ok for now but there’s people here who aren’t coming for these and they’re the ones who need to...like being overweight and stuff. Surely they’re not as healthy”* male, 48 (1677)

## 5.4 Discussion

The previous chapter, Chapter Four, aimed to assess what happens when individuals receive Health Checks in the community and workplace setting. This chapter aimed to provide some information as to how and some reasoning as to why those outcomes came about.

Thematic analysis of the semi-structured interviews provides insight into the reasoning behind why some people engage in the message of the NHSHCs and make healthy lifestyle changes. As depicted in Figure 5.5, the stimuli for health behaviour change for patients screened in the workplace were season, challenge, family, standards, availability, enjoyment and knowledge. Of these, one of the most commonly cited themes was challenge. It appeared that many participants were motivated by the idea of setting new goals such as completing a race or losing a stated amount of weight and/or gained satisfaction from maintaining a certain level of health derived from achieving previous goals. Participants also liked to use the knowledge that they gained from their Health Check to help set more tailored goals that were relevant to the areas they needed to improve.

Analysis of the interviews also provided suggestions as to why others do not engage in making lifestyle changes. Some participants had no intention of making lifestyle changes due to their belief that it would be unnecessary as they were already healthy. However, several participants stated at baseline that they wished to make some changes but did not achieve them by follow-up. The organising themes emerging from the interviews that explained this were lack of motivation, commitments, convenience, condition, work, existing health and cost. Of those organising themes, the one cited most often, as a barrier to making lifestyle changes, was work. All participants in this study worked for the same employer and some were implementing a new system at another site. The participants that were directly affected by this often said that they were stressed and that trying to be healthier would be too difficult at that time as they were working and staying away from home several nights each week, where there

was greater availability of unhealthy food and drink, which was convenient for them to access. However, the greatest barrier overall was lack of time, with almost all participants stating that it was an issue.

A number of the themes highlighted in Figures 5.5 and 5.6 can be directly addressed using an NHS Health Check. One of the main aims of an NHSHC is to educate the participant on which, if any, of the participants' results can be improved upon and how. Through thorough and appropriate explanation of results, an NHSHC can directly influence the knowledge, and therefore concern and awareness, of the participants. As knowledge has been shown to play a key role in behaviour change, ensuring that each patient understands their results and is provided with appropriate advice is an essential element of the Check that should be continued and promoted amongst staff. Other themes that the NHSHCs can influence are challenge and availability. As part of the wider Health Improvement Service, the SHIS funds and organises a range of community based health initiatives ranging from smoking cessation counselling to healthy cooking classes and fitness classes. Advisors providing SHIS Health Checks can inform patients of these groups and encourage their attendance, thereby impacting on the availability of equipment, technology and health foods whilst also providing challenge through weight loss and running groups, for example. The provision of the aforementioned community groups can also address some of the barriers to positive behaviour change, for example attendance of a community group could provide some motivation, which may have previously been lacking. The groups run by SHIS are free of charge, overcoming another of the stated barriers, cost.

Another objective of the research was to discover participant opinion of the NHS Health Check scheme both within the workplace setting and in general.

The opinions of the participants on the NHSHC scheme in general were positive and tended to focus on the knowledge provided by the checks and how that has helped influenced positive changes for them. Some participants remarked on how the Checks would be of more value to those who purposely avoided them because they knew that their results would indicate that they were not healthy.

Opinions of the workplace Health Checks centred around the convenience of the initiative. Many participants remarked on how they would not have had a Health Check in primary care, either because they had no impetus to make an appointment or because they find it difficult to attend an appointment within primary care, for example because they cannot get an appointment or do not want to take time off work.

The use of Point-of-Care Testing (POCT) for the workplace NHSHCs was well received by the participants, with many stating that they found the process more comfortable and convenient than traditional pathology testing.

As well as raising awareness of potential problems for some participants, the Health Checks reassured other participants that they were healthy. Although this may seem like a positive outcome, this reassurance could actually provide false security and provide patients with reason to continue with potentially unhealthy habits because they view their results as confirmation that their existing lifestyle behaviours are healthy (Kinlay and Heller, 1990; Tymstra and Bieleman, 1987), this is known as the 'certificate of health effect'.

#### *5.4.1 Limitations of the study*

Participants may have felt the need to provide more positive answers to the questions in this study because the researcher who delivered some of the Health Checks conducted this study. This could mean that some key information has been omitted.

Participants knew that they would be receiving a follow-up Health Check, this could have influenced choices and actions, thereby having an impact on their thoughts and opinions of the scheme. For example, a participant may have made more effort to lose weight after their first Health Check because they knew that they would be having another Health Check three months later, potentially resulting in more positive results and more positive feelings towards the scheme than they would have had if there was no follow-up.

## 5.5 Conclusion

Although attitudes towards the workplace NHS Health Checks were entirely positive and there was a move towards healthier lifestyle choices, the majority of participants stated that their decision to make the changes was something that they had previously decided upon, prior to the Health Check. This finding is in agreement with the results of the 'Health and Lifestyle questionnaire' (Appendix 4.11), reported in section 4.3.4.2.2 of Chapter Four, suggesting that having an NHS Health Check did not influence the conscious health behaviours of the study participants.

NHS Health Checks provided by local authorities have advantages over primary care NHS Health Checks as they can influence some of the stated stimuli and barriers shown in Figure 5.5 and 5.6 through promotion of other health schemes provided by the local authority. NHS Health Checks provided by local authorities are also more likely to use POCT to measure cholesterol and glucose, which has not only been shown to have a greater influence on patient response (Laurence *et al.*, 2010) but has also been shown in this study to be preferred over traditional pathology testing due to comfort and convenience. However, something that local authority Health Check cannot overcome is the most commonly stated barrier to the adoption of improved health behaviours, lack of time. This barrier raises questions around the ultimate power of the scheme in any setting as how much time an individual has cannot really be influenced.

It would appear that the provision of NHS Health by local authorities in the workplace setting is an appropriate approach for the NHSHC programme. Many participants stated that they would not make any effort to have an NHS Health Check in primary care and so many eligible patients would go unscreened if workplace initiatives were unavailable.



## Abstract

### Introduction

POCT is used in the delivery of NHS Health Checks (NHSHCs). Some local authorities are now providing NHSHCs in the community and workplace setting, with the aim of screening 'hard-to-reach' patients for cardiovascular disease (CVD). This study aimed to assess the accuracy and reproducibility of the cholesterol and glucose results generated by the POCT device used – the Cholestech LDX (Alere San Diego, CA).

### Methods

Three groups tested and recorded the results of historic external quality assessment (EQA) samples, all of which had a reference value to compare against. *To assess the reproducibility of the results intraclass correlation coefficients and coefficient of variation (CV) were calculated.* Agreement between the two methods (group versus reference value) was assessed using a one-sample t-test of the difference score of the methods. Results were plotted as Bland-Altman plots displaying an additional regression line. Shift tables were used to display any clinical significance arising from variation in results.

### Results

Repeatability of the measurements was excellent. However, as shown in the CV% and the t-test results, the accuracy was poor. The one-sample t-test results indicate that there were statistically significant differences between the reference value and the group results. The CV results were >4%, indicating that the dispersion of results was widespread. The only exception to this was Group Two glucose results ( $p=0.437$ ) and CV <4%.

### Conclusion

The results generated by POCT in this study were not entirely reliable and could result in the production of false negative results. In a screening setting, a false negative could make it seem as though a patient is at less risk than they are in reality, potentially resulting in missed opportunities for further testing or treatment.

## 6.1 Introduction

Due to economic pressures and a general drive for more patient-centred care, the global healthcare environment is changing. Many countries, including the United Kingdom, are being forced to limit or reduce healthcare budgets. One method of doing this is to reduce the number of patients treated in the relatively expensive hospital environment by encouraging more patients to be assessed and treated in primary care or the community.

It is thought that healthcare should be organised around the patient, not the provider, something that centralised pathology testing does not really achieve, as the testing process and consultation process are often disconnected and generally less convenient for the patient.

Point-of-care testing is increasingly being utilised to facilitate a more patient-centred healthcare model that can be delivered in the community (St John and Price, 2014).

Today, cardiovascular disease (CVD) is responsible for approximately one-third of deaths worldwide (Deaton *et al.*, 2011; Naghavi *et al.*, 2014) and in England it is the greatest cause of disability (Department of Health, 2013a). The global burden of CVD is set to increase with the increase of the associated risk factors: dyslipidaemia, hypertension, obesity, diabetes, physical inactivity, poor diet, and smoking.

More than 80% of CVD is attributable to the above risk factors. The good news is that the risk factors are modifiable, meaning that health promotion, screening, early detection and treatment are effective in reducing the numbers of cardiac events. The presence of one risk factor increases the risk of CVD two-fold, the presence of dyslipidaemia, smoking, hypertension and diabetes together, increases the risk of CVD forty-fold (Yusuf *et al.*, 2004).

As previously explained, Chapter One section 1.6, the NHS Health Check (NHS HC) scheme aims to reduce the prevalence of CVD by screening for the risk factors, whilst also promoting patient health through advice and education.

Lipids, primarily total cholesterol, and blood glucose are measured during an NHSHC and provide key information used by CVD risk calculators such as QRisk2. There is a proven positive relationship between total cholesterol concentrations and the risk of future coronary events and mortality as a result of CVD (Shephard *et al.*, 2007).




In order to attract 'hard-to-reach' patients, NHSHCs are increasingly being delivered in community settings e.g. at supermarkets, pharmacies, workplaces and on mobile testing facilities like 'health buses'. Point-of-Care Testing (POCT) is often used to facilitate the 'one stop shop' community delivered Health Check approach.



The Salford Health Improvement Service (SHIS) are an arm of the local authority in Salford, who, amongst many other health related activities, perform NHSHCs in the community setting. SHIS staff are trained in the use of the Alere Cholestech LDX (Alere San Diego, CA) for the analysis of the patient's blood glucose and cholesterol. The staff are not required to have any professional healthcare or pathology-based qualifications.

#### *6.1.1 The POCT device*

There are a number of POCT devices available to test the parameters required by the NHS Health Checks. In a publication by the NHS's Centre for Evidence Based Purchasing (CEP, 2009), guidance is provided for the procurement of POCT devices that test for cholesterol. The document provides information on the technical, operational and economical considerations, as well as market reviews of four transportable devices; the Accutrend Plus (Roche Diagnostics), BeneChek PLUS (General Life Biotechnology Co., Ltd.), CardioChek PA (PTS Diagnostics) and the Cholestech LDX (Alere, San Diego, CA). The guide also reviews two desktop POCT cholesterol analysers; the Piccolo Xpress (Abaxis Inc. CA, US) and the Reflotron Plus (Roche Diagnostics).

The device used by SHIS to perform POCT blood tests for cholesterol and glucose is the Cholestech LDX. Table 6.1 summarises the CEP review.

Device	Cost	Advantages	Disadvantages
Accutrend Plus 	Device: £199  £49 for 25 test strips	<ul style="list-style-type: none"> <li>- Cheap</li> <li>- Reagents stored at room temperature</li> <li>- Capillary blood sample</li> <li>-Fast measurement time (3 minutes)</li> <li>- weighs 140g</li> <li>- Sample applied directly to strip</li> </ul>	<ul style="list-style-type: none"> <li>- Not CRMLN certified</li> <li>- Does not test for HDL</li> <li>- Tests performed individually</li> </ul>
BeneCheck PLUS 	Device: £75  £18.90 for 10 test strips	<ul style="list-style-type: none"> <li>- Cheap</li> <li>- Reagents stored at room temperature</li> <li>- Capillary blood sample</li> <li>-Fast measurement time (30 seconds)</li> <li>- weighs 45g</li> <li>- Sample applied directly to strip</li> </ul>	<ul style="list-style-type: none"> <li>- Not CRMLN certified</li> <li>- Does not test for HDL</li> <li>- Tests performed individually</li> <li>- Manual lot calibration</li> </ul>
CardioChek PA 	Device: £479  £106.37 for 25 TC and HDL strips  £67.20 for 15 TC, HDL	<ul style="list-style-type: none"> <li>- CRMLN certified</li> <li>- Reagents stored at room temperature</li> <li>- Capillary blood sample</li> <li>- Fast measurement time (2 minutes)</li> <li>- weighs 122g</li> </ul>	<ul style="list-style-type: none"> <li>- Manual lot calibration</li> <li>- Sample applied to strip using capillary tube</li> </ul>

	and glucose strips		
<p>Cholestech LDX</p> 	<p>Device: £950</p> <p>£76.45 for 10 TC and HDL cassettes</p> <p>£85 for 10 TC, HDL and glucose cassettes</p>	<ul style="list-style-type: none"> <li>- CRMLN certified</li> <li>- Capillary blood, venous or plasma sample</li> <li>- Automatic lot-specific calibration</li> <li>-Fast measurement time (5 minutes)</li> <li>- weighs 1kg</li> </ul>	<ul style="list-style-type: none"> <li>- Reagents require refrigeration or can be stored at room temperature for 30 days</li> <li>- Sample applied to strip using capillary tube</li> </ul>
<p>Piccolo Xpress</p> 	<p>Device: £13,490</p> <p>£106.40 for 10 centrifugal reagent rotors</p>	<ul style="list-style-type: none"> <li>- CRMLN certified</li> </ul>	<ul style="list-style-type: none"> <li>- Reagents require refrigeration</li> <li>- Lithium heparinised venous blood, serum or plasma</li> <li>- larger sample volume required (100 – 120 µl)</li> <li>- no lot specific calibration</li> <li>- 12 minute measurement time</li> <li>- weighs 5.1 kg</li> <li>- Large sample applied to test chamber using pipette</li> <li>-Desktop (less portable)</li> </ul>


	<p>Device: £3,600</p> <p>£29.10 for 30 TC test strips</p> <p>£35.40 for 30 HDL test strips</p>	<ul style="list-style-type: none"> <li>- Reagents stored at room temperature</li> <li>- Capillary or venous whole blood, serum or plasma</li> <li>- Automatic lot-specific calibration</li> <li>-Fast measurement time (2-3 minutes per test)</li> </ul>	<ul style="list-style-type: none"> <li>- Not CRMLN certified</li> <li>- HCD and TC tests performed separately</li> <li>- weighs 5.3kg</li> <li>- Sample applied to strip by pipette</li> <li>-Desktop (less portable)</li> </ul>
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Table 6.1. Summary of the market review covered in the buyer’s guide for Point-of-Care Testing for Cholesterol Measurement.

The particulars of each device in Table 6.1 have been arranged into ‘advantages’ and ‘disadvantages’ in relation to performing an NHS Health Check in the community. For example, it is advantageous for the reagents to be stored at room temperature as refrigeration is not always available in the community setting. It is also advantageous for the device to measure HDL, as this result is used to calculate the patient’s 10 year cardiovascular risk score. A device that is CRMLN certified is approved by the Cholesterol Reference Method Laboratory Network for the measurement of total cholesterol, high-density lipoprotein (HDL) and low-density lipoprotein (LDL).

The NHS’s Centre for Evidence Based Purchasing (CEP) highlights the advantages of the Cholestech LDX as being: a Cholesterol Reference Method Laboratory Network (CRMLN) certified device, able to measure a wide range of lipid based parameters, automatically performs lot specific calibration and small sample sizes required (CEP, 2009).

However, at the time of publication, the Cholestech LDX is also the most expensive of the small (non-desktop) devices reviewed by the CEP, costing £950

without a printer, excluding VAT. By comparison, the CardioChek PA cost £479 and is also CRMLN certified. The Cholestech LDX uses the most expensive reagents of the devices reviewed - £85 for 10 cassettes that test TC, HDL and glucose, compared with the reagents for the CardioChek PA , which cost £67.20 for 15 strips that test the same parameters.

The Cholestech LDX is CLIA waived. When a device is deemed to be simple and have a low risk for erroneous results by the Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) then it can be CLIA waived. For a test to be classified as 'simple' it must be fully automated and provide a direct read-out of results, without interpretation (Corbin et al., 2012). A CLIA waived device can be operated by individuals without a professional pathology testing (FDA, 2014).

The aim of this research was to assess the accuracy and reproducibility of lipid and glucose results generated using POCT in the community setting. The results were analysed statistically as well as analysed for their clinical significance.

## 6.2 Methods

### 6.2.1 Setting and participants

Participants were selected purposively from a cohort of consenting SHIS staff (n=12). These participants formed group one and were asked to perform testing using the Cholestech LDX on known external quality assessment (EQA) samples in the community setting and to record the results. Group two consisted of the researcher performing the same tests on the same EQA samples and device in the community setting. Group three consisted of the researcher conducting the same tests on the same EQA samples, using the same device but this time in the laboratory setting.

### 6.2.2 Testing process

Historic EQA samples were provided by the UK National External Quality Assessment Service (UKNEQAS). The samples are liquid human serum, prepared from serum obtained through National Blood Service.

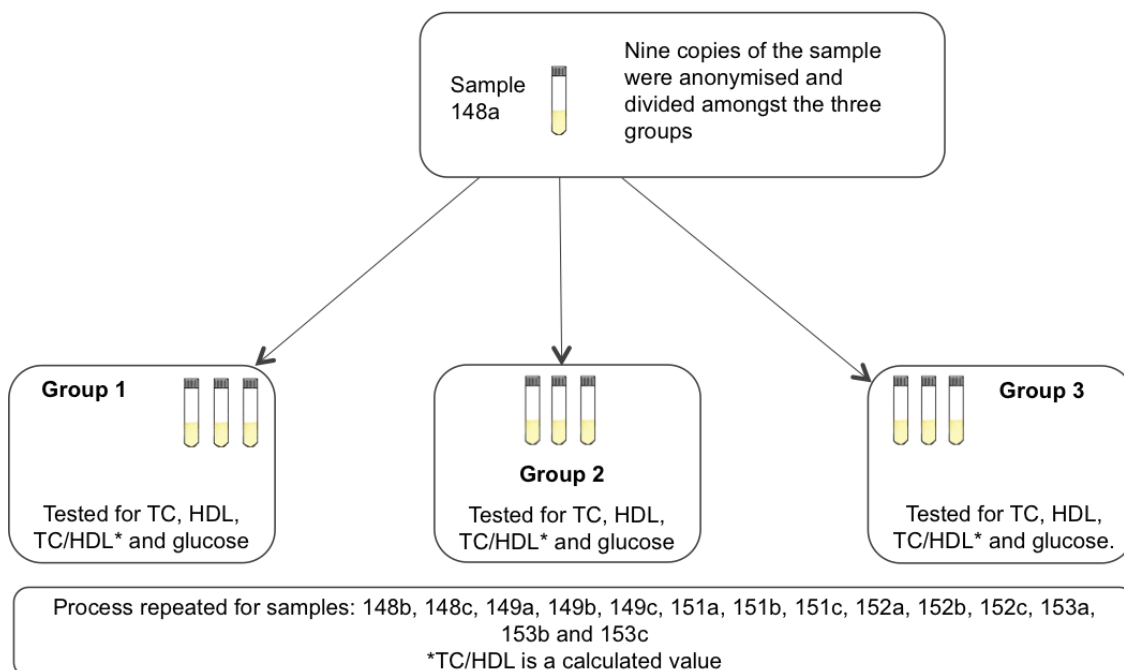


Figure 6.1 Testing process carried out by each group, Group One – SHIS staff in community, Group Two – Researcher in the community and Group Three – Researcher in the laboratory, using sample 148a as an example.



Samples from 5 distributions (148, 149, 151, 152 and 153) were provided. Each distribution contained three different samples (a,b and c), resulting in 15 individual samples, all with a different known values for TC, HDL, TC/HDL and glucose. In this case, the known value was the 'All Laboratory Trimmed Mean' (ALTM), which was calculated by UKNEQAS as part of their Health Check EQA scheme. The ALTM was used as the reference standard or 'gold standard' result. Nine copies of the 15 individual samples were provided in individual vials.

Figure 6.1 depicts the testing process, using one sample as an example. The individual vials were marked with a unique, randomly generated 3-digit identification code, which corresponded to the sample identity e.g. '148a' on a secure spreadsheet. This was done so that the participant did not know the identity of the sample at time of testing and so that the sample results could be translated back to their original sample for comparative analysis.

Participants were instructed to test the sample as if it was a capillary blood sample, using a capillary tube and plunger to collect 40 $\mu$ L of sample from the vial and introduce it to the cassette, as shown in Chapter Four, section 4.2.3.1.

The samples were tested on a Cholestech LDX POCT device using the TC-HDL-GLU cassettes, which provide readings for total cholesterol, high-density lipoprotein (HDL), total cholesterol : HDL ratio (TC/HDL) and glucose, meaning that each sample tested produced four values.

Each sample was tested nine times (three times by each group) and so 135 tests were performed, which resulted in 540 individual result values.

Results recorded on the results forms were transferred on to the spreadsheets for the corresponding samples and parameters. Individual results can be seen in Appendices 6.1 to 6.4.

### 6.2.2.1 Cholestech LDX test principle

Once a cassette is placed in to the Cholestech LDX, the cassette separates the plasma from any blood cells. Following precipitation by dextran phosphate and magnesium acetate, HDL is separated from LDL and VLDL (very low-density lipoprotein). The precipitate containing HDL and glucose is transferred to the HDL and glucose reaction pads.

As depicted in Figure 6.2, the cholesterol TC and HDL are hydrolysed by cholesterol esterase in the filtrate to form free cholesterol and fatty acids. In the presence of oxygen, cholesterol oxidase oxidises the free cholesterol to cholest-4-ene-3-one and hydrogen peroxide. The peroxide reacts with 4-aminoantipyrine and N-ethyl-N-sulfohydroxypropyl-m-toluidine (TOOS), in the presence of horseradish peroxidase to form quinoneimine dye. The resulting dye is used to determine lipid concentrations using reflectance photometry on analyte-specific reaction pads.

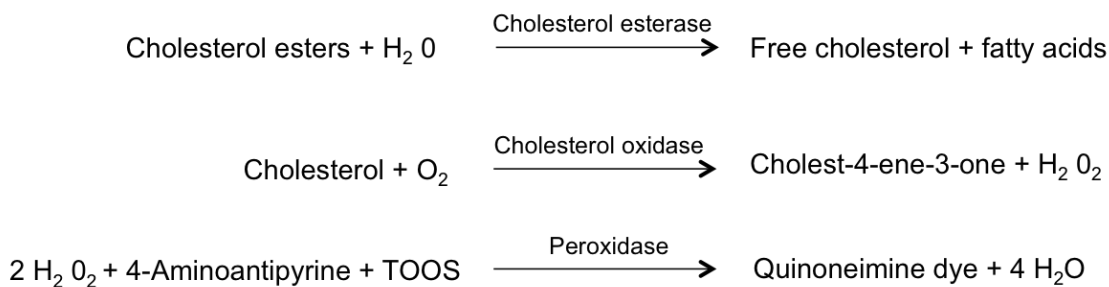


Figure 6.2 Test principle for cholesterol using the Cholestech LDX

Glucose is also measured using an enzymatic reaction. As depicted in Figure 6.3, glucose is oxidised to gluconolactone and hydrogen peroxide. As with the cholesterol reaction, Fig 6.2, the peroxide reacts with 4-aminoantipyrine and N-ethyl-N-sulfohydroxypropyl-m-toluidine (TOOS), in the presence of horseradish peroxidase to form quinoneimine dye. The resultant colour in the dye is measured by reflectance photometry.

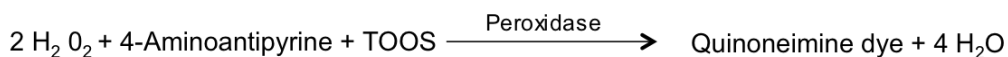
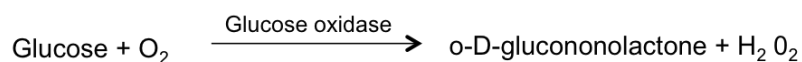


Figure 6.3 Test principle for glucose using the Cholestech LDX

The Cholestech LDX is pre-calibrated by the manufacturer and the brown magnetic strip on the side of the cassette contains encoded calibration information.

#### 6.2.2.2 Cholestech LDX operating conditions

The POCT device was used in accordance with the Alere Cholestech operating guide. The temperature of the room was between 20 and 31 °C for all testing environments, as measured by a portable room thermometer. The device was used on a stable work surface, in a location with no direct heat or light. The optics check cassette was used before testing at each new location or day and results were recorded in the appropriate log. The device was only used if the optics check was in range.

Cassettes were in date and stored in a refrigerator (5°C) from day of receipt until day of use. Before use, cassettes were allowed to come up to room temperature for at least 10 minutes.

#### 6.2.2.3 EQA sample storage and operating conditions

UKNEQAS EQA samples are delivered via postal service. Upon receipt, it is advised that the samples are analysed immediately, if this is not possible, the samples should be stored in a refrigerator at 4°C.

Samples that have been refrigerated should be allowed to come up to room temperature and thoroughly mixed by inverting the vial ten times prior to analysis.

EQA samples should be analysed as if they were blood samples, keeping the Cholestech LDX on the 'whole blood' setting

## 6.2.3 Analysis

### 6.2.3.1 Comparator

Results generated by the three groups were compared to the All Laboratory Trimmed Mean (ALTM). The ALTM was provided by UKNEQAS for each sample. ALTM is calculated by assessing all results generated by participating EQA laboratories/sites, removing any outliers that could distort the distribution and then calculating the mean of the remaining results. ALTM usually agrees closely with the “true value” in schemes with a large number of participants (Hill *et al.*, 1996).

For the distributions provided (148, 149, 151, 152 and 153), UKNEQAS reported results for laboratories using the Reflotron, CardioChek and Cholestech, (Table 6.1).

### 6.2.3.2 Repeatability of measurements

Intraclass correlation coefficients (ICC) were calculated for each set of results. ICCs describe how strongly units in the same group resemble each other and are therefore seen as a measure of repeatability. An ICC of <0.4 indicates poor reproducibility, an ICC of 0.4 - 0.75 indicates good reproducibility and an ICC of >0.75 indicates excellent reproducibility (Dale *et al.*, 2008). Results are shown in Table 6.2.

The coefficient of variation (CV) was calculated (standard deviation/mean x 100) for each result and reported in Table 6.2 as a percentage. CV is a measure of dispersion of a distribution and is a standardisation of the standard deviation, which allows comparison of variability estimates regardless of the magnitude of analyte concentration (Reed *et al.*, 2003). The lower the CV%, the better. It is generally accepted that a CV of  $\leq 5\%$  shows a good level of method performance (Zady, 2009).

### 6.2.3.3 Plotting the data (accuracy)

Agreement between the two measurements was initially assessed using a one-sample t-test of the difference score of the two methods, group results versus ALTM.

In place of displaying the results using simple XY plots, Bland-Altman plots were used for each set of results, as they are a better measure of agreement. XY plots comparing method 'A' to method 'B' by design, show the data to cluster around the regression line, especially if a wide-spread data set is analysed (Altman and Bland, 1987).

Bland-Altman plots are difference plots that display the agreement between two different assays. The Bland-Altman plots displayed in this chapter (Figs. 6.4 – 6.15) have additional bivariate lineal regression lines (green line), which show the difference between the score (Y) and the average of the score (X). As explained in section 6.3.1.1, a regression line showing good levels of agreement will typically be flat; a slope would suggest proportional bias. For example a positive slope indicated that the group results become less accurate as the result score increases.

### 6.2.3.4 Impact on clinical significance

Shift tables were devised to display the number of results that were in agreement and disagreement with the reference standard, the ALTM. These were firstly categorised using referral cut-off points as used by the SHIS in the NHS Health Checks that they provide. A total cholesterol (TC) of <7.5 mmol/L does not warrant referral to GP, whereas a TC of >7.5 mmol/L does. A random blood glucose of <6.0 mmol/L does not warrant referral, a result of 6.1-11.0 mmol/L warrants referral to GP for a fasting blood glucose test or HbA1c within 4 weeks, a result of 11.1-17.9 mmol/L warrants a one week referral to GP and a result  $\geq$  18 mmol/L warrants referral within 48 hours. See Appendix 4.9 for more details of SHIS referral and signposting guidance.

As discussed in Chapter One (section 1.6) the NHS Health Check includes calculation of CVD risk scores using the results generated during the check. The SHIS tends to use the QRisk2 score for this purpose, however, as QRisk2 is

calculated using an algorithm it was not applicable to use with a shift table as discrete result boundaries are needed. Therefore, the results were categorised in accordance with the Framingham general CVD (10-year risk) profile (Wilson *et al.*, 1998), which predicts absolute CVD risk over a 10-year period from the following variables: age, sex, treated- and untreated-systolic blood pressure, total cholesterol, HDL cholesterol, smoking status and presence of diabetes.

The Framingham 10 year risk score works on a points basis with healthier results receiving negative or zero points and less healthy results receiving positive points, therefore the higher the overall score, the higher the risk score, which is indicative of an increased likelihood of a cardiac event. For total cholesterol, the 5 categories are as follows: <4.14 mmol/L, 4.15 - 5.17 mmol/L, 5.18 – 6.21 mmol/L, 6.22 – 7.24 mmol/L and  $\geq 7.25$  mmol/L, lower results are preferred for this parameter and so receive negative Framingham points. For HDL cholesterol the categories are: <0.9 mmol/L, 0.91 – 1.16 mmol/L, 1.17 – 1.29 mmol/L, 1.30 – 1.55 mmol/L and  $\geq 1.56$  mmol/L. Higher results are preferred for HDL and so they receive negative Framingham points.

## 6.3 Results

### *6.3.1 Accuracy and repeatability*

As shown in Table 6.2, the general repeatability of the measurements was excellent, with all ICCs above 0.75. However, as shown by the CV and the t-test for the difference between the group result and ALTM, the accuracy of the results was poor. The one sample t-test results indicate that there is statistically significant differences between the ALTM and the group results. The CV results were >4%, indicating that the dispersion of results was widespread. The only exception to this was Group Two glucose results ( $p=0.437$ ) and CV <4%.

There are only 42 observations for total cholesterol and TC/HDL. The Cholestech LDX lower limit of detection (LLD) for total cholesterol is 2.6 mmol/L. The results reported for sample 151a in all groups was <2.59, therefore these

results, along with the calculated TC/HDL result for this sample could not be included in analysis.

The coefficient of variation (CV) reported in Table 6.2 is an average for each group.

Analyte	Group	Observations (n)	Mean difference t-test (p) to ALTM	CV (%)	Intraclass Correlation Coefficient (ICC)	Slope	Intercept	Bland- Altman lower limit	Bland- Altman upper limit
TC	1	42	0.000	4.33	0.956	1.130	-0.337	-0.393	0.918
	2	42	0.000	4.38	0.969	1.143	-0.307	-0.264	0.908
	3	42	0.000	4.04	0.932	1.271	-0.742	-0.423	1.270
HDL	1	45	0.000	8.27	0.833	1.035	0.173	-0.264	0.695
	2	45	0.000	6.22	0.798	1.050	0.186	-0.188	0.679
	3	45	0.000	5.42	0.833	1.121	0.058	-0.197	0.613
TC/HDL	1	42	0.003	8.04	0.939	0.948	0.433	-0.712	1.185
	2	42	0.002	7.20	0.903	1.081	-0.112	-0.542	0.939
	3	42	0.000	6.87	0.933	1.166	0.169	-0.323	1.179
Glucose	1	45	0.009	4.07	0.989	1.009	0.162	-1.052	1.605
	2	45	0.437	3.55	0.980	1.010	-0.064	-0.918	1.034
	3	45	0.000	4.79	0.989	1.036	0.398	-0.860	2.516

Table 6.2 Assessment of the accuracy and reproducibility of community POCT (Groups One and Two) and laboratory based POCT (Group Three) compared to reference value, ALTM.



### 6.3.1.1 Interpreting the Bland-Altman difference plots

Figures 6.4 to 6.15 are Bland-Altman difference plots, which compare the difference between the results generated by the three groups and the reference values (ALTM) for each parameter. On each plot, the two red lines indicate the 95% limits of agreement (average difference  $\pm$  1.96 standard deviation of the difference), which shows how far apart measurements by the two methods are likely to be for 95% of operators. The blue line is where  $y=0$  and indicates perfect average agreement between the methods. The purple line is the observed average agreement of the two methods; this will sit close to the line of perfect average agreement (blue line) if there is a good level of agreement between the two methods. The green line represents the bivariate lineal regression line, which show the difference between the score (Y) and the average of the score (X). A regression line showing good levels of agreement will typically be flat; a slope would suggest proportional bias. For example a positive slope indicated that the group results become less accurate as the result score increases. The small yellow dots indicate the individual data points.

A Bland-Altman plot displaying good levels of agreement will typically have limits of agreement that are reasonably close together. This cannot simply be assessed on first glance, however, as the range on the y-axis must also be taken in to account. For example, the Figures 6.14 and 6.15 represent the agreement between Group Two glucose results versus ALTM and Group Three glucose results versus ALTM. The upper and lower limits of agreement appear to be closer in for Group Three (Fig. 6.15) than they do for Group Two (Fig. 6.14) but the y-axis indicates that there is a larger range of values represented in Figure 6.14 and so the limits of agreement are actually closer in Figure 6.13 (-0.918 to 1.034 and -0.860 to 2.515, respectively). Using this example, it means that the difference between the measurements of Group Two compared with ALTM results should fall within a smaller range approximately 95% of the time, compared with the results generated by Group Three. Therefore, the closer the upper and lower limits of agreement, Table 6.2 and Figs 6.4 - 6.15, the better the agreement of that groups results to the ALTM.

If the group results were in perfect agreement with the reference value (ALTM) then the purple line (observed average agreement) would be on top of the blue line (perfect average agreement), none of the groups in this study achieved this. The further the blue line from the purple line, the lower the level of agreement. Group Two glucose results vs. ALTM, Fig. 6.14, was the closest to achieving perfect agreement.

If the regression line is flat across the x-axis i.e. there is no slope, this would indicate that the expected results would not change from one end of the x-axis to the other. Conversely, if there were a slope present on the regression line, this would indicate some non-uniformity of the error, which could be down to concentration dependant or proportional bias. For example, a positive slope, such as the one seen in Fig. 6.6 Group Three total cholesterol results vs. ALTM, would suggest that the group results became less accurate as the concentration of the sample increased.

### *6.3.2 Total cholesterol results*

Although the ICC results suggest excellent reproducibility, the TC results of all three groups differed significantly from the ALTM ( $p=0.000$ ). The Bland-Altman plots (Figures 6.4 – 6.6) show a scatter of the results, with the observed average agreement distinctly separate to the perfect level of agreement ( $y=0$ ). The regression line on the plots for all three groups suggests some concentration dependant bias. This is shown on the plot where the result points become more scattered toward higher concentrations (the right side of the x-axis). This shows that the group results are less agreeable with the ALTM at higher concentrations, therefore the group results are less accurate at higher concentrations. After assessment of the confidence limits, the plots suggest that Group One performed the best and Group Three the worst as the distance between the upper and lower limits was closest for Group One. This conclusion is supported by the mean difference plot shown in Figure 6.16.

### *6.3.3 HDL cholesterol results*

Although the ICC results suggest excellent reproducibility, the HDL results of all three groups differed significantly ( $p=0.000$ ) from the ALTM. The Bland-Altman plots (figs 6.7 – 6.9) illustrate this lack of agreement with the observed average agreement distinctly separate to the perfect level of agreement ( $y=0$ ) in all groups. As Group Three had the closest confidence limits and the line of observed average agreement is closest to the line of perfect average agreement in this group, it appears that this group performed marginally better than the other groups for this parameter. The plots for all three groups display a large scatter of the results across the x-axis, suggesting systematic bias and error.

### *6.3.4 TC/HDL results*

Again, the ICC results suggest excellent reproducibility of results across all groups. However, the scatter of results across all three plots (Fig 6.10 – 6.12), and the distance between the observed average agreement and the perfect average agreement lines shows that the results differ significantly from the ALTM for all groups. All groups suffer with concentration dependant bias, with Group Three displaying the largest scatter and widest gap between the line of observed average agreement and the line of perfect average agreement.

### *6.3.5 Glucose results*

The Bland-Altman plots (Figs. 6.13-6.15) show that the observed average agreement lines sit closer to the perfect level of agreement ( $y=0$ ) lines in these plots when compared with the plots for the other parameters, this is particularly evident in the plots for Groups One and Two. This is because the results for glucose tended to be closer to the ALTM than for the other parameters, especially in Group Two, the only group to achieve results that were not significantly different to the ALTM. The scatter in all plots for this parameter suggests some systematic bias/error.

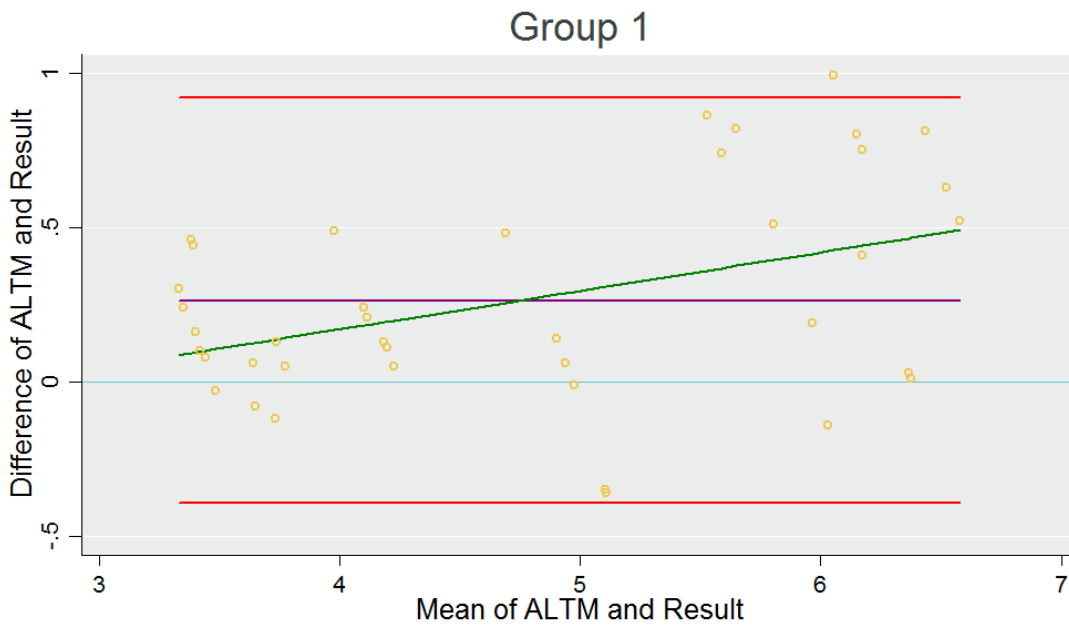


Fig. 6.4 Bland-Altman plot displaying Group One (SHIS staff) results vs. ALTM for total cholesterol

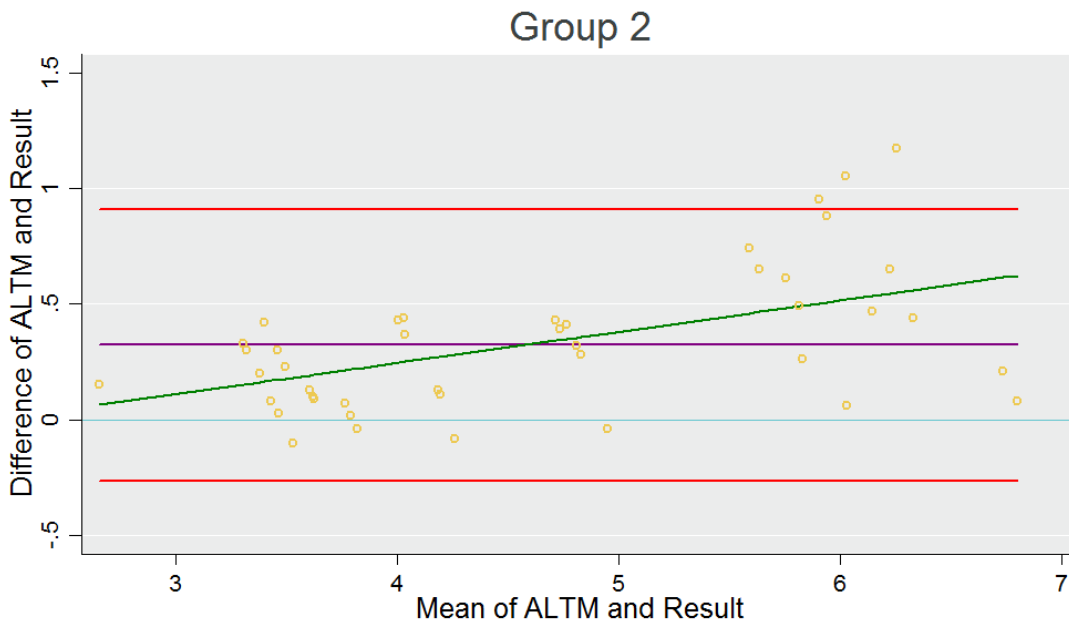


Fig. 6.5 Bland-Altman plot displaying Group Two (researcher in the community) results vs. ALTM for total cholesterol

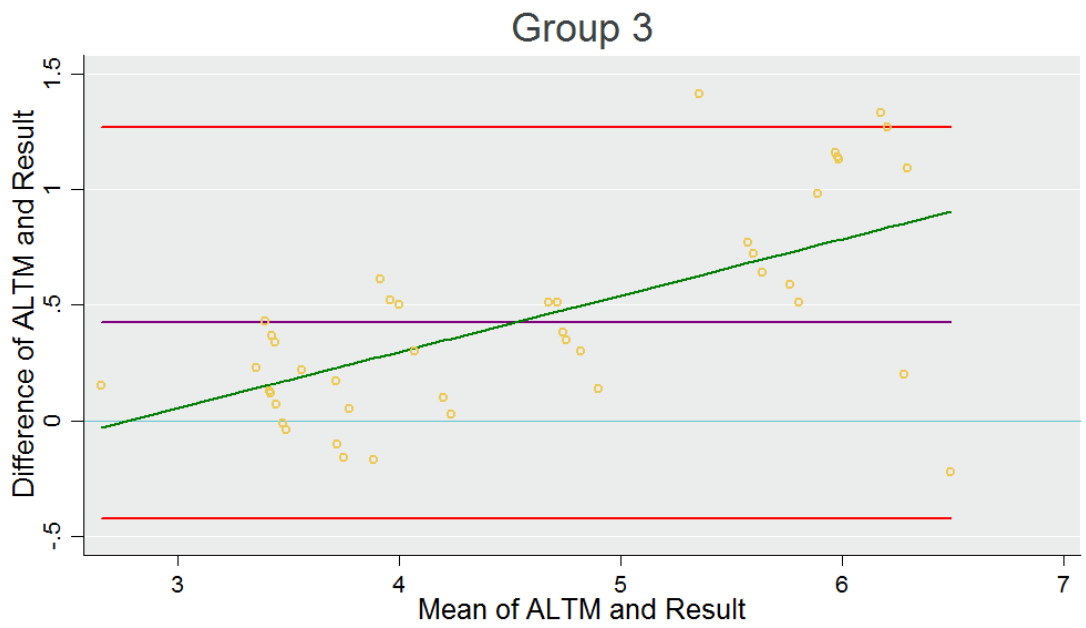


Fig 6.6 Bland-Altman plot displaying Group Three (researcher in lab) results vs. ALTM for total cholesterol

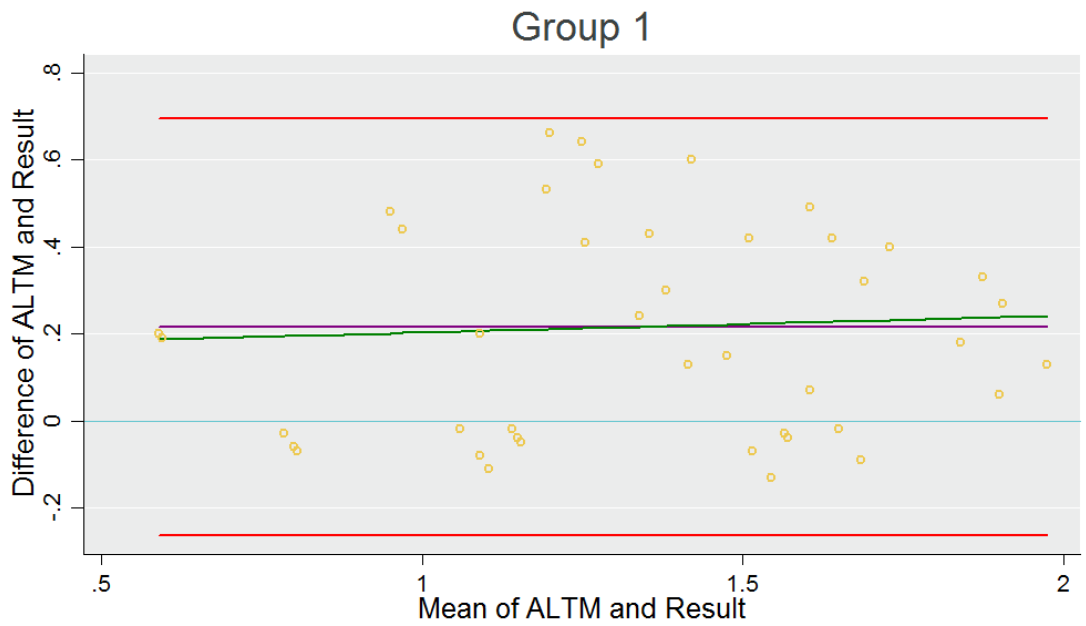


Fig 6.7 Bland-Altman plot displaying Group One (SHIS staff) results vs. ALTM for HDL cholesterol

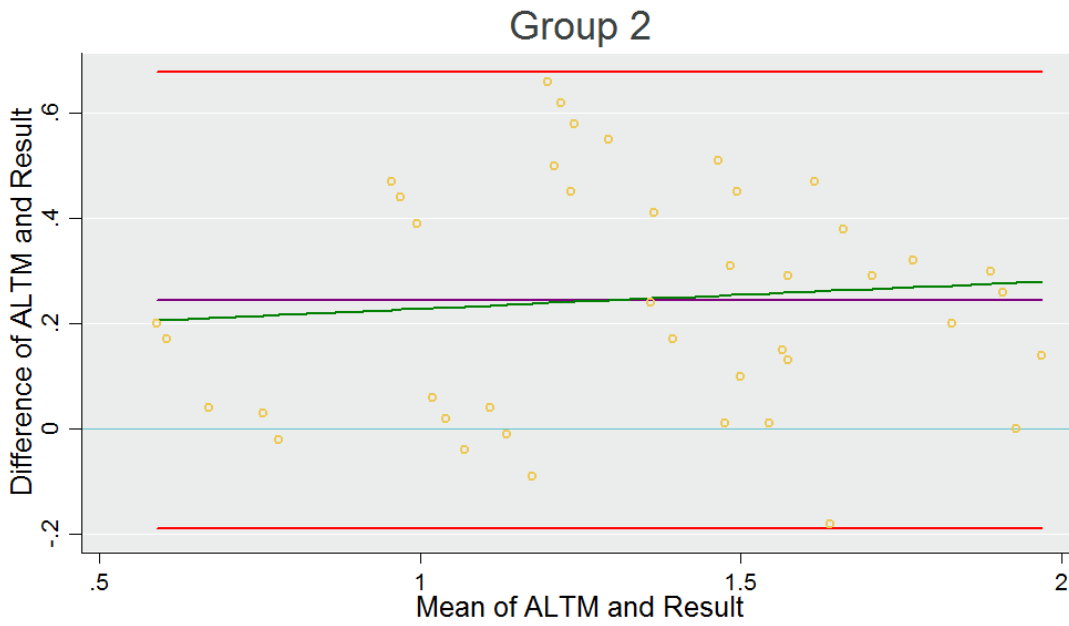


Fig. 6.8 Bland-Altman plot displaying Group Two (researcher in the community) results vs. ALTM for HDL cholesterol

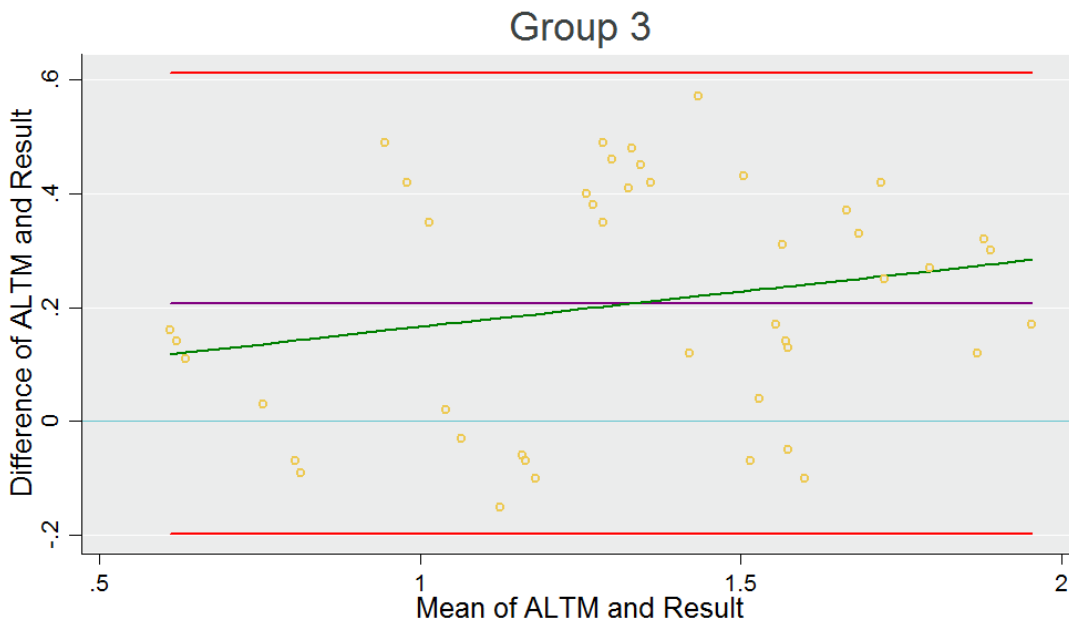


Fig 6.9 Bland-Altman plot displaying Group Three (researcher in lab) results vs. ALTM for HDL cholesterol

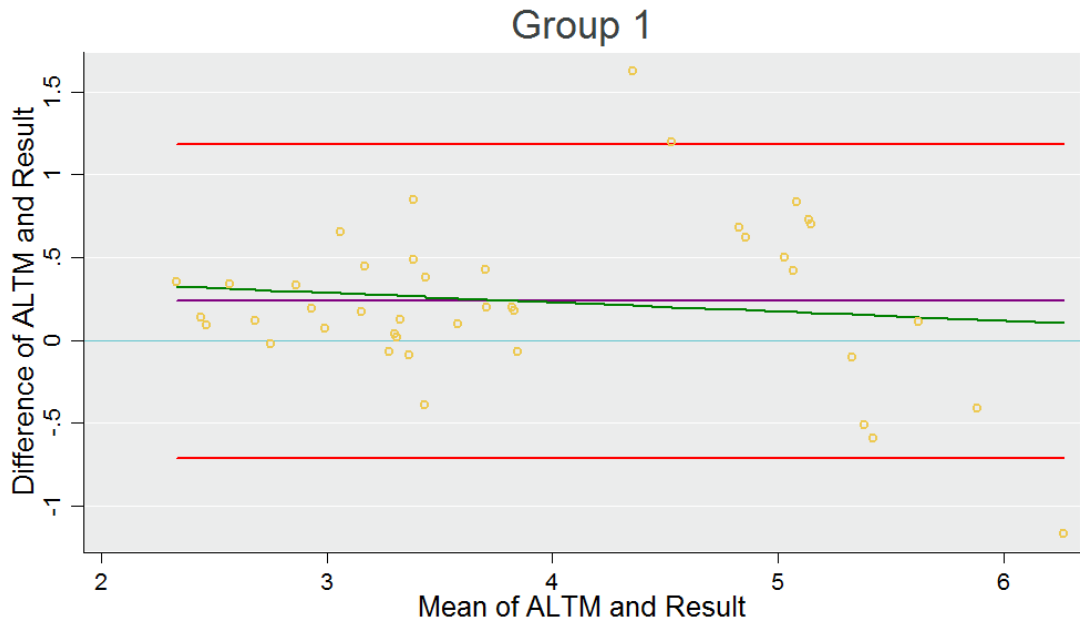


Fig 6.10 Bland-Altman plot displaying Group One (SHIS staff) results vs. ALTM for TC/HDL

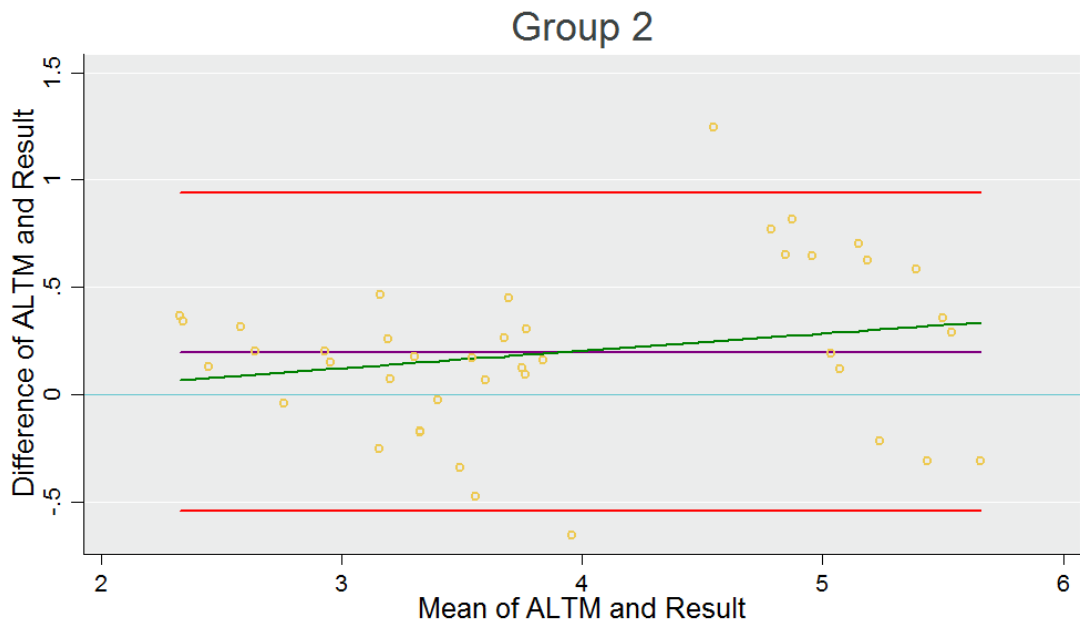


Fig. 6.11 Bland-Altman plot displaying Group Two (researcher in the community) results vs. ALTM for TC/HDL

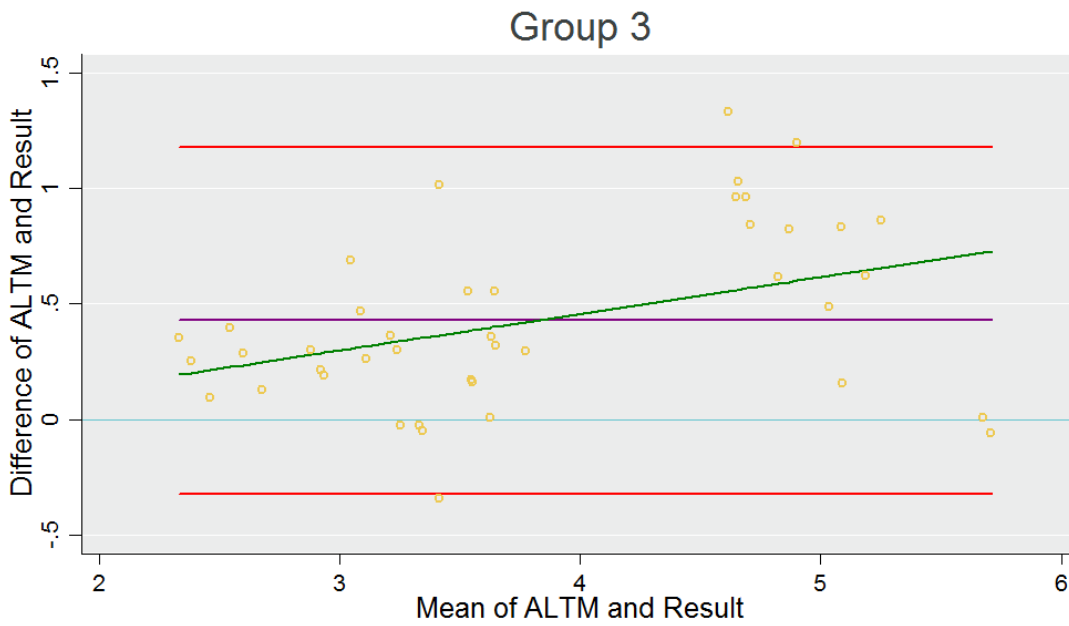


Fig 6.12 Bland-Altman plot displaying Group Three (researcher in lab) results vs. ALTM for TC/HDL

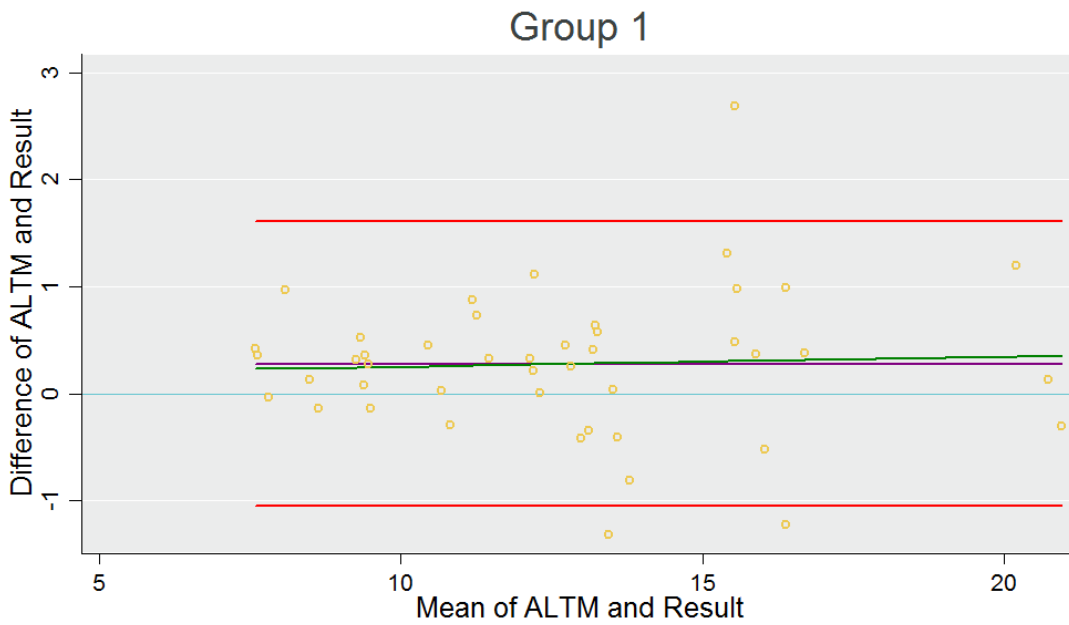


Fig 6.13 Bland-Altman plot displaying Group One (SHIS staff) results vs. ALTM for glucose



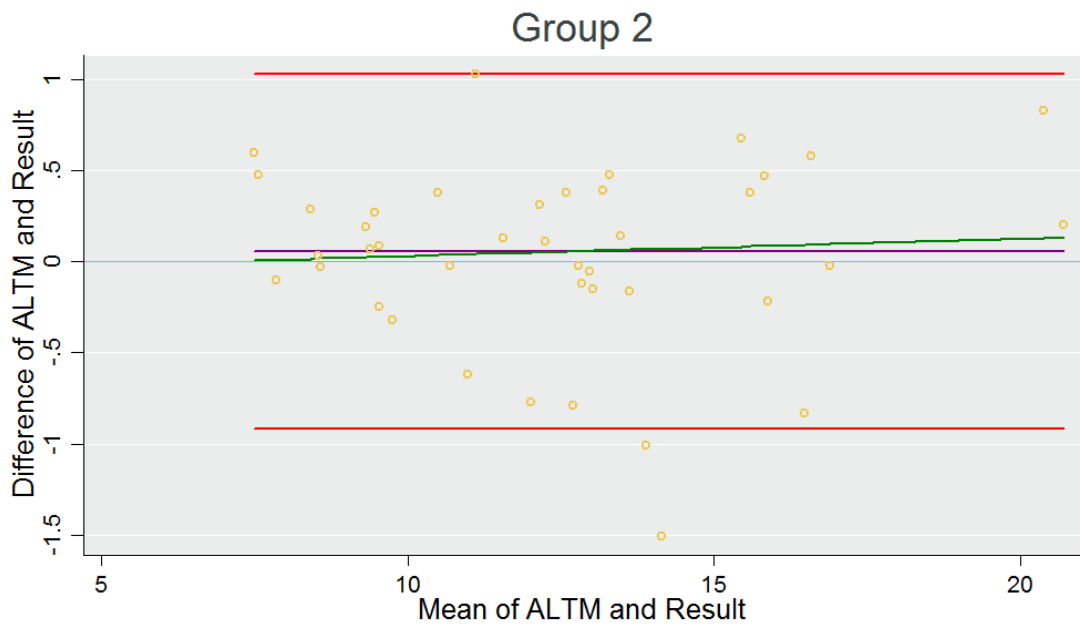


Fig. 6.14 Bland-Altman plot displaying Group Two (researcher in the community) results vs. ALTM for glucose

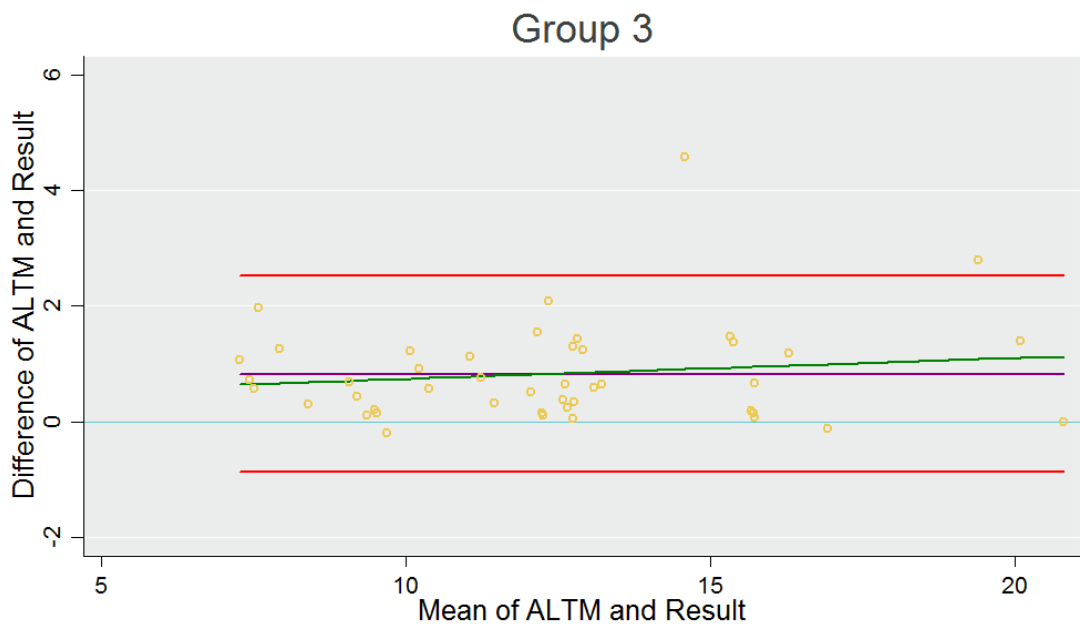


Fig 6.15 Bland-Altman plot displaying Group Three (researcher in lab) results vs. ALTM for glucose

Figures 6.16 to 6.19 collate the mean results for each parameter and display the difference between those averages and the ALTM. These plots summarise the performance of each group in the analysis of each parameter. As shown in Figure 6.16, Group One achieved results closest to the ALTM and Group Three generated the results that were in least agreement with the ALTM. Figure 6.17 shows that Group Three performed marginally better than the other two groups for HDL results. It appears that Group Two achieved results that were on average closer to the ALTM than the other groups for TC/HDL, Fig. 6.18. Figure 6.19 illustrates the closeness of Group Two glucose results to the ALTM, this is to be expected as this was the only data set that was not significantly different to the ALTM when analysed statistically.

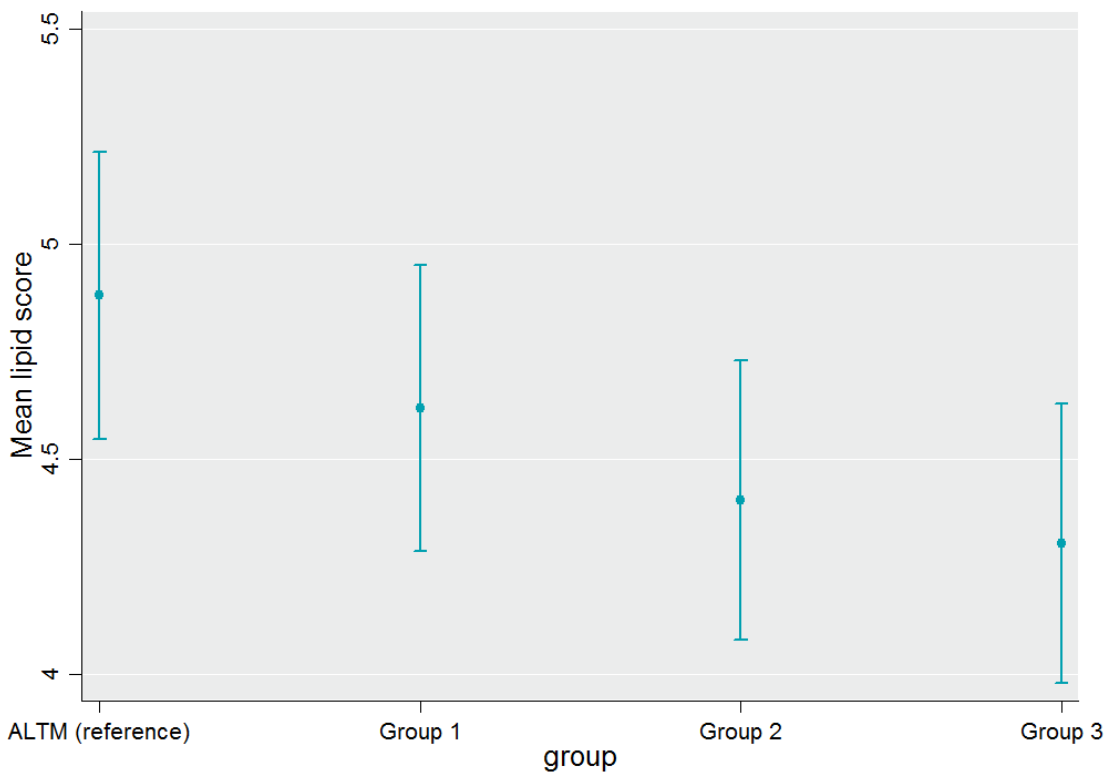


Figure 6.16 Mean difference plot displaying each groups performance for total cholesterol in comparison to the reference value

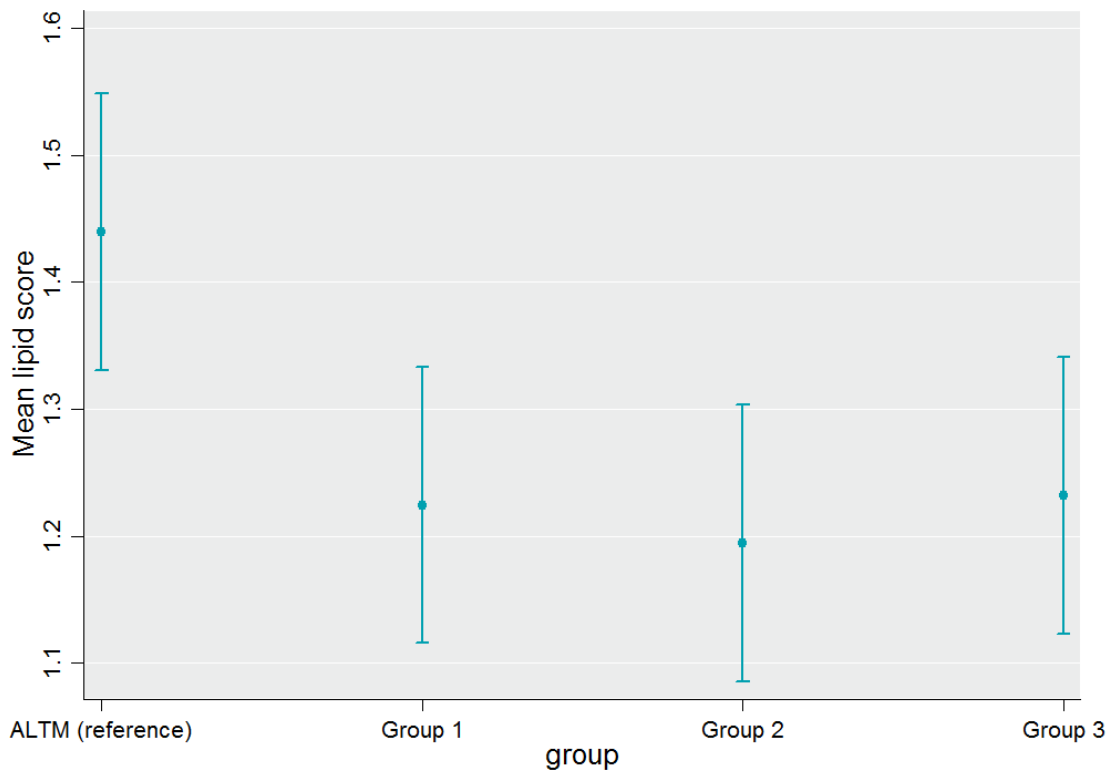


Figure 6.17 Mean difference plot displaying each groups performance for HDL cholesterol in comparison to the reference value

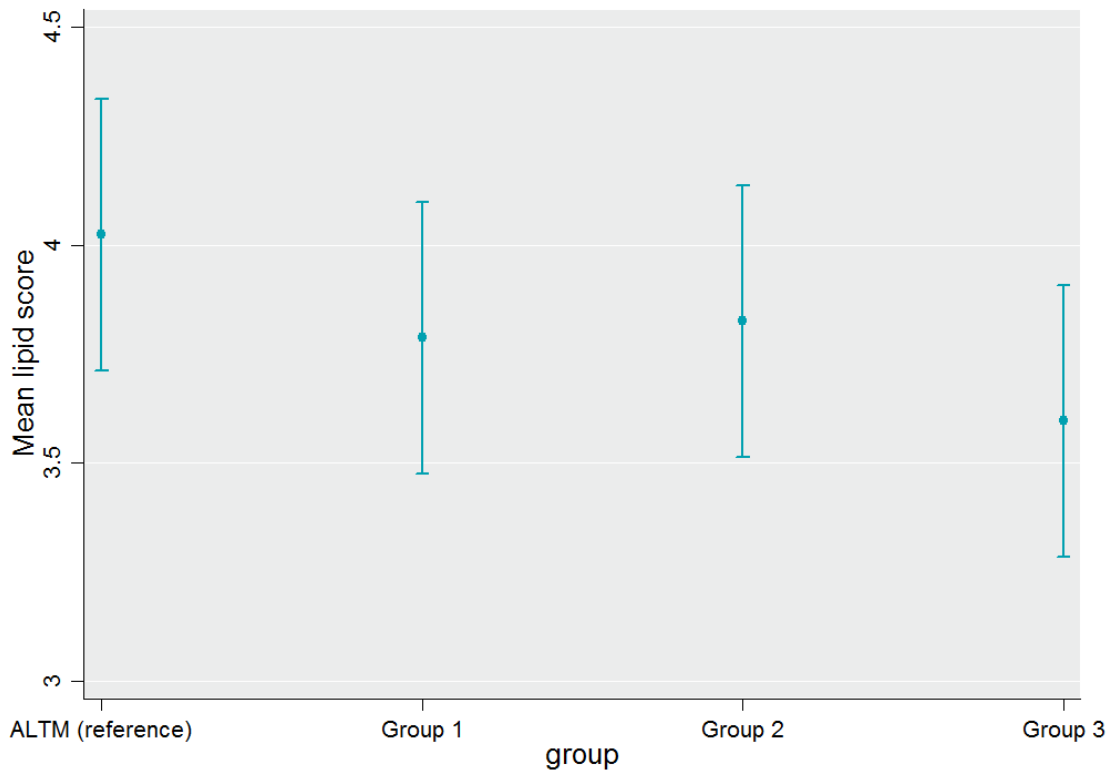


Figure 6.18 Mean difference plot displaying each groups performance for TC/HDL ratio in comparison to the reference value

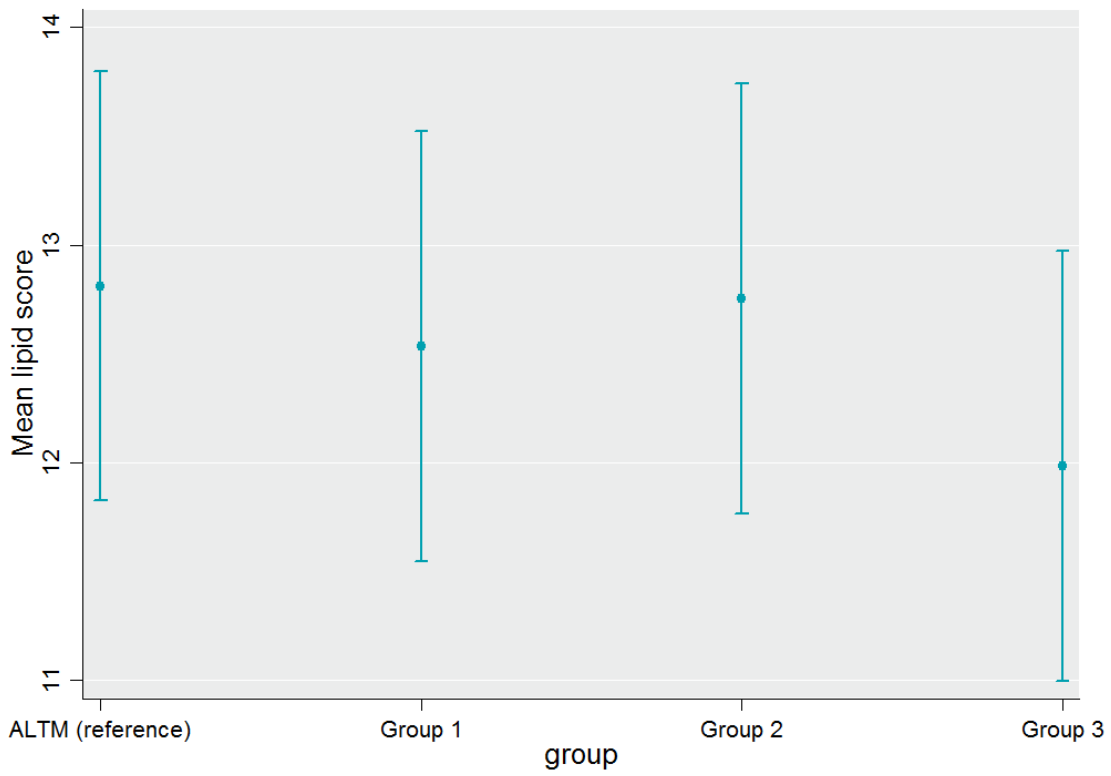


Figure 6.19 Mean difference plot displaying each groups performance for glucose in comparison to the reference value

### 6.3.6 Clinical significance

#### 6.3.6.1 Effect on signposting and referral

Tables 6.3 – 6.6 are shift tables which illustrate how the results of each group fit with the reference values (ALTM) and what effect the group results may have on patient referral and signposting to other services, such as primary care. Shaded cells represent the group results that agree with the ALTM. Values above and below shaded cells represent results that have been over (above cell) or under (below cell) estimated.

	Group One			Group Two			Group Three		
		<7.5 mmol/L	>7.5 mmol/L		<7.5 mmol/L	>7.5 mmol/L		<7.5 mmol/L	>7.5 mmol/L
A									
L	<7.5 mmol/L	42	0	<7.5 mmol/L	45	0	<7.5 mmol/L	45	0
T									
M	>7.5 mmol/L	0	0	>7.5 mmol/L	0	0	>7.5 mmol/L	0	0

Table 6.3 Shift tables for group result versus ALTM by the total cholesterol referral guidance used by SHIS.

As illustrated in Table 6.3, the results of all groups were in agreement with that of the ALTM. In this case, no results warranted further testing or referral.

	<6.0 mmol/L	6.1-11.0 mmol/L	11.1-17.9 mmol/L	≥ 18 mmol/L
<6.0 mmol/L	0	0	0	0
6.1-11.0 mmol/L	0	15	0	0
11.1-17.9 mmol/L	0	0	25	0
≥ 18 mmol/L	0	0	2	3

Table 6.4 Shift table displaying the agreement between Group One glucose results and ALTM in reference to SHIS referral guidance

	<6.0 mmol/L	6.1-11.0 mmol/L	11.1-17.9 mmol/L	≥ 18 mmol/L
<6.0 mmol/L	0	0	0	0
6.1-11.0 mmol/L	0	15	0	0
11.1-17.9 mmol/L	0	0	26	0
≥ 18 mmol/L	0	0	1	3

Table 6.5 Shift table displaying the agreement between Group Two glucose results and ALTM in reference to SHIS referral guidance

	<6.0 mmol/L	6.1-11.0 mmol/L	11.1-17.9 mmol/L	≥ 18 mmol/L
<6.0 mmol/L	0	0	0	0
6.1-11.0 mmol/L	0	15	0	0
11.1-17.9 mmol/L	0	0	26	0
≥ 18 mmol/L	0	0	1	3

Table 6.6 Shift table displaying the agreement between Group Three glucose results and ALTM in reference to SHIS referral guidance

Tables 6.4 – 6.6 are shift tables that illustrate the agreement and disagreement of group results with the reference value (ALTM). Table 6.4 shows that two results were underestimated by Group One when compared to the reference standard. The two results should have fallen within the 11.1-17.9 mmol/L but fell within the 6.1-11.0 mmol/L, meaning that, had these been patient results, the patient would have received a less urgent referral to their GP for further glucose testing.

Groups Two and Three fared slightly better only underestimating one result when compared with the ALTM. As with group one, this was in the 11.1-17.9 mmol/L category, meaning that, had this been a patient result, they would have received a less urgent referral to their GP for further glucose testing.

#### 6.3.6.2 Effect on Cardiovascular risk score

Tables 6.7 – 6.9 are shift tables that illustrate how the total cholesterol results of each group fit with the reference values (ALTM) and what effect the group results may have on CVD risk score categories.

Group 1 underestimated a total of 12 total cholesterol results. In the clinical setting, this would decrease the overall CVD risk score, making it appear as though those patients were at a decreased risk of a cardiovascular event.

Group 2 had more TC results in categories that agreed with the ALTM but still underestimated a total of 8 results. This again would decrease the overall CVD risk score, making it appear as though those patients were at a decreased risk of a cardiovascular event, in the clinical setting.

Group 3 fared the worst of all three groups by underestimating 13 total cholesterol results. In the clinical setting, this would decrease the overall CVD risk score, making it appear as though those patients were at a decreased risk of a cardiovascular event.

	<4.14 mmol/L	4.15 – 5.17 mmol/L	5.18 – 6.21 mmol/L	6.22 – 7.24 mmol/L	≥7.25 mmol/L
<4.14 mmol/L	15	0	0	0	0
4.15 – 5.17 mmol/L	0	7	0	0	0
5.18 – 6.21 mmol/L	0	5	6	0	0
6.22 – 7.24 mmol/L	0	0	1	3	0
≥7.25 mmol/L	0	0	0	6	0

Table 6.7 Shift table displaying the agreement between Group One and ALTM total cholesterol results in relation to Framingham risk score categories

	<4.14 mmol/L	4.15 – 5.17 mmol/L	5.18 – 6.21 mmol/L	6.22 – 7.24 mmol/L	≥7.25 mmol/L
<4.14 mmol/L	18	0	0	0	0
4.15 – 5.17 mmol/L	0	10	0	0	0
5.18 – 6.21 mmol/L	0	2	6	0	0
6.22 – 7.24 mmol/L	0	0	0	3	0
≥7.25 mmol/L	0	0	0	6	0

Table 6.8 Shift table displaying the agreement between Group Two and ALTM total cholesterol results in relation to Framingham risk score categories

	<4.14 mmol/L	4.15 – 5.17 mmol/L	5.18 – 6.21 mmol/L	6.22 – 7.24 mmol/L	≥7.25 mmol/L
<4.14 mmol/L	18	0	0	0	0
4.15 – 5.17 mmol/L	0	8	0	0	0
5.18 – 6.21 mmol/L	0	4	5	0	0
6.22 – 7.24 mmol/L	0	0	1	1	0
≥7.25 mmol/L	0	0	0	8	0

Table 6.9 Shift table displaying the agreement between Group Three and ALTM total cholesterol results in relation to Framingham risk score categories

Tables 6.10 – 6.12 are shift tables that illustrate how the HDL cholesterol results of each group fit with the reference values (ALTM) and what effect the group results may have on CVD risk score categories



Group One overestimated 2 and underestimated 16 results. Those that were overestimated would give the impression of a healthier result in the clinical setting, as higher HDL results are more desirable, generating a lower CVD risk score. Conversely, more points would be added to the Framingham score sheet for those with underestimated results, resulting in a falsely higher CVD risk score.

Group Two overestimated 2 and underestimated 21 results. The overestimated results would provide a falsely low CVD risk score and those that were underestimated would produce a falsely higher CVD risk score.

As with the TC results, Group Three fared the worst, overestimating 6 and underestimated 19 results. If these were patient results, 6 patients would have a falsely lower risk scores generated compared with the risk score they would have received from more accurate results. 19 patients would have a CVD falsely higher risk score generated than they would have done from correct results as the underestimation of HDL produces less healthy looking results.

	<0.9 mmol/L	0.91 – 1.16 mmol/L	1.17 – 1.29 mmol/L	1.30 – 1.55 mmol/L	≥1.56 mmol/L
<0.9 mmol/L	6	2	0	0	0
0.91 – 1.16 mmol/L	0	4	0	0	0
1.17 – 1.29 mmol/L	0	0	0	3	0
1.30 – 1.55 mmol/L	0	0	3	6	0
≥1.56 mmol/L	0	0	0	3	8
					10

Table 6.10 Shift table displaying the agreement between Group One and ALTM HDL cholesterol results in relation to Framingham risk score categories

	<0.9 mmol/L	0.91 – 1.16 mmol/L	1.17 – 1.29 mmol/L	1.30 – 1.55 mmol/L	≥1.56 mmol/L
<0.9 mmol/L	6	1	0	0	0
0.91 – 1.16 mmol/L	0	5	0	0	0
1.17 – 1.29 mmol/L	0	0	0	1	0
1.30 – 1.55 mmol/L	0	0	3	4	0
≥1.56 mmol/L	0	0	0	7	7
					11

Table 6.11 Shift table displaying the agreement between Group Two and ALTM HDL cholesterol results in relation to Framingham risk score categories

	<0.9 mmol/L	0.91 – 1.16 mmol/L	1.17 – 1.29 mmol/L	1.30 – 1.55 mmol/L	≥1.56 mmol/L
<0.9 mmol/L	6	4	0	0	0
0.91 – 1.16 mmol/L	0	2	0	0	0
1.17 – 1.29 mmol/L	0	0	0	2	0
1.30 – 1.55 mmol/L	0	0	0	4	0
≥1.56 mmol/L	0	0	0	6	5
					13

Table 6.12 Shift table displaying the agreement between Group Three and ALTM HDL cholesterol results in relation to Framingham risk score categories

## 6.4 Discussion

Due to the push for cardiovascular screening programmes and the growing POCT market, it is likely that the need for POCT of lipids and other associated parameters, such as glucose, will increase. The current guidance from NICE suggests that statins should be offered to patients for the primary prevention of cardiovascular disease (CVD) if they: are aged 18-84 years and have a CVD risk score of  $\geq 10\%$ , have diabetes or have familial hypercholesterolaemia (NICE, 2014b).

POCT offers many advantages for use in screening programmes like NHS Health Checks, it frees up clinician time as non-medical staff can be trained to perform the Checks, results are made available within the consultation and it is generally more convenient for the patient. With the NHS under constant pressure and stretched for resources, the provision of NHS Health Checks by other organisations, such as the SHIS, should, in some small way, relieve some of the pressure placed on the NHS. The availability of results during the consultation has been shown to have a positive effect on the patient, giving them more understanding and motivation to make changes where necessary (Laurence *et al.*, 2010). Unfortunately, the population that is most likely to be affected by CVD is also the least likely to attend screening. Providing NHSHCs in the community and workplace setting goes some way to negate this problem, in some cases the tests are brought to the patient rather than the patient having to seek them out.

This study compared the analytical performance of three groups: SHIS staff in the community setting, researcher in the community setting and researcher in the laboratory setting. All groups used the Alere Cholestech LDX to analyse identical EQA samples. In theory, all three groups should be able to produce results that are in agreement with the reference value, the ALTM provided by UKNEQAS. In this study, POCT group results were generally underreported and none of the groups achieved agreement with the ALTM for any parameter, with the exception of Group Two glucose ( $p=0.437$ ). Some studies assessing the analytical performance of this device have shown similar results, for

example Panz *et al.* (2004) found that the Cholestech LDX generally underreported results or TC and LDL cholesterol (Panz *et al.*, 2004).

Group Three generally performed poorest, not managing to achieve a p value greater than 0.000 for any set of results (Table 6.2). This could be explained by the change in environment and individual device. As highlighted in Figures 6.16 to 6.19, the average results generated by Group Three were consistently further from the average reference value (ALTM). The Cholestech used by Group Three in the laboratory was the same model as the ones used by Groups One and Two in the community and therefore should produce results inline with the other two devices. Previous studies have shown that the Cholestech LDX performs consistently from device to device in the laboratory environment (Rogers *et al.*, 1993) therefore it is likely to be an environmental factor that accounts for the variation in these results.

In terms of clinical significance, had these been patient results, the results generated by all three groups could have caused a different outcome for the patient. As all group results for each of the 45 tests performed were in agreement with the ALTM for the referral guidance based on total cholesterol, no change in outcome would be seen, Table 6.3. However, the referrals based on glucose results would differ from their correct number, according to the ALTM. Of the 45 tests run by Group One, 43 tests were placed in agreeable categories with the ALTM and 2 were underestimated and so placed in the wrong category. This category change would mean that 2 patients were referred for further glucose testing in four weeks instead of one. Of the 45 tests run by Group Two, 44 were in agreement and 1 was underestimated, again resulting in a less urgent referral. Group Three produced the same error as Group Two.

The inaccuracies seen in the group results would also have an impact on CVD risk scores. Total cholesterol results were underestimated in many cases: Group One underestimated 12 results, Group Two underestimated 8 and Group Three underestimated 13 results. An underestimation of total cholesterol, especially at higher concentrations, skews the CVD risk calculation and generates a more positive, lower risk score. For example, where a result falls

within the 5.18-6.21 mmol/L, when its true value is within the 6.22-7.24 mmol/L, if using the Framingham calculation, a male patient would receive 1 point instead of two points. This 1 point difference can have quite a big impact on the total points and therefore the corresponding risk score. A falsely low risk score has the potential to be dangerous. With the Framingham calculation, 6 cholesterol points equates to a risk score of 10% in males. If just 1 point is dropped, the risk falls to 8%. This 2% decrease can have implications for the resulting clinical decisions, the latest guidance is to offer lipid-lowering medication for patients with CVD risk scores of 10% or higher, and so a falsely low risk score could mean that some patients slip through the net and may not receive medication that prevents them from having a future cardiac event.

Other studies that have assessed the analytical performance of the Cholestech LDX have found similar results. Panz *et al.* (2004) found underestimations in TC and LDL cholesterol using this device, placing results in inappropriate risk categories (Panz *et al.*, 2004).

The HDL cholesterol results appeared to be in even less agreement with the ALTM, with a mixture of under and overestimations seen in all groups (Group One: 16 under and 5 over, Group Two: 21 under and 2 over, Group Three: 19 under and 6 over). Underestimations of HDL would cause a falsely higher risk score and overestimations of HDL would cause a falsely lower risk score. Worry could be caused in a patient if they received a risk score that is falsely high but what is potentially more dangerous is when a patient receives a falsely low one. A falsely low-risk score makes it appear as though that patient is at lower risk and could reduce the chances of positive health and lifestyle changes as it provides the patient with a sense of health security. It could also affirm unhealthy behaviours, leading the patient to believe that their lifestyle choices have no impact in their health.

Ideally, tests used in screening programmes should be accurate, producing results that are close to the true value, and precise, producing results that are consistent with each other. In this study, the results achieved by all groups were generally neither precise nor accurate.

The number of underestimations seen in Tables 6.7 to 6.12 and the majority of the group results being significantly different from ALTM, Table. 6.2 ( $p=0.05$  in all except one) would suggest that the POCT results in this study were not accurate. For a test to be accurate, it must produce results close to a known value, in this case, the ALTM.

When a patient's results are underestimated, it can appear as though they do not have a the disease or risk factors being tested for, when in reality this may not be the case, potentially resulting in a false negative. False negatives are avoided in screening programmes. A false negative could mean that a patient is not referred on for further testing to rule out or confirm disease, which could mean that they do not receive further treatment or advice where it may be necessary.

#### *6.4.1 Limitations of the study*

It is difficult to determine the cause of the errors seen between the groups as different Cholestech devices were used and so it could be a result of calibration issues.

The ALTM, as a comparator has its limitations. The results used to create the ALTM number are 'trimmed' which can skew the results and so shift them one way or another, thus changing the mean of the results. However, a 'true result' was not available to use in its place so it was seen as an appropriate substitute. The value of the samples available tended to be around the centre of the possible range and so samples with extreme results were not often tested. For example, none of the total cholesterol results were  $\geq 7.25\text{mmol/L}$ . Of particular interest would be group results versus ALTM for samples with higher concentrations because the implications of underestimations at higher concentrations would be of even greater clinical significance.

The samples tested in this study were serum samples. In practice, whole blood patient samples are tested during an NHS Health Check. This difference in sample type is an important consideration due to the possibility of matrix effects. "Matrix" refers to the components of a sample that are not of interest i.e. not the analyte(s) (Hall *et al.*, 2012). The EQA serum samples will have a number of

common components, however, not all are known and levels may vary from sample to sample. The varying levels of matrix components of a sample may affect the result of the analyte, potentially leading to erroneous reporting of sample concentrations (Hall *et al.*, 2012). This is somewhat overcome in this study as each group tested samples from the same distribution, which should have the same concentration of matrix component as well as analyte. However, because whole blood samples are used in practice, it is difficult to say whether the results would be more or less accurate than the results seen in this study. Although efforts were made to ensure the EQA samples were stored and used in the recommended way, as described in section 6.2.2.3, the stability of EQA samples used cannot be guaranteed. This may lead to variation in the results generated.

## 6.5 Conclusion

Quality in pathology testing is essential to any processes where the results generated are used for a clinical decisions making. The findings of this study suggest that, whilst the results were consistent, the POCT used in the community for the NHS Health Checks is not entirely reliable, producing results that were statistically different to that of the reference value (ALTM). The varying quality of POCT has not gone unnoticed, with academics remarking that POCT devices would benefit with further development and enhancements to cope with the difficult testing environments in which they are used (Kazmierczak, 2011).

Ideally, the test would detect only the individuals in a population who had abnormal lipid and cholesterol levels, as defined by the SHIS and NHS cut off points and would not fail to detect any of those individuals.

The findings of this study have some clinical significance as the results generated were generally underreported, suggesting a lack of sensitivity and production of false negative results. With screening tests, importance is normally placed on sensitivity, as many are used as 'rule-out' tests. In this setting, a false negative could make it seem as though a patient is at less risk than they are in reality, potentially resulting in missed opportunities for further testing or treatment. However, in this screening programme, slightly more tolerance can be applied to the results, as the tests are not used to make clinical management decisions and so are likely to be of acceptable clinical performance.



This thesis describes some of the applications of POCT and some of the factors associated with its implementation. There is a wealth of publications related to the use of POCT in emergency and secondary care, as described in Chapter One. There are also many papers investigating the use of POCT in community and primary care settings, however, these tend to be set outside the UK, where there is often a greater need for POCT outside of hospitals due to populations living in remote locations with no or little provision from central laboratories. The lack of literature on POCT use within UK primary and community care provided impetus to identify where and how POCT is currently used; to assess its impact on patient outcomes and experience within a community setting and to evaluate its performance in the community setting.

Surveying UK primary care staff revealed that there is an awareness of POCT within UK primary care, with 86% of respondents reporting that their surgery used some form of POCT on a regular basis. The most popular POCT appeared to be urinalysis, human chorionic gonadotropin (hCG) and blood glucose. The survey also highlighted areas that may need addressing to ensure quality of results and ultimately patient safety, for example, at least 10% of POCT operators had not received device-specific training and only 20% of those performing POCT were registered with an EQA scheme. Attitudes towards POCT varied amongst respondents. The largest concern in adopting POCT in primary care was the potential expense incurred. Although positive attributes that POCT could provide were appreciated, the response to undertaking more POCT in the future was undecided and 100% of respondents found current laboratory services acceptable – these results are not indicative of change to the current pathology testing processes within primary care.

The transportable nature of POCT has enabled screening programmes, such as the NHS Health Checks, to be conducted outside healthcare settings. The research presented in Chapter Four, the only research to focus on NHS Health

checks delivered by non-NHS staff in the community setting, evaluated the impact of this programme on its patients. Some slight, but not statistically significant, reductions to the CVD risk of the overall participant population after they received a Health Check were observed. The only exception to this was the significant CVD risk reduction observed in the participants who intended to make lifestyle changes and were referred for further testing ( $P < 0.0001$ ). Of the 91 participants that were seen at both time points, two new diagnoses were made. Similar studies have found similar diagnosis rates (Robson *et al.*, 2012). Overall, there were high levels of satisfaction with the service and the health of participants improved slightly. The majority of participants stated that they preferred receiving their Health Check in the community setting, a service that could not be provided without the use of POCT, and nearly all participants reported that they preferred the blood sampling process for POCT to that of venous sampling for laboratory testing.

Results of the qualitative study provide insight into the reasons for adopting, or not, healthy lifestyle behaviours post NHSHC. Although attitudes towards the workplace NHS Health Checks were entirely positive and there was a move towards healthier lifestyle choices, the majority of participants stated that their decision to make the changes was something that they had previously decided upon, prior to the Health Check. This suggests that the NHSHC had little influence on their lifestyle decisions. A positive outcome that is unique to the workplace and community delivered NHS Health Checks that they are able to capture patients who would not normally visit their GP, many participants stated that they would not make any effort to have an NHS Health Check in primary care, and therefore would not be screened.

The literature review highlighted that most papers evaluate trained medical professionals using POCT. Chapter Six of this thesis reports the findings of an evaluation of the analytical and operator performance of the POCT used for the NHSHC, when operated by non-medical staff. The study found that both cholesterol and glucose results were generally underreported when compared with the reference value of the samples, the ALTM. None of the groups

achieved agreement with the ALTM for any parameter, with the exception of Group Two glucose ( $p=0.437$ ). Some studies assessing the analytical performance of this device have shown similar results (Panz *et al.*, 2004). These findings were clinically significant. If the results generated were from patient samples, the results generated by all three groups could have caused a different outcome for the patient in terms of referral for further testing and CVD risk categories. The results suggest that the POCT results in this study were not accurate and could potentially make patients results appear as though they are without disease or risk factors, which could mean that they do not receive further treatment or advice where it may be necessary.

### Recommendations

Whilst POCT can facilitate some initiatives that are opportunely placed in the community, the value of those initiatives should still be assessed in that setting. It is difficult to justify a scheme which only produces slight improvements in patient health. However, NHSHCs conducted in the community appear to capture patients who would not normally receive a Health Check, as they do not visit their GP surgery. It is recommended that community-based NHS Health checks exploit their ability to reach those hard-to-reach patients, who may have the most improvements to make, by focussing on targeting those patients, perhaps through incentivisation.

As laboratory testing is well established and produces a high quality of results, it is recommended that POCT should only be used where it has proven to be more effective. Examples of this include where fast turnaround times are required in the emergency setting or where laboratory services are not available, for example, remote settings and community based testing where the patients may only be seen once.

Adoption of POCT in any setting should be fully managed, ensuring that all users are trained and competent in its use and that the devices are well maintained.



## Appendix 3.2 – POCT survey

### Chapter Three: POCT in primary care survey – screen shots from the Bristol Online Survey



## Near Patient Testing - Blood and urine testing in the practice

### Welcome

Thank you for taking a moment to complete this questionnaire. It should take a maximum of five minutes to complete and has a total of 9 questions. If you provide an name, email address and contact phone number you will be placed in our randomly selected draw with the chance to win a digital camera or coffee machine with starter kits, we have two of each to give away so your chances are favourable! The information obtained from this questionnaire will inform the research of Metro-POCT, a group based at Manchester Metropolitan University which collaborates with the NHS. This survey is primarily for practice managers and healthcare professionals; if this does not apply to you then it would really be appreciated if you could pass this on to a colleague to complete. The information you supply will be used by the Metro-POCT project for research purposes within the terms of the Data Protection Act 1998. Data will be published in scientific literature and participants will remain anonymous. No confidential information will be passed on to third parties. By clicking continue at the bottom of this page, you are consenting to these conditions.

If you encounter any problems whilst completing this questionnaire, please contact [poct@mmu.ac.uk](mailto:poct@mmu.ac.uk).

### Near Patient Testing

Please answer all questions to the best of your knowledge. Don't forget to leave your name and contact details at the end in the space provided if you would like to be entered into the prize draw!

1 What is your professional role?

- GP
- Healthcare Assistant
- Nurse
- Nurse Practitioner
- Practice Manager
- Other

a If you selected Other, please specify:

2 How many patients are registered at your practice

- <1000
- 1,000-3,000
- 3,000-6,000
- 6,000-9,000
- 9,000-12,000
- 12,000-15,000
- >15,000
- Don't know

3 Are you aware of Near Patient Testing, also known as Point of Care Testing? i.e. samples taken and test performed on-site such as urine dipsticks or blood glucose, as opposed to samples sent to the laboratory for testing.

- Yes
- No

4 Below is a list of tests that may be performed on patients attending a GP practice. Please tick the ones which tests are performed on site and analysed in your practice (as a near patient test) only.

- Urinalysis
- Blood Glucose
- HbA1c
- INR
- Cholesterol
- Full Blood Count
- Haemoglobin
- Pregnancy
- Sexual Health
- Cardiac marker
- None of these
- Don't know

a Others? (please state)

5 Who usually performs the tests that are done on site as a Near Patient Test?

- GP
- Nurse
- Nurse Practitioner
- Assistant Practitioner
- Healthcare Assistant
- An external company e.g. IntraHealth
- Don't know
- Other

a Why is this person best placed to perform these tests?

6 Has the person performing the Near Patient Test been trained to run the test?

- Yes
- No
- N/A

7 Does your place of work participate in any external quality assessment (EQA) schemes for the Near Patient Tests that you run onsite? e.g. UK NEQAS

- Yes
- No
- Don't know

8 Which of the following statements regarding Near Patient Testing do you foresee as being advantages and disadvantages?

Having trouble with the format of this question? [View in tableless mode](#)

	Advantage	Neutral	Disadvantage
Near Patient Testing uses small, often portable devices that can therefore be used in a variety of locations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
From the time of taking and running the sample, test results are given within minutes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Small volumes of blood are needed, so capillary finger-prick samples are used	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training is required in the use of Near Patient Testing devices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Test for test, Near Patient Testing could be more expensive than central laboratory testing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Less follow-up appointments are required as decision to test - result time is minimal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Test results are given clearly on screen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In some cases, patients can test themselves using Near Patient Testing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Near Patient Testing can help earn QOF points	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9 If you don't currently perform any Near Patient Testing then would your place of work consider running Near Patient Testing in future?

- Yes- some of our healthcare staff could do it
- Yes- using an external company
- No
- Don't know



## Near Patient Testing - Blood and urine testing in the practice

---

Thank you!

Thank you on behalf of the Metro-POCT team. The information that you have provided for us will go a long way in helping us understand what point-of-care testing is done in the community and how it can be improved. If you know of anyone who could answer the questions in this questionnaire then please do not hesitate in passing this on to them as it will strengthen our results and make future research more tailored and appropriate. If you would like more information on the Metro-POCT project please contact [poct@mmu.ac.uk](mailto:poct@mmu.ac.uk) or 0161 247 1555

Respondents can now leave the survey - you could offer them a link like this one:

Please follow this link to return to the:

[Bristol Online Surveys Homepage](#)

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# Health and Lifestyle Questionnaire

Thank you for taking part in this study. The aim of this questionnaire is to assess your health behaviours and well-being as well as to gain an understanding of your experience of your NHS Health Check today. Please take your time to answer these questions as fully and honestly as possible. If you have any questions, please ask.  
Your results are confidential and will not affect your treatment in any way.

**Question 1-5 are about how you feel, for each question please tick the box which most closely matches how you have felt over the past 2 weeks.**

Over the last 2 weeks:	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1 I have felt cheerful and in good spirits						
2 I have felt calm and relaxed						
3 I have felt active and energetic						
4 I have woke up feeling refreshed and rested						
5 My daily life has been filled with things that interest me						

**Question 6-11 are about what your lifestyle is like and how you think about yourself**

**6. When I exercise, I:** (please tick all that apply)

- Run
- Swim
- Play a team sport e.g. football
- Lift weights
- Walk
- Cycle
- Attend fitness classes
- Other (please write in space below)
- .....
- I don't do any exercise

**7. Normally, I exercise:**

- 3+ hours per week
- 1-3 hours per week
- Less than 1 hour per week
- Never

**9. I believe I am:**

- Underweight
- Just right
- Overweight

**8. I eat fresh fruit and vegetables:**

- Everyday
- Most days
- Every now and then
- Hardly ever
- Never

**10. I believe I am:**

- Very healthy
- Reasonably healthy
- Slightly unhealthy
- Very unhealthy

**11. Do you regularly suffer from any symptoms of ill-health?** E.g. shortness of breath or pain. If yes, please state in the space below:

.....

Appendix 4.3 – Baseline health and lifestyle questionnaire (page 2)

Questions 12-16 are about your experience of your NHS Health Check today.  
This section should be completed after you have had your NHS Health Check.

12. When I was given my results today, I: (please tick one answer only)

- Fully understood them with no explanation needed
- Fully understood the results **after** the explanation from the advisor
- Have some idea of what the results meant after the explanation from the advisor
- Still do not understand what the results meant

13. After getting your NHS Health Check done today, do you intend on making any lifestyle changes? E.g. doing more exercise, stopping smoking, drinking less alcohol

- Yes (please explain what changes you intend to make in space below)

.....  
.....

- No (please explain your reasons for this in space below)

.....

14. I preferred coming here to have my NHS Health Check rather than going to my GP surgery

- Agree
- Disagree
- Neither agree nor disagree

Please explain your answer to question 14 in the space below:

.....  
.....

15. My overall experience of the NHS Health Check today has been:

- Excellent
- Good
- Average
- Poor
- Unacceptable

Because: (please explain your answer to question 15 in the space below)

.....  
.....

The final question is for those that had the full NHS Health Check ONLY

16. The blood test using a few drops of blood from my finger was: (please tick all that apply)

- Painless
- Slightly uncomfortable but still better than giving a blood sample from a vein in my arm
- More painful than giving a blood sample from a vein in my arm
- Convenient, I liked that I got my results there and then
- Too quick, I prefer to wait a few days until I get my results

Please print your name here: .....

# Health and Lifestyle Questionnaire

Thank you for taking part in this study. The aim of this questionnaire is to assess your health behaviours and well-being as well as to gain an understanding of your experience of your NHS Health Check today. Please take your time to answer these questions as fully and honestly as possible. If you have any questions, please ask.  
Your results are confidential and will not affect your treatment in any way.

Questions 1-5 are about how you feel, for each question please tick the box which most closely matches how you have felt over the past 2 weeks.

Over the last 2 weeks:	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1 I have felt cheerful and in good spirits						
2 I have felt calm and relaxed						
3 I have felt active and energetic						
4 I have woke up feeling refreshed and rested						
5 My daily life has been filled with things that interest me						

Questions 6-10 are about what your lifestyle is like and how you think about yourself

6. When you exercise, please tick all that apply)

- Run
- Swim
- Play a team sport e.g. football
- Lift weights
- Walk
- Cycle
- Attend fitness classes
- Other (please write in space below)

.....

- I don't do any exercise

7. Normally, how often do you exercise?

- 3+ hours per week
- 1-3 hours per week
- Less than 1 hour per week
- Never

9. How do you believe you are?

- Underweight
- Just right
- Overweight

8. How often do you eat fresh fruit and vegetables?

- Everyday
- Most days
- Every now and then
- Hardly ever
- Never

10. How do you believe you are?

- Very healthy
- Reasonably healthy
- Slightly unhealthy
- Very unhealthy

Appendix 4.3 – Follow-up health and lifestyle questionnaire (page 2)

Questions 11-16 are about what has happened since your last Health Check.

**11. Have you been to visit your doctor as a result of your last Health Check?**

- Yes
- No

**12. If yes to question 11, have you been diagnosed or are you being treated for any new conditions?**

- Yes (please state e.g. diabetes, high cholesterol)  
.....
- No

**13. Since your last Health Check, have you made any lifestyle changes?**

- Yes (please state e.g. more exercise, diet).  
.....
- No

**14. If 'yes' to question 13, why have you made those changes?**

- Because of the results and/or advice from the previous Health Check
- Had already planned to make the changes
- Other

**15. If 'no' to question 13, has anything stopped you from making lifestyle changes?**

- No – I did not plan on making any lifestyle changes
- Yes – I have not had the time
- Yes – I do not know which lifestyle changes to make
- Yes – I have not been motivated enough to make any changes
- Other .....

**16. Would you recommend having a Health Check to family and friends?**

- Yes
  - No
- Because.....

Please print your name here: .....

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