Is Quality Improvement for treatment of acute coronary syndromes worthwhile?

*Results from the EQUIP-ACS trial*

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Thesis for the Degree of Doctor of Philosophy
Abstract
This thesis constitutes an assessment of a Quality Improvement (QI) programme delivered to healthcare professionals managing patients with non-ST elevation Acute Coronary Syndromes (ACS). This is a mixed methods evaluation of a QI programme encompassing a range of quantitative analyses and a qualitative semi-structured interview programme.

Data from ACS registries demonstrate that management of non-ST elevation ACS is sub-optimal with respect to guideline recommendations. A range of interventions such as educational programmes, financial incentives and publication of performance have been implemented in healthcare showing evidence of improved standards of care. Whilst these results are encouraging, further research is needed to understand the factors that facilitate improvement and whether results achieved are sustained.

The European Quality Improvement Programme for Acute Coronary Syndromes (EQUIP-ACS) project was a cluster-randomised QI programme for healthcare professionals delivered to 38 hospitals in five European countries. Data for 2,582 non-ST elevation ACS admissions were entered onto a web-based database over approximately 12 months. The primary outcome was a composite of eight guideline-recommended treatments for ACS compared before and after delivery of the QI intervention. Additional exploratory analyses have been performed to assess: the use of risk stratification methods and effect of patient risk, effect of patient and hospital characteristics, long term results of the QI intervention and a qualitative evaluation based on semi-structured interviews conducted with healthcare professionals.

The EQUIP-ACS QI intervention led to increased use of ACS treatments. Improvement achieved was not consistent across all patients however and those with comorbidities received poorer management. Use of risk stratification was independently associated with improved management. Improvement was sustained at two of the centres one year after the programme, although a trend for decline over time was observed. Qualitative interviews revealed a range of factors that may influence delivery of QI and should be considered for future QI programmes.
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Declaration of Originality

The thesis was written entirely by me with support from supervisors Professor Martin Cowie and Professor Marcus Flather. The figures and tables presented in this thesis are my own work, except where otherwise indicated.

The EQUIP-ACS project was designed and conducted by the EQUIP-ACS Steering Committee, I had a central role in the preparation of the trial protocol, ethical submissions, preparation and management of data management systems, and have acted as the Trial Manager throughout the duration of the study. I was instrumental in arranging and implementing the QI intervention.

The statistical analyses for the main trial results (Chapter 2) were performed by Mr Winston Banya and Mr Tony Brady but repeated by me for this thesis. All other statistical analyses (Chapters 3, 4 and 5) were conducted by me with support from Mr Winston Banya. Analysis of the qualitative evaluation (Chapter 6) was undertaken by me and a sample of interview transcripts (three out of fifteen) were reviewed by Dr Sharon Fleming to validate themes identified. Interviews were transcribed by an independent transcription agency.
Acknowledgements

This thesis and the research that it is based on would not have been possible without the valuable support of my supervisors, colleagues, friends and family.

I would like to thank my supervisors Professors Martin Cowie and Marcus Flather for their guidance, encouragement and support throughout my PhD. Thanks are also due to my Mentor Professor Sian Harding for her support and advice. I am grateful to the EQUIP-ACS Steering Committee members and participating centres for their contribution to the project. The project was funded by an educational grant provided by GlaxoSmithKline and Sponsored by the Royal Brompton and Harefield NHS Foundation Trust.

Mr Winston Banya has been an invaluable support throughout my PhD and I am extremely grateful to him for his patience, tutoring and advice. For the qualitative aspects of this thesis I am indebted to Dr Jill Riley and Dr Sharon Fleming for their expert advice and guidance. I would like to thank the 15 EQUIP-ACS Investigators who kindly gave up their time to take part in the interviews for Chapter 6.

My colleagues and friends at the Clinical Trials and Evaluation Unit of the Royal Brompton Hospital have helped me from the very first day and continue to support my research. They encouraged me to persist with my research and helped me through many a stressful moment over the years. I would especially like to thank my assistant supervisor Dr Belinda Lees for her mentorship, support and friendship.

Last but not least, I am indebted to my partner Gareth, my parents sister and my friends for their kindness and support throughout. They have endured numerous conversations about management of heart attacks and plenty of holidays with my laptop and piles of articles. They will probably be as pleased as I am to see the finished result.
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Abbreviations

ACS  Acute Coronary Syndromes
ACC  American College of Cardiology
A&E  Accident and Emergency
AHA  American Heart Association
ACE  Angiotensin Converting Enzyme inhibitors
ARB  Angiotensin II Receptor Blockers
AMI  Acute Myocardial Infarction
ANOVA  Analysis of Variance
BHF  British Heart Foundation
BL  Baseline
CABG  Coronary Artery Bypass Graft Surgery
CAD  Coronary Artery Disease
CCU  Coronary Care Unit
CHD  Coronary Heart Disease
CI  Confidence Interval
CKD  Chronic Kidney Disease
CPG  Clinical Practice Guidelines
CQC  Care Quality Commission
CQI  Continuous Quality Improvement
CVD  Cardiovascular Disease
DBP  Diastolic Blood Pressure
DOH  Department of Health
ECG  Electrocardiogram
EQUIP-ACS  European Quality Improvement Programme for Acute Coronary Syndromes
ESC  European Society of Cardiology
GP  General Practitioner
GWTG  Get With the Guidelines
GRACE  Global Registry of Acute Coronary Syndromes
GUSTO  Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries
ICC  Intra-cluster Correlation Coefficient
ICP  Integrated Care Pathway
1.1 Cardiovascular disease and acute coronary syndromes

Cardiovascular disease (CVD) is the leading cause of death from non-communicable diseases worldwide, with over 17 million deaths due to cardiovascular causes recorded during 2008. (World Health Organisation 2008) The British Heart Foundation (BHF) estimates that Coronary Heart Disease (CHD) is the main cause of death in the UK; approximately 73,000 deaths are recorded per year. (British Heart Foundation Health Promotion Research Group and Department of Public Health 2012)

In addition to the cost to human lives, CVD is associated with a huge economic cost. The overall cost of CVD was estimated at £19 billion in 2009, 46% (over £9 billion) was due to healthcare costs, 34% productivity losses and 20% to informal care for patients with CVD. The overall cost of CHD is estimated at £6.7 billion per year, with 27% due to healthcare costs, 47% to productivity loss and 26% to informal care of CHD. (British Heart Foundation Health Promotion Research Group & Department of Public Health 2012)

Acute Coronary Syndromes (ACS) are one of the most important causes of mortality and morbidity, creating a considerable economic burden through multiple hospital admissions, time taken out of work and the implications in terms of disability and chronic treatment. A range of effective treatments are available and yet the healthcare burden of ACS persists. Rates of death, myocardial infarction (MI) and readmission to hospital remain high. There is an urgent need to address this problem and find sustainable solutions to improve care of ACS.

1.2 Aetiology

ACS is a result of atherosclerosis in the coronary arteries, which is the narrowing of arteries or thickening of artery walls due to the presence of atheromatous plaque. It is usually triggered by acute thrombosis caused by ruptured coronary plaque which, along with partial or total obstruction of the coronary arteries, causes a severe reduction in blood flow. On rare occasions, ACS aetiology is not linked to atherosclerosis in cases such as trauma, dissection, thromboembolism, congenital anomalies, complications of cardiac catheterisation or cocaine abuse. (Hamm et al. 2009)

1.2.1 Diagnosis and classification of Acute Coronary Syndromes

Acute Coronary Syndromes include myocardial infarction (MI) and unstable angina (UA). The typical presentation of ACS is acute chest pain, typically described as radiating to the left arm or jaw and may be intermittent or persistent.
1.2.2 Electrocardiogram (ECG)

Classification of ACS is based on the admission electrocardiogram (ECG) and cardiac markers detected in blood tests. Patients with persistent ST-segment elevation on the ECG are defined as ST elevation MI (STEMI) and those without persistent ST-segment elevation on the ECG are defined as non-ST elevation ACS (Non-ST ACS). Non-ST elevation ACS patients may have any of the following on their presentation ECG: transient ST-segment elevation, ST-segment depression, T-wave inversion, flat T waves, or no ECG changes where diagnosis is made purely on the basis of cardiac markers measured in blood. (Hamm C.W., Mollman, Bassand, & Van de Werf 2009; Hamm et al. 2011)

1.2.2.1 Cardiac troponin

Non-ST elevation ACS patients are further classified into non-ST elevation MI (NSTEMI) and unstable angina (UA) on the basis of the release of cardiac troponin into the blood. In the presence of chest pain and ECG changes, elevated cardiac troponin indicates myocardial damage. Troponin rises within 4 hours of symptom onset and can remain elevated for up to two weeks. (Thygesen et al. 2007) Classification of ACS is summarised in Figure 1.

![Figure 1. Classification of ACS](image)

1.2.2.2 Comparison of STEMI and Non-ST elevation ACS

It is estimated that about two thirds of ACS are non-ST elevation and about a third are STEMI, although this varies in different populations. (Fox et al. 2010b; Yeh et al. 2010)
hospital outcomes are worse for STEMI patients, but six-month mortality rates are similar for STEMI and non-ST elevation ACS, and long term outcomes are worse for non-ST elevation ACS. Four years after the event, the mortality rate for NSTEMI patients is approximately double that observed for STEMI patients. For this reason, it is important to consider long-term management as well as the acute phase of non-ST elevation ACS. (Hamm C.W., Mollman, Bassand, & Van de Werf 2009; Terkelsen et al. 2005)

1.2.3 Treatment of ACS

Patients diagnosed with STEMI are treated with an urgent reperfusion strategy either by primary percutaneous coronary intervention (PCI) or thrombolysis. Non-ST elevation ACS patients require risk stratification, medical management and may also require a reperfusion strategy if indicated by their clinical symptoms, ECG and risk profile. This thesis focuses on the management of non-ST elevation ACS patients only.

1.2.3.1 Risk stratification

In addition to performing a clinical assessment including full medical history, ECG and measurement of cardiac markers, overall risk can be assessed using risk stratification “scores”. There are several such scores used to predict ischaemic risk: GRACE, TIMI, GUSTO and PURSUIT for example.

1.2.3.1.1 GRACE score

The Global Registry of Acute Coronary Syndromes (GRACE) risk score was developed from data collected during a multinational, observational registry of unselected ACS patients. The GRACE registry was conducted from 1999 to 2009 in 123 hospitals in 14 countries in North and South America, Europe, Australia and New Zealand. (Fox et al. 2002a; Fox, Eagle, Gore, Steg, Anderson, & for the GRACE and GRACE2 Investigators 2010b; Fox and Langrish 2010; Goodman et al. 2009; Granger et al. 2003) The GRACE score is calculated from the following factors: Killip Class, systolic blood pressure, age, heart rate, creatinine, ST segment deviation, cardiac arrest and elevated serum cardiac enzymes. Scores for each of the factors are added up to give a total risk score which is associated with a calculated in-hospital mortality risk. There is also an equivalent score for predicting risk of mortality and myocardial infarction at 6 months. (Eagle et al. 2004)

The score is calculated using a programme which can be downloaded onto a desktop or handheld computer, or calculated online (http://www.outcomes.org/grace). Calculation of the GRACE score is now a simple task that can be performed quickly on any smartphone.
1.2.3.1.2 TIMI score

The TIMI score is also widely used to assess risk associated with ACS events.(Antman et al. 2000) The score was developed using data from two randomised controlled trials conducted in the late 1990s, the TIMI(Antman et al. 1999) and ESSENCE(Cohen et al. 1997) trials. Seven factors were identified as predictive of risk using multiple logistic regression: age above or below 65, presence of at least three risk factors for coronary artery disease, prior coronary stenosis of 50% or more, ST segment deviation on ECG, severe angina symptoms (at least 2 events in last 24 hours), use of aspirin in last seven days and elevated cardiac markers.

The TIMI score is simple to calculate and does not require a computer programme; a score of zero or one is assigned to each of the seven risk factors and these are added up giving a minimum total score of zero and maximum total score of seven.

1.2.3.1.3 GUSTO

The GUSTO risk score(Califf et al. 2000) was developed from a randomised controlled trial of thrombolysis with aspirin and beta-blockers conducted from 1990 to 1993(Alexander et al. 1998). The score can be used to predict one-year survival in patients with STEMI surviving to 30 days. It is calculated using data on age, heart rate, ejection fraction, previous MI and in-hospital congestive heart failure or pulmonary oedema.

1.2.3.1.4 PURSUIT score

The PURSUIT score(Boersma et al. 2000) was developed on the basis of the PURSUIT trial which recruited over 10,000 non-ST elevation ACS patients from 1995 to 1997.(The PURSUIT Investigators 1998) The PURSUIT score can be used to estimate the risk of 30-day mortality for non-ST elevation ACS patients. The variables associated with increased risk of 30-day mortality and the composite of mortality and MI are: age, gender, Canadian Cardiovascular Society (CCS) angina class, heart rate, systolic blood pressure, signs of heart failure and ST depression on ECG.

1.2.3.1.5 Comparison of risk scores

Direct comparisons of GRACE, TIMI and PURSUIT identify GRACE as the score with the highest discriminative accuracy both in terms of 30-day and 1-year mortality. Predictive accuracy was assessed using the C-statistic (Aragam et al. 2009;de Araujo et al. 2005;Yan et al. 2007a) The inclusion of age as a continuous variable and taking renal function into account are considered to contribute to the predictive power of this score.(de Araujo et al. 2005;Yan et al. 2007a) It is also important to note that the score was derived from a large
observational cohort rather than a clinical trial population which tends to be more selected. The difference in prognostic value may be associated with the omission of important clinical factors such as history of heart failure, blood pressure and heart rate and also the fact that age is treated as a binary factor i.e. above or below 65 years.(Aragam et al. 2009;Ginghina et al. 2011;Gray and Henderson 2011;Khalil et al. 2009)

1.2.3.2 Management of non-ST elevation ACS

Evidence from the literature is used to develop guidelines which provide recommendations for optimal management of patients based on an evaluation of all available evidence. Clinical practice guidelines (CPG) have been developed in all therapeutic areas and are regularly updated to reflect the latest evidence (Grimshaw et al. 2004).

CPGs provide recommendations for the management of ACS on the basis of evidence accumulated from clinical trials, observational registries and other data sources. CPGs provide a classification for each recommendation according to the level of evidence available. CPG committees set up specific groups or ‘Task Forces’ to develop and update guidelines on a regular basis and membership of the groups is comprised of experts in the field.

In the UK, CPGs are developed and published by the National Institute for Health and Care Excellence (NICE). NICE guidelines are publicly available and are published in a range of formats; as public information or full clinical guidelines available online, and as short clinical guidelines that can be downloaded in a booklet format. NICE has published guidelines on all aspects of ACS management including early management of unstable angina and NSTEMI and secondary prevention of MI (Gray et al. 2010;National Institute for Health and Clinical Excellence (NICE) 2010;National Institute for Health and Clinical Excellence (NICE) 2015;NICE 2013) Development groups for NICE guidelines are made up of healthcare professionals with expertise in the relevant areas but also include patient or carer representatives.

The European Society of Cardiology (ESC) publishes guidelines on the management of non-ST elevation ACS(Hamm et al. 2011;Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology et al. 2007). Task Force membership for ESC consists of healthcare professionals who are primarily cardiologists. ESC guidelines are published as full clinical guidelines in the European Heart Journal and can also be purchased as pocket guidelines and a mobile application version from the ESC website.
The American College of Cardiology and American Heart Association (ACC/AHA) have also published guidelines on the management of non-ST elevation ACS (Amsterdam et al. 2014). The process for development of guidelines is similar to the ESC and the guidelines are published in the journal Circulation.

The ESC and AHA/ACC guidelines for management of non-ST elevation ACS make similar recommendations but comparison of these with the NICE guideline recommendations highlights some minor differences:

i. ESC and ACC/AHA guidelines classify patients into three risk categories whereas NICE uses 6 risk categories in accordance with the Myocardial Ischaemia National Audit Project (MINAP) database definitions.
ii. NICE are the only guidelines to provide a public version and also include lay members on guideline development groups.
iii. NICE guidelines place more emphasis on non-medicinal secondary prevention measures than the ESC and ACC/AHA i.e. cardiac rehabilitation programme, smoking cessation and modifications to diet and physical activity.
iv. Recommended timelines for coronary angiography are within 72 hours for ESC and ACC/AHA but within 96 hours for the NICE guidelines. For very high risk admissions ACC/AHA and ESC recommend angiography within 24 hours of admission to hospital.

The CPGs described above define best care for non-ST elevation ACS including diagnosis, in-hospital treatment and long-term management for secondary prevention of further events. Key recommendations made by the above guidelines are summarised below.

1.2.3.3 Acute treatment with medical therapy

Non ST elevation ACS are treated with the following during the acute phase:

i. Anti-ischaemic agents i.e. beta-blockers, nitrates, calcium channel blockers
ii. Dual antiplatelet therapy i.e. aspirin and one of: clopidogrel, prasugrel or ticagrelor
iii. Glycoprotein IIb/IIIa inhibitors
iv. Anticoagulants

1.2.3.4 Coronary revascularisation

In non-ST elevation ACS patients, coronary revascularisation is performed in selected patients to relieve angina and myocardial ischaemia, and to reduce the risk of MI or death. Revascularisation is performed by percutaneous coronary intervention (PCI) or coronary...
artery bypass surgery (CABG). International guidelines state that coronary angiography should be performed in intermediate to high risk patients to determine the appropriate revascularisation strategy. (Amsterdam et al. 2014; Gray et al. 2010; Hamm et al. 2011; National Institute for Health and Clinical Excellence (NICE) 2010)

Risk stratification guides the decision on the need for and the timing of angiography and revascularisation. At one end of the spectrum of non-ST elevation ACS, low risk patients will be managed conservatively with angiography being performed only in selected cases whereas very high risk patients will be referred for urgent angiography, i.e. within 24 hours of admission, and subsequent revascularisation if appropriate. As noted earlier, the current recommendation from the ESC guidelines (Hamm et al. 2011) is that patients with ‘intermediate’ to ‘high’ risk scores should be referred for angiography within 72 hours. The ESC guidelines define ‘intermediate’ risk as a GRACE score of 109-140 which is equivalent to an in-hospital mortality rate of 1-3%, and ‘high’ risk as a GRACE score of more than 140 equivalent to in-hospital rate of 3% mortality. (Hamm et al. 2011)

1.2.3.5 Long-term treatment

The following treatments are prescribed for secondary prevention of further ACS events:

i. Antiplatelet: aspirin and clopidogrel or prasugrel
ii. Beta blockers
iii. Statins
iv. Angiotensin Converting Enzyme (ACE) inhibitors or Angiotensin II Receptor Blockers (ARB) if ACE are not tolerated
v. Enrolment in a cardiac rehabilitation programme
vi. Smoking cessation
vii. Modification to diet and physical activity

1.2.4 Adherence to guidelines

1.2.4.1 Clinical registries

Data on the management of ACS are collected via national and international registries, in order to assess adherence to clinical practice guidelines. In Sweden, the RIKS-HIA registry of all acute MI admissions started in 1995 and in 2009 the registry was merged with all cardiac registries in Sweden into what is now called the SWEDEHEART registry. (Jernberg et al. 2010; Stenestrand et al. 2001) Similarly, the Euro-Heart Survey captures data on all cardiovascular disease from a number of centres across Europe. (EUROASPIRE II Study group 2001; Hasdai et al. 2002; Mandelzweig et al. 2006) In the UK, the MINAP
registry (Birkhead et al. 2004; Herrett et al. 2010) was set up to assess management of MI and in the US the Get-With-the-Guidelines (GWTG) registries evaluate adherence to ACC/AHA guidelines across the range of cardiovascular diseases.

In the case of coronary artery disease (CAD) two national US registries, the National Cardiovascular Data ACTION Registry and the GWTG-CAD Registry were merged in 2007 into one comprehensive CAD registry called ‘ACTION Registry-GWTG’. (Peterson et al. 2009; Roe et al. 2009) Another important registry of ACS is the Global Registry of Acute Coronary Events (GRACE) registry mentioned earlier. GRACE is a global database of ACS, capturing data from 123 hospitals in 14 countries. Clusters of hospitals were identified in each country to ensure that a range of hospitals were represented and data collection started in 1999.

### 1.2.4.2 Sub-optimal adherence to guidelines

It has been shown that improved guideline-adherence for management of ACS is associated with improved clinical outcomes. (Allen et al. 2004; Fermann et al. 2009; Fox et al. 2007a; Mukherjee et al. 2004; Roe et al. 2005; Rosamond et al. 2008) Data from the CRUSADE observational programme from more than 60,000 patients, admitted for ACS from 2001 to 2003, demonstrated that in-hospital mortality was significantly reduced for patients in the highest quartile of ACC/AHA guideline adherence. (Peterson et al. 2006) Improvement of 10% in guideline-adherence was associated with a 10% reduction in in-hospital mortality.

Despite the evidence that guideline-adherence is associated with improved outcomes, the registries described earlier report a considerable gap between guideline recommendations and management of ACS. (Birkhead et al. 2004; Blomkalns et al. 2007; Bueno et al. 2005; Cabana et al. 1999; Collinson et al. 2000; Erhardt et al. 2008; Grimshaw et al. 2004; Hasdai et al. 2002; Mandelzweig et al. 2006; McNamara et al. 2014) Data from the GRACE registry have also confirmed this gap. (Fox et al. 2002b; Steg et al. 2002) Registries have shown that, even in the case of overwhelming evidence of clinical benefit, the adoption of a new treatment into practice is often delayed (Bassand 2000). There is some evidence of improvement over time but the standard of care still remains sub-optimal. (Mandelzweig et al. 2006; Yan et al. 2007b)

In addition to demonstrating sub-optimal management of ACS in general, it appears that adherence to guidelines varies in different patient populations, with a tendency to under-treat high risk and elderly patients (Banihashemi et al. 2009; Brilakis et al. 2009; Collinson et al.)
2000; Heras et al. 2006; Mandelzweig et al. 2006). A similar problem has been noted for patients with chronic kidney disease (CKD) (Hanna et al. 2011) and diabetes. (Bakhai et al. 2005; Norhammar et al. 2003)

A survey conducted by Huynh et al reported that clinicians are not aware of this reported lack of adherence to guidelines and consider that they are treating ACS patients adequately. (Huynh et al. 2009) Efforts have been made to bridge the gap between guideline recommendations and clinical practice using a range of methods including professional education, financial incentives and structured training programmes based on quality improvement (QI) methods derived from industry models (Oxman et al. 1995). The next section describes these methods.

1.3 Quality improvement

1.3.1 QI methodology

There are two strands to the application of QI methods in healthcare: one approach is based on improving managerial quality and the second on improving clinical quality. It is necessary to implement both of these to achieve improved standards of care though they have often been treated as separate strategies, conducted in parallel. QI approaches to improve managerial quality have made use of statistical methods to assess manufacturing processes. A chronological overview of the key QI industry methods is provided below, the methods and tools presented are those that are more relevant for healthcare.

The pioneers of QI methods in the industry setting are considered to be Joseph Juran and W. Edwards Deming. Both applied statistical principles to improve manufacturing processes during their extensive work with the Japanese manufacturing industry after the Second World War. (Boaden et al. 2008; Mayer 1992)

Juran’s work was based on the use of statistical process control (SPC) to achieve total quality management (TQM). He developed quality control systems to improve the manufacturing process from start to finish and focussed on the managerial aspects of a process. (Juran 1951; Juran 1964; Juran 1967) Deming developed a 14-point theory for improving quality and organisational culture which focused on all levels of an organisation from the factory floor to leaders and managers. (Deming 1986) He emphasised the importance of good communication and teamwork across all levels in an organisation and also that quality must be addressed from the start of a manufacturing process. Deming also developed the Plan-Do-Check-Act (PDCA) cycle, also known as the Plan-Do-Study-Act.
cycle, which was based on the work of Shewhart (Shewhart 1931) and is a tool commonly used in QI work.

Other pioneers in industrial quality improvement include Philip Crosby who promoted the concepts of achieving zero defects in a process and getting things right the first time, and Armand Feigenbaum who was the Chief of Manufacturing at General Electric in the 1960s and considered management and leadership to be crucial for improving quality. (Boaden et al. 2008)

The application of QI methodology to healthcare dates back to 1918 and Ernest Avery Codman (Codman 1918) whose work highlighted the importance of measuring standards of care and making these results available to patients as well as healthcare professionals. Codman is considered the pioneer of outcome-based patient care, a concept central to healthcare delivery today. Donabedian developed these concepts further, defining healthcare as a complex multi-factorial system and establishing a model which comprised structure, process and outcome (Donabedian 1988). This idea has been the basis for QI work since its inception and introduces the idea of process-driven improvement.

The contemporary ‘guru’ of QI in healthcare is Donald Berwick, former president of the Institute for Healthcare Improvement (IHI), a not-for-profit organisation leading improvement programmes throughout the world and also a key adviser to the U.S. Department of Health as Administrator of the Centers for Medicare & Medicaid Services (Berwick 2008). Berwick has applied the principles of industrial quality improvement described above to improving healthcare and his work emphasises the importance of understanding current performance requiring accurate measurement, and of setting appropriate targets. Recently, Berwick was invited to conduct a review of the Mid-Staffordshire NHS services following the Francis report. (Berwick 2013; Francis 2013)

1.3.2 QI models

1.3.2.1 The ‘model for improvement’ and PDSA cycle

One of the earliest and most commonly used tools in QI work is the Plan-Do-Study-Act (PDSA) model, originally termed Plan-Do-Check-Act (PDCA). (Deming 1986; Shewhart 1931). PDSA is used to improve work processes: an idea for change is conceived, the idea is then tested, results from tests are reviewed and actions taken either to modify the idea and re-test, or to implement it on a larger scale if it is effective. PDSA can lead to a chain of multiple
cycles and is an efficient structured method of implementing ideas for improvement in the healthcare setting.

The ‘Model for Improvement’ is a QI approach developed by the Associates in Process Improvement. The approach is based on PDSA and aims to implement and test rapid changes to improve a process. (Langley et al. 1994; Langley et al. 2009) The Model for Improvement asks three key questions to identify a need for change and assess the ability of this change to lead to an improvement. The model is summarised in Figure 2.

![Figure 2. The PDSA (Deming) cycle and model for improvement](NHS Institute for Innovation and Improvement 2015)

1.3.2.2 Cause and Effect Analysis

The cause and effect diagram, also known as ‘fish-bone’ diagram, was developed by Kaoru Ishikawa in the 1960s. (Ishikawa 1982) The tool is used to identify a problem and break this down into potential causes, or categories of causes. This can help to identify a solution to the problem by addressing each cause in turn. Categories are sometimes defined as: people, process, management. A theoretical example ‘cause and effect’ diagram is shown in Figure 3.
1.3.2.3 **Statistical Process Control**

Statistical Process Control (SPC) originates from the work of Shewhart (Balestracci 1998; Berwick 1991; Shewhart 1931) and is widely used in assessment of healthcare as a measurement tool rather than a full QI method. SPC is applied either as a stand-alone tool or in combination with other tools. (Carey 2002; Thor et al. 2007). SPC uses statistical methods to measure performance. Performance over time is plotted on a control chart and this can be used to demonstrate time-periods of reduced or improved performance but also to assess the impact of a QI intervention. SPC is also a valuable tool for assessing variation in performance and the method aims to improve performance and reduce variation, with the aim of creating a more reliable and stable process. (Levett and Carey 1998)

1.3.2.4 **Six Sigma**

Six sigma is a QI method originating from statistical models, notably those of Shewhart (Shewhart 1931) described above, which focuses on reducing variation and defects in a process. The name comes from the Greek symbol for standard deviation ‘σ’, in reference to variation around a mean value, as the method sets a target of achieving a defect-free result 99.99966% of the time which is equivalent to 6 standard deviations. (Boaden, Harvey, Moxham, & Proudlove 2008; Harry 1990) The model was developed by the manufacturing industry to reduce product variation, with Motorola designing the original model in the 1980s and further modifications introduced by General Electric. (Boaden et al. 2008) It uses both statistical data-driven tools and change management principles.

The full Six Sigma method is not widely used in healthcare, although there are many references to using Six Sigma principles and tools. (Liberatore 2013; Silich et al.)

![Cause and effect diagram](image)
Assessment of these references shows that it is not always correctly applied and that results are not always in favour of using the method. (DelliFraine et al. 2014; Liberatore 2013)

1.3.2.5 LEAN

Another model adopted from Industry is the LEAN model for improvement. LEAN is attributed to Toyota and its main principles are focussed on improving the flow of a work process by eliminating waste and unnecessary steps. (Bhasin and Burcher 2006; Womack et al. 1990; Womack and Jones 1996)

The LEAN model incorporates the following tools:

a) Value stream or process mapping: To outline a work process, identify waste or redundant steps, problem areas, bottlenecks and propose methods to eliminate these and create reliable processes. The Toyota method identifies 7 possible forms of waste: Overproduction, waiting, transport, inappropriate processing, unnecessary inventory, unnecessary motion and defects.

b) 5S: Five principles of lean thinking: sort, simplify, shine/scrub, standardise, sustain

c) Kaizen Blitz/Rapid Improvement Events: Intensive period of improvement work to implement radical change, following initial data gathering. Influenced by the Japanese concept of ‘kaizen’ which refers to continuous management

LEAN principles are widely applied in health care, an important example being the NHS 18 week pathway, a Department of Health initiative aiming to reduce waiting times from GP referral to hospital treatment (Department of Health 2004; Manos et al. 2006). Another important use of LEAN methodology in the NHS is the Productive Series, which is an initiative set up by the NHS Institute for Innovation and Improvement and now managed by NHS Improving Quality. The Productive Series aims to streamline NHS processes and reduce waiting time in a range of settings such as GP practices, wards and operating theatres. (NHS Institute for Innovation and Improvement 2013)

A range of programmes conducted recently have combined tools from the LEAN and Six Sigma models. The combined ‘LEAN Six Sigma’ approach is proving to be more popular than use of Six Sigma on its own. (Ahmed et al. 2013; Fischman 2010; Mason et al. 2014).

1.3.2.6 Theory of constraints (TOC)

The Theory of Constraints (TOC), developed by Goldratt (Goldratt and Cox 1984) is based on the principle that every system has at least one constraint and that this is an opportunity for improvement. TOC identifies 5 focussing steps: (i) identify the constraint, (ii) decide how
to exploit this constraint, (iii) subordinate everything else to the above decision, (iv) elevate the system’s constraint and then, (v) go back to the first step if a new constraint has arisen. TOC is not widely used in healthcare. This may be because further work is needed to adapt the theory to the healthcare setting and at present only Goldblatt has focussed on the application of this method in industry. (Breen et al. 2002; Patwardhan et al. 2006; Sadat et al. 2013)

1.3.2.7 Total Quality Management (TQM)

Total Quality Management, sometimes called Continuous Quality Improvement (CQI), is a continuous organisation-wide strategy to achieve a high quality process. This means that quality improvement is built-in to all aspects of an organisation in order to continually improve standards. This approach is not clearly defined but rather it is a concept for continuous improvement derived from the manufacturing industry and can include any combination of QI tools and models described above. Central themes to TQM include ensuring an organisation meets the ‘customer’s’ needs, that quality is derived from the processes within an organisation and the importance of individuals contributing to each process. TQM uses measurement of data to identify problem areas within a process and identify areas for improvement. (Watson 1995; Wilkinson et al. 1992)

1.3.3 Benchmarking and reliability in QI

The manufacturing industry has implemented these and other models in order to achieve reliable work processes. The principal focus has been identifying problem areas, referred to as ‘defects’, and subsequently finding possible solutions to these which are tested out in a controlled environment before implementation on a large scale. The aviation and automobile industry in particular have used these tools and QI experts have turned to this approach to inform benchmarking in healthcare.

The Institute for Healthcare Improvement (IHI) has studied how targets are set in industry and concludes that tolerance of ‘defects’ is much lower than in healthcare. Private healthcare and insurance companies have experience in implementing QI tools to identify problem areas and suggest effective methods to overcome these within an organisation. As in the case of corporate businesses, tolerance levels of errors are extremely low as they translate into important financial losses. The IHI describes this phenomenon with mathematics i.e. $10^{-1}$ defects are considered reasonable in healthcare whilst in Industry anything less than $10^{-3}$ is unacceptable. (Nolan et al. 2004) This means that clinicians are not dissatisfied if more than one in 10 patients do not receive a life-saving treatment and rates of 70-80% are tolerated (Resar 2006). Although healthcare is not equivalent to the
manufacturing industry, the concept described by the IHI strives to achieve reliable processes in healthcare and highlights that there is considerable room for improvement.

Literature demonstrates that levels of recommended treatments are surprisingly low. For example McGlynn et al (McGlynn et al. 2003;Schuster et al. 2005) report that just over 50% of patients receive recommended care in the United States whether this be preventative, acute or chronic treatment, and similar rates have been reported in Europe, for example the treatment of ACS according to the Euro-Heart Survey.(Mandelzweig et al. 2006) The low rates reported appear to be tolerated in healthcare, more than would be the case for the manufacturing industry.

1.3.4 Clinical Quality Improvement

1.3.4.1 Clinical Practice Guidelines and educational programmes

The importance of CPGs and evidence-based practice was noted earlier in this chapter. Much of clinical QI work is built on the dissemination of CPGs and training initiatives to raise awareness and implementation of these (Califf et al. 2002;Farquhar et al. 2002;Ferlie and Shortell 2001). This approach was used in the PROMIS-UK study(Booth et al. 2006) whereby the ESC guidelines formed the basis for educational sessions and tools provided to participating centres. The QI intervention in PROMIS was delivered using a cluster-randomised design, enabling a robust comparison of the intervention and control groups. A modest improvement in implementation of the ESC guidelines was noted.

Another example of a cluster-randomised educational intervention was a training programme for GPs treating alcohol related disorders (Ruf et al. 2009). This latter study implemented training via an internet-based system but the results were modest, with a limited number of GPs showing a commitment to using the systems.

The Discharge Management of Acute Coronary Syndrome (DMACS) project also involved the use of educational initiatives to enhance compliance with guidelines for management of ACS. Comparison of data collected before and after delivery of the educational initiative showed an improvement in prescription of four guideline-recommended treatments and referral for cardiac rehabilitation during the study measurement period.(Peterson et al. 2012;Wai et al. 2012)

While knowledge of current guidelines is central to delivering high quality clinical care, QI programmes based on educational interventions have shown only modest results and
demonstrate weaknesses when factors such as staff changeover and on-call staff are considered (Grimshaw et al. 2004; Grol 2001).

1.3.4.2 Care pathways

Care pathways are used in clinical practice to standardise evidence-based healthcare processes. Pathways can be designed to translate CPGs into daily practice, to map out a clinical process so as to ensure steps are not omitted or duplicated and finally to act as decision-support tools. Use of care pathways has shown encouraging results, particularly in improving the use of evidence-based treatments. The National Heart Attack Alert Program conducted a systematic review of use critical pathways in management of ACS and reported that improvement in use of guideline recommended treatments was observed. (Cannon et al. 2002) Another systematic review of ‘decision support systems’ across a range of settings and therapeutic areas showed that interventions including a clinical pathway in the form of a decision support system were statistically more likely to improve clinical practice. (Kawamoto et al. 2005) There are also examples in the setting of cardiovascular disease indicating that use of evidence-based treatments increases in the presence of formalised clinical pathways. (Ketola et al. 2000; Mehta et al. 2000; Scott 2009).

1.3.4.3 Clinical governance

Clinical governance is a system which imposes a legal duty on organisations to deliver a high quality of care and to be accountable for patient care. This places a responsibility on the NHS to continuously improve standards of care. (Scally and Donaldson 1998; Secretary of State for Health 1997) Clinical governance strives to improve patient care by focusing on the following: education and training, clinical audit, clinical effectiveness, research and development, openness, risk management and information management.

1.3.4.4 Pay-for-performance

Pay-for-performance schemes have shown noteworthy results. The majority of these taking place in countries where the contribution of private healthcare is important, such as the U.S. (Centers for Medicare and Medicaid services; Glickman et al. 2008; Lindenauer et al. 2007). There are also successful examples from public health systems and an important example is the Quality and Outcomes (QOF) framework, an incentive and rewards scheme for GPs set up by the NHS in 2004 (Campbell et al. 2007; Campbell et al. 2009). Improvements were seen in chronic treatments for asthma, diabetes and coronary heart disease but it appears that once targets were reached, no further improvement was achieved. It is also not clear whether the improvements noted can be attributed to payment incentives only as a range of other improvement initiatives were ongoing at the time. Thus,
financial incentives can lead to improvements but these can be small and the ultimate improvement is limited by targets. It may be that the targets set in QOF were not challenging enough and should have been revised to encourage further improvement in patient care. (Calvert et al. 2009; Langdown and Peckham 2014)

1.3.4.5 Performance measurement

Evidence shows that publication of hospital performance can lead to improvements and this can take the form of public ‘scorecards’ showing a hospital’s performance with respect to evidence based indicators, or audits and disease registries which have the facility to feedback results to participating centres. (Cannon et al. 2009; Kiefe et al. 2001; Scott 2009; Tu et al. 2009)

A systematic review conducted by Fung and colleagues to assess the effect of public performance measures on quality improvement (Fung et al. 2008) found a lack of evidence of impact. There were few examples in the literature of studies to evaluate public reporting systems and the effect these have on quality of care. There was some evidence that hospitals undertake local QI initiatives in response to publication of clinical audit data, with the majority of these examples taking place in US hospitals, but there were also examples in the UK setting indicating that publication of performance measures can dis-incentivise QI work in some cases. (Mannion et al. 2005; Mannion and Goddard 2001; Mannion and Goddard 2003)

In the UK, the Society for Cardiothoracic Surgery started publishing consultant outcome data in 2005 on their website. (Society for Cardiothoracic Surgery in Great Britain and Ireland 2015) This initiative was reported to be successful as it was associated with an improvement in patient outcomes. (Bridgewater et al. 2007; Bridgewater et al. 2013)

In 2013, public reporting of individual consultant data was extended to include eleven surgical specialties following the plans set by the ‘Everyone counts’ initiative. (NHS Commissioning Board 2014) Data is currently available on the NHS choices website (NHS Choices 2015) for individual consultants in the following specialties: adult cardiac surgery, bariatric surgery, colorectal surgery, endocrine and thyroid surgery, head and neck cancer surgery, interventional cardiology, lung cancer, neurosurgery, orthopaedic surgery, urological surgery and vascular surgery.

This initiative built on the initial decision to publish all hospital mortality data in 2009, following the Mid Staffordshire NHS Foundation Trust scandal (Francis 2013), expanding this
to include mortality and complication data for all NHS Trusts and all consultants. This initiative was driven by NHS England and managed by the Healthcare Quality Improvement Partnership (HQIP), an independent organisation with a focus on quality of care using clinical audit data. (Healthcare Quality Improvement Partnership 2014)

There is currently no information available about whether the public’s choices are determined by availability of individual consultant data and this would merit further evaluation. It is also important to note that volume of procedures for some of the specialties is low which could mean that the data presented for individual consultants are not adequately powered to be representative. (Walker et al. 2013)

The MINAP, ACTION-GWTG and SWEDEHEART (Birkhead et al. on behalf of the MINAP Steering Group 2004; Herrett et al. on behalf of the MINAP Academic Group 2010; Jernberg et al. 2010; McNamara et al. 2014; Roe et al. on behalf of the CRUSADE and ACTION-GWTG Registry Participants 2009; Xian et al. 2010) registries cited earlier are examples of performance monitoring in ACS, enabling direct comparison with other participating organisations as well as providing data on temporal trends for management of cardiovascular disease. The latest ESC guidelines on management of non-ST elevation ACS now recommend continuous performance monitoring to improve adherence to guidelines. (Hamm et al. 2011)

1.3.5 QI organisations

In addition to government improvement initiatives, there are a numerous large-scale QI programmes ongoing which are led by independent, not-for-profit organisations. The Institute for Healthcare Improvement (IHI) (Institute for Healthcare Improvement 2015) is considered a global leader in evaluation of QI work. The field of evaluation of QI methodology is known as Improvement Science and IHI is a leader in this field. The IHI has developed some of the established tools used to implement QI initiatives, notably the ‘Breakthrough Series’, a QI approach developed to effect rapid improvement changes in healthcare settings. (Institute for Healthcare Improvement 2003)

The IHI Breakthrough Series is divided into ‘Learning Sessions’ and ‘Action Periods’. Representatives of the participating organisations and QI experts attend the Learning Sessions where they discuss the area requiring improvement and methods to achieve this. There are usually about 3 Learning Sessions, enabling participants to discuss their progress over the course of the programme during collaborative meetings. The Action Periods take place between Learning Sessions and the participating teams use this time to test ideas to
improve their work processes and evaluate them. Testing and implementation of ideas for improvement is carried out using the 'Model for Improvement' which was described earlier in this chapter.(Institute for Healthcare Improvement 2003;Langley, Nolan, & Nolan 1994;Langley et al. 2009)

In the UK, the leader in improvement science was the NHS Institute for Innovation and Improvement which has now closed and been replaced by NHS Improving Quality (NHSIQ).(2015a) The NHS Institute ran national QI programmes but also developed training and education opportunities for healthcare professionals to encourage local QI projects. The Institute also instigated a number of QI initiatives, targeting issues such as surgical outcomes and hospital-acquired infections and reducing waiting time for referral to hospital as mentioned earlier (Boaden et al. 2008;Department of Health 2004;Institute for Healthcare Improvement 2003). The Health Foundation (2015b) in the UK is an independent charity leading in evaluation of quality improvement programmes for healthcare and improvement science. The Health Foundation has recognised the need for rigorous research of QI methods and is undertaking a range of tasks to further improvement science in the UK including funding fellowships, reviews of literature(The Health Foundation 2011) and forming a partnership with the British Medical Journal Quality and Safety Journal to support publication of QI research.

1.3.6 QI in Acute Coronary Syndromes

1.3.6.1 Observational QI programmes

Several programmes assessing ability of QI to improve management of ACS have been conducted. The Can Rapid Risk Stratification of Unstable Angina Patients Suppress ADverse Outcomes with Early Implementation of the ACC/AHA Guidelines (CRUSADE) initiative was an observational study of non-ST elevation ACS admissions conducted in over 400 US hospitals. The initiative comprised a registry of all non-ST elevation ACS admissions, an educational programme for clinicians and a data feedback tool. Assessment of compliance with ACC/AHA guidelines over time showed modest improvement in treatment.(Bhatt et al. 2004;Hoekstra et al. 2002;Mehta et al. 2006;Ohman et al. 2004)

The Guidelines Applied in Practice (GAP) initiative was a QI programme for AMI management that took place in ten acute care hospitals in Michigan. The ten QI hospitals were selected from a group of 31 hospitals taking part in the Southeast Michigan Hospital Profiling Project. A further 11 hospitals from the group were identified as non-randomised ‘control’ centres. The QI intervention consisted of an initial training meeting, a QI toolkit to encourage prescription of key treatments, identification of local opinion leaders at
participating sites, visits to sites by trial team and measurement of data before and after the QI intervention. Statistically significant improvements of 5-10% were observed for use of aspirin and beta-blockers at admission, and also for aspirin and smoking cessation counselling at discharge. Prescription of aspirin at discharge improved more in the QI group compared to the control group by 5%, all other changes in treatments were not statistically significant. (Mehta et al. 2002)

Both GAP and CRUSADE were observational studies so it is important to note that background temporal improvements in use of guideline-recommended treatments cannot be excluded. In the case of GAP, baseline data were collected at least a year before the QI intervention was delivered which means that practice could have changed considerably over the course of the study.

The ‘Get With The Guidelines’ (GWTG) programme discussed earlier, was created by the American Heart Association (AHA) and the American Stroke Association (ASA) (Horwich et al. 2009; Laskey 2010; Lewis et al. 2008; Smaha 2004) to improve the care of patients with cardiovascular disease by improving adherence to guidelines. GWTG has programmes in each of the following areas: stroke, atrial fibrillation, heart failure, resuscitation and coronary artery disease. GWTG uses a number of the QI tools described in this chapter. Participating hospitals are given access to a web-based data collection and patient management tool, interactive workshops and performance feedback. A study was performed to compare guideline adherence at GWTG-CAD hospitals to non-GWTG-CAD hospitals using data collected from January to June 2004. (Lewis et al. 2008) Data for 223 GWTG hospitals and 3407 non-GWTG hospitals were obtained from the publicly available Centers for Medicare and Medicaid Hospital Compare database. Adherence to guidelines, defined as a composite of eight AMI treatments, was 4.7% higher in the GWTG hospitals than in the non-GWTG hospitals. Adherence to the GWTG-CAD performance measures, expressed as a composite of four key AMI treatments, was also higher for GWTG hospitals, by 6.5%. The GWTG programme has now been merged with the CRUSADE registry mentioned above, providing a rich database and incorporating QI feedback reports (Peterson et al. 2009).

The Quality Improvement in Coronary Care (QUICC) study took place in 38 hospitals in Sweden from July 2001 to April 2004, using data collected on the RIKS-HIA clinical registry. (Carlhed et al. 2006; Carlhed et al. 2012) The study had a matched control design; 19 hospitals were invited to take part in the QI programme and they were matched to 19 ‘control’ hospitals on RIKS-HIA database that were not aware they were being used as a comparator. The QI intervention was multifactorial and included a performance feedback tool
and interactive workshops. The intervention was influenced by the IHI Breakthrough Series (Institute for Healthcare Improvement 2003) and implemented use of PDSA cycles to test ideas for improving performance. (Deming 1986) Comparison of performance before and after delivery of the QI intervention demonstrated improvements in five guideline recommended ACS treatments. The improvements observed were statistically higher for four out of five treatments in the case of the QI hospitals and ranged from 5-15%. The improvements observed for the QUICC study provided encouraging evidence of guideline adherence improving after QI but as the study was not randomised, results cannot be attributed solely to the effects of the QI intervention. Furthermore, the QI centres were invited to participate in a programme and would have been motivated to perform well, whereas the 19 control hospitals were not aware that the programme was ongoing.

1.3.6.2 Randomised QI programmes

There are also some examples of randomised controlled trials (RCTs) of QI initiatives in ACS. The Administrative Data Feedback for Effective Cardiac Treatment (AFFECT) trial was a randomised trial conducted in 76 acute care hospitals in Quebec, Canada. The trial evaluated use of a confidential feedback report card on 12 AMI process of care measures and hospitals were randomised to receive the report either immediately after randomisation or 14 months after randomisation. The report cards provided feedback on all AMI admissions during 1999-2000 and performance during the post intervention period was assessed using data from 2002-2003. There was no difference between the groups for the primary outcome of prescription of beta-blockers at discharge. No significant difference was observed for use of ACE-inhibitors, lipid-lowering treatments or aspirin. (Beck et al. 2005) The authors hypothesised that a more intensive feedback report may be required to achieve a greater improvement.

The Enhanced Feedback for Effective Cardiac Treatment (EFFECT) trial was a cluster-randomised QI programme that took place in 86 hospitals in Ontario, Canada from 2002. Hospitals were randomised to receive a public report card either ‘early’ (January 2004) or ‘late’ (September 2005). The study had two co-primary endpoints: a) a composite of 12 AMI process of care indicators and b) a composite of five indicators or congestive heart failure (CHF). Comparison of data collected during the baseline phase with the follow-up phase (April 2004 – March 2005) showed no significant difference between the two groups of hospitals. Surveys conducted during the trial revealed that the majority of hospitals randomised to the early feedback group undertook QI initiatives following receipt of the public report card but these were locally driven and varied considerably. The authors of the study also note that some of the delayed feedback centres undertook QI activities even
though they had not received any feedback about their baseline performance. Publicity surrounding the study meant that the delayed group were not fully blinded to the nature of the QI intervention and this could have led to contamination of the control group. (Tu et al. 2009)

Two further randomised QI programmes have been conducted in ACS since the EQUIP-ACS project, which is the QI programme this thesis will evaluate. These are the BRIDGE-ACS trial and the CPACS trial. The BRIDGE-ACS trial took place in 34 hospitals in Brazil from 2011 to 2012, and over 1000 patients were enrolled over the course of the trial. (Berwanger et al. 2012a; Berwanger et al. 2012b) Half the hospitals were randomised to receive a multi-faceted QI intervention and the other half were randomised to the control group. The QI intervention included use of reminder tools, checklists, educational materials, on-site visits from the trial team and web-based and telephone training. The primary outcome was a composite of ACS treatments given acutely and at discharge. An improvement of about 8% in the composite of all treatments was observed in the intervention group compared to the control group. Patients were followed up for 12 months after discharge from hospital but the study was not powered to detect a difference in clinical endpoints.

Another cluster-randomised QI project reported recently was the CPACS trial. (Du et al. 2014) The study was conducted in 75 centres in China from October 2007 to August 2010 recruiting a total of 3500 patients, i.e. approximately 50 cases per centre. The study implemented clinical pathways for risk stratification, STEMI and NSTEMI/Unstable Angina patients as the QI tool. Centres were allocated to receive this either ‘early’ i.e. at the start of the study (intervention group), or ‘late’ i.e. 12 months later (control group). A statistically significant improvement of 10% was observed for prescription of discharge medications 12 months after the intervention was delivered. Improvement in prescription of discharge medication was not accompanied by an improvement in clinical endpoints, but the study was not adequately powered to assess this.

1.3.7 Need for randomised controlled trials of QI

The QI methods described above have been evaluated primarily in observational studies and hence have not taken background changes into consideration. This can only be achieved robustly by measuring performance before and after an intervention and by evaluating an intervention in a randomised setting (Krumholz and Herrin 2000; Perneger 2006). There are some recent examples of randomised QI programmes but the majority of these have used simple interventions based on one QI approach, showing modest or no
improvement. Results from the observational studies and early randomised or matched controlled studies do not provide adequate evidence of effectiveness of QI. The only examples of randomised QI programmes evaluating a multi-faceted QI approach for management of ACS are the BRIDGE-ACS and EQUIP-ACS trials, the latter which will be evaluated in detail in this thesis.

Further research is needed to understand whether QI programmes are effective and identify the factors that drive or hinder their success.(Hulscher et al. 2013; Schouten et al. 2008b; Scott 2009; The Health Foundation 2011; van Bokhoven et al. 2003) Emphasis to date has been on delivering QI work, without investing the necessary resources and time to evaluate each project and inform future programmes. Despite the lack of evidence to support wider implementation of QI programmes, governments and charities continue to invest considerable resources in these.

The reasons that investment in QI continues despite the lack of convincing evidence are not clear. One possible explanation is that QI may lead to cost saving for health systems. Evidence of cost-effectiveness is limited however and the majority of examples of cost-effectiveness are local small projects, not large-scale programmes capable of considerable savings.(Marshall and Ovretveit 2011) As healthcare resource is increasingly compromised both in the UK and worldwide, it is important to identify the factors that lead to successful QI programmes and thereby ensure successful delivery of QI in future.

Another possible explanation is that the same criteria are not applied to QI and medicinal treatments. Perhaps the same principles of evidence-based medicine should be applied to QI to encourage more robust research in this area. Furthermore, Improvement Science, i.e. the evaluation of QI methods and programmes, may require a different approach and different skills to traditional clinical research. (Margolis et al. 2009)

1.4 Qualitative research

Implementing a QI intervention in a healthcare setting is a complex undertaking. In addition to the need for further studies evaluating QI interventions, better methods for evaluating these are also needed. QI experts maintain that RCTs and quantitative methods cannot fully evaluate the effects of a QI programme because they do not take context into account (Berwick 2008; Pope and Mays 1995). Context describes the environment in which an intervention is implemented and includes behavioural factors that traditional quantitative methods are unable to identify (Davies 2001; Ovretveit and Gustafson 2002). QI programmes are complex social interventions and as such, they may be better evaluated using social
science research methods. As the context that a QI intervention is delivered in could vary widely, it is not adequate to determine whether an intervention has succeeded; it is also important to determine how and why it may or may not be effective. (Walshe 2007; Walshe and Freeman 2002)

Qualitative methodology, as applied to healthcare, uses data from previous work to develop a theoretical framework for the research. Qualitative research uses a range of methods such as interviews with healthcare professionals and patients, focus groups, questionnaires and observation techniques to obtain qualitative data and formulate hypotheses (Ampt et al. 2009; Anderson et al. 2007; Bryman 2004). In this respect, qualitative methodology is the reverse of quantitative since data from previous work are collected and analysed to form a hypothesis, whereas in quantitative research the hypothesis exists at the outset and research is conducted in order to confirm or reject this hypothesis.

The process of generating a hypothesis from data collected is called ‘Grounded Theory’ and was developed by Glaser and Strauss. (Glaser and Strauss 1967) Grounded Theory analyses data collected from interviews or similar sources and sorts this into codes or themes, these are then compared to further data to arrive at a range of key themes. Analysis using qualitative methods has been applied to a range of healthcare settings to enrich the understanding of areas such as patient compliance and adherence to guidelines and can provide valuable information regarding implementation of QI interventions. (Mehrotra et al. 2003; Miles and Huberman 1994; Pope et al. 2000; Pope and Mays 2006; Sandelowski 1996)

1.4.1 ‘Mixed methods’ research

An emerging area of healthcare research involves combining qualitative and quantitative methods, also referred to as ‘mixed methods research’. The five main designs for mixed methods research are outlined below. (Andrew 2009; Creswell and Plano Clark 2007)

1. Convergent parallel design

Qualitative and quantitative methods are used in parallel and given equal weight. Results are analysed independently before they are ‘mixed’ to obtain an overall interpretation. Beck and Gable used a convergent parallel design to evaluate the prevalence of secondary traumatic stress in labour ward nurses and explore nurses’ experiences of attending traumatic births. 464 nurses were asked to complete the Secondary Traumatic Stress Scale for the quantitative aspect of the study. The qualitative component consisted of asking 322 nurses to describe their experiences of being present at traumatic births. 35% of the nurses reported moderate to severe symptoms of secondary traumatic stress and the qualitative findings helped the researchers to understand the context for this and make
recommendations about providing educational support to nurses in future. (Beck and Gable 2012)

2. **Sequential explanatory design**

In this approach, priority is given to the quantitative aspect of the study which is conducted first. Qualitative studies are conducted afterwards to provide an explanation for quantitative findings. The two methods are conducted in sequence and overall results are triangulated at the end.

An example of a study with a sequential explanatory design is a mixed methods assessment of the Health Foundation's Safer Patients Initiative (SPI) which was a QI programme to improve quality and safety of care in 24 acute hospital Trusts between 2004 and 2008. The study used semi-structured interviews and surveys with participating Trusts to evaluate perceptions of SPI at a local level. Analysis of qualitative and quantitative results identified organisational culture and multi-professional engagement as important factors for implementation of QI work. (Benn et al. 2009)

Other examples of mixed methods studies using the sequential explanatory design include an investigation of referral rates for cardiac interventions by clinical specialty using an electronic decision tool and semi-structured interviews (Bowling et al. 2006), and a study to explore factors contributing to pre-hospital delay for STEMI episodes in Saudi Arabia, which used quantitative questionnaires and qualitative interviews. (Alshahrani et al. 2014)

3. **Sequential exploratory design**

For this sequential design, priority is given to the qualitative approach which takes place first and a subsequent quantitative study is conducted to evaluate qualitative findings. An example of sequential exploratory design study is the “No more couch potato” study conducted by Mooney et al to assess the role of pre-operative cardiac rehabilitation for patients waiting for CABG surgery. (Mooney et al. 2007) A pilot qualitative interview programme was conducted with eight participants to support design of a quantitative study for patients on the waiting list for cardiac bypass surgery. The key themes identified will be used to support design of the quantitative phase of the study which will evaluate the effect of cardiac rehabilitation on clinical outcomes.

4. **Embedded design**

In this design a small qualitative component is embedded within a larger quantitative study or vice versa. This could be a case study which enhances the results of the overall method.

5. **Multiphase design**

This design combines both parallel and sequential approaches and is usually implemented to evaluate a complete programme of research rather than a single research study.
There is little evidence from mixed methods studies performed of complete integration of results and further work is needed to support planning of future QI projects. (Lewin et al. 2009) Applying a mixed methods approach to the evaluation of QI interventions should enhance the understanding of how these work and improve design and implementation of QI programmes in the future.

This thesis will use a mixed methods approach to evaluate the QI programme delivered during the EQUIP-ACS trial. The study design in this case is sequential explanatory as the qualitative approach is implemented after completion of quantitative methods to explain quantitative findings. The design of the research is “emergent” because a decision to perform a qualitative evaluation was taken after the initial results were available.

1.5 Summary

Management of ACS remains sub-optimal with respect to guideline recommendations. There is evidence that QI work may improve management however QI interventions are multifaceted and are implemented in complex healthcare settings, leading to varied results. There has been a trend to continually develop new QI approaches and to test these out in different settings without evaluating how or why existing strategies work. No single successful method to achieve optimal standards of patient care has been identified and it is clear that there is no ‘magic QI bullet’ that can be standardised and applied to all healthcare settings. Considering the resources invested in QI work and the fact that standards of patient care remain sub-optimal, it is crucial that we obtain a better understanding of the issues that drive the success or failure of a QI intervention.

1.6 Hypothesis

The use of a quality improvement programme for health professionals caring for patients with non-ST elevation ACS can lead to measurable, meaningful and persistent improvements in standards of patient care.

The hypothesis will be tested by evaluating a European QI programme for management of non-ST elevation ACS (EQUIP-ACS), using the following:

- Comparison of performance measures to assess management of non-ST elevation ACS before and after the delivery of the programme using a randomised controlled trial, the EQUIP-ACS project, in 38 hospitals
- Use of risk stratification methods during the EQUIP-ACS project and effect of patient risk on QI intervention
• Assessment of the effect of patient and hospital characteristics on delivery and outcome of the EQUIP-ACS QI intervention
• Longer term results of EQUIP-ACS QI intervention
• Qualitative evaluation of EQUIP-ACS QI intervention using semi-structured interviews with healthcare professionals that took part in the QI programme
• Triangulation of quantitative and qualitative results using a mixed methods approach to assess effectiveness of the EQUIP-ACS QI programme and make suggestions for further work.
CHAPTER 2. European Quality Improvement Programme for Acute Coronary Syndromes; the EQUIP-ACS project. Methods, Results and Discussion
2.1 Introduction

This chapter will summarise the design, methods and results of the EQUIP-ACS project, which was a cluster-randomised trial to evaluate the use of a Quality Improvement (QI) programme for healthcare professionals managing patients with non-ST elevation ACS. The trial protocol and results have been published (Flather et al. 2010; Flather et al. 2011) and are included in the Appendices of this thesis. The aim of the trial was to determine if measurable improvements in use of guideline recommended treatments could be achieved following the implementation of a multi-factorial QI intervention.

2.1.1 Trial design

EQUIP-ACS was a multi-centre, cluster-randomised trial conducted in 38 centres in 5 countries: France, Spain, Poland, Italy and the UK. The trial was divided into 3 phases:

a) A baseline phase to assess performance prior to the QI intervention
b) A QI implementation phase during which the QI intervention was delivered
c) A post-implementation phase to look for improved standards of care after the programme

2.2 Methods

2.2.1 Selection of centres

National Coordinators (NCs) were appointed in each of the 5 countries based on experience in management of ACS and previous collaborations. The NCs were asked to identify a list of potential centres in their respective countries. Emphasis was on hospitals that could manage the full range of ACS treatments and procedures from admission to discharge from hospital. Centres could either have coronary angiography facilities on-site or easy access to angiography facilities at another site. 40 hospitals were randomised to receive a QI training programme (20 hospitals) or no QI training programme (20 hospitals) using a cluster-randomised method (Eldridge et al. 2006)

2.2.2 Randomisation

Randomisation was stratified by country and presence of on-site PCI facilities to ensure these factors were balanced in each of the groups. Centres were randomised at the start of the trial and were informed of their allocation. This was necessary so that arrangements could be made for Investigators at the QI centres to attend the QI training programme.
2.2.3 Eligibility criteria

Investigators were asked to enter data for consecutive eligible patients admitted to their hospital for treatment of non-ST elevation ACS over an 11-month period. The eligibility criteria are listed in Table 1. Patients treated at another hospital prior to admission at the participating hospital were excluded. Patients over 80 years of age were also excluded from the study as the Steering Committee considered that there was not sufficient evidence to support standardised guideline-recommended treatment in this population.

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
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<tbody>
<tr>
<td>Patients with a good clinical history of ACS and at least one of the following:</td>
<td>1. Evidence of persistent ST elevation on the ECG</td>
</tr>
<tr>
<td>1. New or transient ST or T wave changes on the ECG consistent with acute</td>
<td>2. Use of early reperfusion therapy (thrombolysis or primary PCI)</td>
</tr>
<tr>
<td>myocardial ischaemia</td>
<td>3. Patients &gt;80 years</td>
</tr>
<tr>
<td>2. Elevation of serum troponin or other cardiac markers to levels indicative of</td>
<td>4. Patients transferred from another hospital</td>
</tr>
<tr>
<td>myocardial necrosis according to local laboratory values</td>
<td></td>
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Table 1. Patient eligibility criteria

2.2.4 Ethical and regulatory considerations

The trial had multi-centre research ethics approval in each of the countries and institutional approval was obtained at each participating hospital prior to the start of the trial. The Sponsor of the trial was the Royal Brompton and Harefield NHS Foundation Trust and a research contract was in place between each participating organisation and the Sponsor.

To ensure that consecutive patients could be enrolled, and to avoid the influence of selection bias, ethical and institutional approval to collect anonymous routine in-hospital data without seeking individual patient consent was obtained in each country. The rationale for proceeding without seeking individual consent was that there were no changes to patient treatment as a result of the study and all data collected would be anonymised. The study was carried out in accordance with the NHS Research Governance Framework for Health and Social Care, the Declaration of Helsinki and the Data Protection Act. 1998(Department of Health 2005;Parliament 1998;World Medical Association 2008)

2.2.5 Data collection

Data were entered onto a web-based database developed by Uppsala Clinical Research (UCR) and adapted from the Swedish RIKS-HIA database. (Peterson et al.
2007; Stenestrand, Wallentin, & for the Swedish Register of Cardiac Intensive Care (RIKS-HIA) 2001; Stenestrand and Wallentin 2003) An example of the UK version of the case report form is included in Appendix 1. This was translated into local languages and included a report-generating facility which provided real-time information about local performance and a comparison with other participating centres. The report-generating facility provided two types of reports:

a) Control charts: these reports summarised the proportion of patients that received a treatment over the course of the study at a particular centre. The database generated a chart of each of the 8 treatments and the example included below is for prescription of anticoagulation. Each ‘X’ represents 10 patients and the dashed horizontal line represents the mean performance during that phase of the study for that centre.

![Control chart example](image)

**Figure 4. Example control chart summarising use of anticoagulation at one of the centres during the trial**

b) Performance compared with top three hospitals: These reports included tables summarising the number and percentage of patients receiving each of the treatments, compared with the corresponding percentages achieved at the top three hospitals. These results were also presented in a graphical form as shown in Figure 5 below for Barnet hospital.
Database and study training was delivered to investigators by telephone and there was a run-in phase to allow centres to familiarise themselves with the protocol and data collection system. Data collection for the study was commenced in January 2008 for all centres and lasted for 11 months (4 months baseline phase, 4 months QI intervention phase and 3 months post-QI intervention).

### 2.2.6 Data management

Key data were reviewed on a regular basis in order to monitor quality and completeness of data entered by investigators, and to ensure timely entry of study data onto the web-based system. Investigators were allowed to enter data either in ‘real-time’ i.e. while the patient is still in hospital, or retrospectively. Data were reviewed both directly off the web-based system and as files downloaded into Microsoft Access®, the latter being used for preparing Steering Committee and data management reports.
2.2.7 Trial oversight

A trial Steering Committee (consisting of the 5 National Coordinators, the Trial Manager and 2 QI experts) was responsible for overseeing the progress and conduct of the study. The Steering Committee developed and approved the protocol and all subsequent amendments, had oversight of study set-up, recruitment, delivery of the QI programme and reviewed results prior to presentation and publication.

2.2.8 Data Monitoring Committee

This was an open-label study with no study intervention at the patient level. Centres knew which group they had been allocated to and patients received routine care for non-ST elevation ACS. It was not therefore necessary to convene a Data Monitoring Committee for this study. This decision was ratified by the Steering Committee and Sponsor of the trial.

2.2.9 Quality Improvement intervention

Centres randomised to the QI programme were asked to set up a local QI team and nominate a senior cardiologist and another health professional (junior physician or nurse) to attend the QI meetings and act as local “champions” for the QI programme. The QI training was led by QI experts involved in the delivery of the Swedish Quality Improvement in Coronary Care (QUICC) study. (Carlhed et al. for the QUICC study group 2006) The EQUIP-ACS QI programme was delivered during three one-day meetings, held approximately 5-12 weeks apart.

The QI intervention implemented in the EQUIP-ACS project was similar to that used in the QUICC study which was based on the IHI’s Breakthrough series (Institute for Healthcare Improvement 2003) and included use of PDSA cycles, elements of LEAN thinking, Cause and Effect diagrams and control charts.

2.2.10 Outcome measures

The primary outcome of the study was a composite of eight outcome measures based on guideline-recommended ACS treatments. The outcome measures were identified from the ESC guidelines, focussing on recommendations with the highest level of evidence from the literature. (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007) The following treatments for non-ST elevation ACS were selected:

1) Risk stratification using a formal, documented method and performed within 24 hours of admission
2) Coronary angiography performed within <72 hours of admission in intermediate to high risk patients, where intermediate to high risk patients are defined as:
   1) Elevated troponin levels
   2) Dynamic ST or T wave changes (symptomatic or silent) (≥0.5mm)
   3) Diabetes mellitus
   4) Reduced renal function (GFR<60mL/min/1.73m²)
   5) Depressed LVEF<40%
   6) Early post-MI angina
   7) PCI within 6 months
   8) Previous CABG
   9) Intermediate to high risk according to a risk score

3) In-hospital anticoagulation for all patients
4) Beta-blockers at discharge in patients with reduced LV function. For the purposes of the programme, reduced LV function was defined as LVEF≤50%
5) Statins prescribed within 4 days of admission for all patients
6) ACE-inhibitors in patients with LVEF<40%, hypertension, diabetes or chronic kidney disease
7) Clopidogrel loading dose administered within 24 hours
8) Clopidogrel prescribed at discharge

Each of the individual non-ST elevation ACS treatments was also assessed as a secondary outcome.

2.2.11 Goals of QI programme

The study outcome measures were also defined as the “goals” of the QI programme so that the QI teams could use these to assess ACS management at their sites and observe changes in management over the course of the QI programme. The local QI teams had access to reports summarising use of the above treatments via the online database and they were encouraged to meet on a regular basis and review their results. Reports summarising rates of these quality indicators were also reviewed during the QI meetings.

2.2.12 QI meetings

The first meeting was held at the end of the baseline phase. Centres were asked to work in teams and analyse their local work processes using established QI tools. (Bodenheimer et al. 2007; Institute for Healthcare Improvement 2003) The teams were asked to represent their patient pathways using process maps in order to analyse these processes systematically.
and identify any problem areas or barriers. The barriers identified were then broken down using 'case and effect' diagrams (Ishikawa 1982) to identify potential causes and help the teams to identify strategies to resolve these.

Results from the baseline phase were presented and discussed, and potential areas for improvement were identified. In addition to continuing to enter data for eligible patients onto the trial database, centres were asked to continue to review their results via the online reports, analyse their local work processes and identify the main barriers to delivering optimal care.

Barriers to achieving optimal results were presented by each of the teams at the second meeting. The teams also came up with potential solutions to these which were reviewed and assessed using Plan-Do-Study-Act cycles (Shewhart 1931). The QI teams were asked to continue holding regular local meetings, to work together to identify at least 2 improvement ideas that could be implemented in their departments and to test these out using the QI tools provided during the programme.

At the third and final meeting, the teams presented the improvement ideas they had developed and the results achieved after these were implemented in their departments. The group discussed how to continue local improvement work after the end of the EQUIP-ACS project and suggested further improvement ideas that could be tested and implemented.

Throughout the delivery of the QI intervention, centres continued to enter data for all eligible patients, met with their teams on a regular basis to review local results and were invited to attend conference calls and communicate with each other via a web-portal. Use of the web-portal was limited however and only a few comments were posted over the course of the QI intervention phase.

2.2.13 Statistical Methods

2.2.13.1 Sample size estimations in cluster-randomised trials

In order to estimate the sample size for a cluster-randomised trial, it is necessary to correct for clustering of data within a centre. This is required to account for the fact that patients within a centre are likely to be treated in a similar way and cannot be treated as statistically independent entities. This effect leads to variation between clusters, and the relationship between this variation and the variation within a centre is represented by the intra-cluster correlation coefficient (ICC) (Eldridge et al. 2004; Kerry and Bland 1998a; Kerry and Bland...
The ICC, also represented by the symbol ‘\( \rho \)’ can be calculated by the equation below:

\[
\text{ICC or } \rho = \frac{s_b^2}{(s_b^2 + s_w^2)}
\]

where \( s_b^2 \) = the variance between clusters, and \( s_w^2 \) = the variance within clusters.

Values for the ICC range from 0 to 1 and for EQUIP-ACS, the ICC was estimated as 0.2 taking into account the ICC found for the PROMIS-UK study. (Booth et al. 2006)

The formula to calculate the sample size for a cluster-randomised trial is:

\[
N_{\text{cluster}} = [1 + (m - 1) \times \text{ICC}] N_{\text{simple}}
\]

Where “\( N_{\text{cluster}} \)” and “\( N_{\text{simple}} \)” are the sample sizes for cluster randomisation and simple randomisation respectively. “\( m \)” is the number of patients per cluster (i.e. per hospital).

### 2.2.13.2 Sample size estimation for EQUIP-ACS

A scoring system was used to estimate the sample size on the basis of previous work in the PROMIS-UK study (Booth et al. 2006). Not all patients are eligible for each of the eight ACS treatments and it was estimated that 3 of the 8 are applicable to all patients, the other 5 applying to a subset of patients or being contraindicated in some cases. The scoring system assigns ‘1’ for a treatment given and ‘0’ for not given. A realistic maximum score per patient was taken to be 5 (out of 8) and a range of possible differences in score between the QI and non-QI centres was considered. A maximum score of 5 means that each point is equal to 20% i.e. an improvement of one treatment is equivalent to 20% or 1 point on the scoring system. For the EQUIP-ACS sample size estimation an improvement of approximately 8%, was considered clinically meaningful.

The sample size calculation was based on a direct comparison of results during the post-QI phase of the study only as the main power of the study was expected to be in this phase. Using approximately 40 centres, the power calculation showed that 500 patients per group (1000 in total) would be required during the post-QI implementation phase of the study to detect a difference in score of 0.3-0.4 between the two groups. A difference in score of 0.3-0.4 corresponds to approximately 8% improvement in number of indicators achieved.

The range of sample sizes considered for the trial is summarised in Table 2 below and the scenario selected is highlighted in bold type. The power (\( \beta \)) in each case was 80% and the significance level (\( \alpha \)) was 5%.
<table>
<thead>
<tr>
<th>ICC</th>
<th>Centres per Group</th>
<th>Patients per Centre</th>
<th>Patients per Group</th>
<th>SD</th>
<th>Detectable Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>20</td>
<td>20</td>
<td>400</td>
<td>0.9</td>
<td>0.312</td>
</tr>
<tr>
<td>0.1</td>
<td>20</td>
<td>25</td>
<td>500</td>
<td>0.9</td>
<td>0.302</td>
</tr>
<tr>
<td>0.1</td>
<td>20</td>
<td>30</td>
<td>600</td>
<td>0.9</td>
<td>0.295</td>
</tr>
<tr>
<td>0.1</td>
<td>20</td>
<td>40</td>
<td>800</td>
<td>0.9</td>
<td>0.286</td>
</tr>
<tr>
<td>0.1</td>
<td>20</td>
<td>50</td>
<td>1,000</td>
<td>0.9</td>
<td>0.281</td>
</tr>
<tr>
<td>0.2</td>
<td>20</td>
<td>20</td>
<td>400</td>
<td>0.9</td>
<td>0.401</td>
</tr>
<tr>
<td>0.2</td>
<td>20</td>
<td>25</td>
<td>500</td>
<td>0.9</td>
<td><strong>0.394</strong></td>
</tr>
<tr>
<td>0.2</td>
<td>20</td>
<td>30</td>
<td>600</td>
<td>0.9</td>
<td>0.390</td>
</tr>
<tr>
<td>0.2</td>
<td>20</td>
<td>40</td>
<td>800</td>
<td>0.9</td>
<td>0.384</td>
</tr>
<tr>
<td>0.2</td>
<td>20</td>
<td>50</td>
<td>1,000</td>
<td>0.9</td>
<td>0.380</td>
</tr>
</tbody>
</table>

Table 2. Sample size calculation based on score of medication use

2.2.13.3 Statistical analysis

The statistical analysis plan was agreed by the trial Steering Committee and trial statisticians prior to receiving the final database for analysis (Flather et al. 2010). All analyses were performed by the trial statistician using STATA® software. All analyses presented here were repeated by the author of this thesis following further data cleaning.

2.2.13.4 Baseline characteristics

Baseline characteristics for each group (QI centres, non-QI centres) and each time-point (baseline, post-QI) were analysed to look for changes over time and differences between groups. Categorical variables were analysed as numbers and percentages, N(%) and the χ²−squared test used to assess any differences between the two groups. Continuous variables were reported as mean ± SD and the t test used to assess any differences. In the case of continuous variables that are not normally distributed, the median and interquartile range (IQR) are reported.

2.2.13.5 Primary outcome

The primary outcome was determined by comparing the change in composite of all 8 indicators from baseline between the QI and non-QI groups. This analysis was carried out by multi-level hierarchical logistic regression to take account of the clustered nature of the data. (Zucker 2003)

Indicator variables for time period and allocation were entered as fixed effects. Other centre-level covariates that were entered as fixed effects were country and ability to perform PCI on site, since these were stratification factors in the randomisation. The interaction between allocation and time period gave a P-value and an estimate of the treatment effect expressed
as an odds ratio (OR) with a 95% confidence interval (CI) for the relative probability of a quality indicator being fulfilled in the post-QI phase, adjusted for baseline imbalances.

2.3 Results

2.3.1 Recruitment

A total of 4,230 patients were enrolled by 38 centres (19 in each cluster-randomised group) over the course of the EQUIP-ACS project. 2,582 patients were included in the analysis of the primary outcome and the remaining 1,648 were excluded because these were patients recruited during the QI training phase which cannot contribute to the primary analysis. Secondary analyses explored in later chapters of this thesis will take all of these patients into account.

The participation of centres and number of patients recruited is summarised in Table 3, Figure 6 and Figure 7.

Key: Red dot = EQUIP-ACS participating centre; Blue dot: Central coordinating centre at Clinical trials and Evaluation Unit and Uppsala Clinical Research in Uppsala, Sweden

Figure 6. Location of EQUIP-ACS participating centres
Figure 7. Consort diagram showing flow of centres and number of patients recruited at each time-point
<table>
<thead>
<tr>
<th>Centre name</th>
<th>Baseline phase</th>
<th>Post-QI phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-QI centres</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital del Mar IMAS</td>
<td>28</td>
<td>27</td>
</tr>
<tr>
<td>Hospital de Tortosa Virgen de la Cinta</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>Hospital Josep Trueta Girona</td>
<td>51</td>
<td>60</td>
</tr>
<tr>
<td>Hospital Universitario Germans Trias</td>
<td>26</td>
<td>34</td>
</tr>
<tr>
<td>Hôpitaux Drome de Romans-sur-Isere</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>Centre Hospitalier Guy Thomas de Riom</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Dept A’ CHU Hôpital G. Montpied</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>Dept B’ CHU Hôpital G. Montpied</td>
<td>5</td>
<td>19</td>
</tr>
<tr>
<td>Ospedale Civile di Mirano</td>
<td>32</td>
<td>30</td>
</tr>
<tr>
<td>Ospedale Livorno</td>
<td>66</td>
<td>22</td>
</tr>
<tr>
<td>Ospedale Generale Provinciale di Macerata</td>
<td>31</td>
<td>25</td>
</tr>
<tr>
<td>Radomski Szpital Specjalistyczny</td>
<td>24</td>
<td>14</td>
</tr>
<tr>
<td>Szpital we Wloclawku</td>
<td>92</td>
<td>44</td>
</tr>
<tr>
<td>Szpital w Ciechanowie</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>Szpital w Siedlcach</td>
<td>22</td>
<td>21</td>
</tr>
<tr>
<td>Szpital Zachodni</td>
<td>16</td>
<td>35</td>
</tr>
<tr>
<td>Warwick Hospital</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Yeovil District Hospital</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>York District Hospital</td>
<td>73</td>
<td>55</td>
</tr>
<tr>
<td><strong>Sub-total non-QI centres</strong></td>
<td>580</td>
<td>474</td>
</tr>
<tr>
<td><strong>QI centres</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital de Terrassa</td>
<td>21</td>
<td>15</td>
</tr>
<tr>
<td>Hospital Universitario Joan XXIII de Tarragona</td>
<td>43</td>
<td>46</td>
</tr>
<tr>
<td>Hospital Universitario Valle d'Hebron</td>
<td>101</td>
<td>93</td>
</tr>
<tr>
<td>Centre Hospitalier d'Ussel</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Centre Hospitalier de Chambéry</td>
<td>27</td>
<td>10</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire de Grenoble</td>
<td>32</td>
<td>28</td>
</tr>
<tr>
<td>Centre Hospitalier Pierre Bazin, Voiron</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Centre Hospitalier d’Annecy</td>
<td>20</td>
<td>19</td>
</tr>
<tr>
<td>Ospedale Morgagni-Pierantoni, Forli</td>
<td>33</td>
<td>20</td>
</tr>
<tr>
<td>Ospedale M. Bufalini- Cesena</td>
<td>9</td>
<td>49</td>
</tr>
<tr>
<td>Medical Academy of Warsaw</td>
<td>81</td>
<td>47</td>
</tr>
<tr>
<td>Świętokrzyskie Centrum Chorob Serca</td>
<td>157</td>
<td>92</td>
</tr>
<tr>
<td>Szpital w Grojcu</td>
<td>32</td>
<td>33</td>
</tr>
<tr>
<td>Szpital w Plocku</td>
<td>16</td>
<td>37</td>
</tr>
<tr>
<td>Szpital Specjalistyczny SPZOZ w Radomiu</td>
<td>26</td>
<td>31</td>
</tr>
<tr>
<td>Antrim Area Hospital</td>
<td>29</td>
<td>36</td>
</tr>
<tr>
<td>Barnet General Hospital</td>
<td>74</td>
<td>79</td>
</tr>
<tr>
<td>Basildon Hospital</td>
<td>59</td>
<td>46</td>
</tr>
<tr>
<td>Royal Albert Edward Infirmary, Wigan</td>
<td>35</td>
<td>20</td>
</tr>
<tr>
<td><strong>Sub-total QI centres</strong></td>
<td>813</td>
<td>715</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1,393</td>
<td>1,189</td>
</tr>
</tbody>
</table>

Table 3. Number of patients recruited by centre during the Baseline and Post-QI phases

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2.3.2 Baseline characteristics

Baseline characteristics in the two groups were similar before and after the QI programme; mean age was 65.5 years, 70% male, 28% had prior MI, and 44% presented with ST depression on the ECG. The proportions of patients with a confirmed ACS diagnosis (myocardial infarction or unstable angina) at discharge for the non-QI centres at baseline and post-QI implementation were 97.1% and 95.6%, and for the QI centres the rates were 93.5% and 92.2% respectively. Table 4 summarises key baseline characteristics. Characteristics for patients recruited by each group and during the baseline and post-QI phase are shown.
Table 4. Baseline characteristics for patients recruited during the baseline and post-QI implementation phase of the EQUIP-ACS study

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<table>
<thead>
<tr>
<th>Description*</th>
<th>Non-QI centres</th>
<th>QI centres</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline phase</td>
<td>Post-QI phase</td>
</tr>
<tr>
<td></td>
<td>N=580</td>
<td>N=474</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>419 (72.2)</td>
<td>341 (71.9)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>165 (28.6)</td>
<td>133 (28.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>374 (64.9)</td>
<td>306 (65.0)</td>
</tr>
<tr>
<td>Smoker</td>
<td>143 (25.7)</td>
<td>121 (27.3)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>164 (28.6)</td>
<td>136 (28.9)</td>
</tr>
<tr>
<td>History of heart failure</td>
<td>81 (14.0)</td>
<td>53 (11.2)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>101 (17.5)</td>
<td>81 (17.2)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>39 (6.8)</td>
<td>37 (7.8)</td>
</tr>
<tr>
<td>Prior Stroke</td>
<td>39 (6.7)</td>
<td>20 (4.2)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>60 (10.4)</td>
<td>37 (7.8)</td>
</tr>
<tr>
<td>Pathological Q-wave</td>
<td>49 (8.5)</td>
<td>47 (9.9)</td>
</tr>
<tr>
<td>RBBB</td>
<td>35 (6.0)</td>
<td>21 (4.4)</td>
</tr>
<tr>
<td>ST-depression</td>
<td>259 (44.9)</td>
<td>217 (45.9)</td>
</tr>
<tr>
<td>Pathological T-wave</td>
<td>133 (23.1)</td>
<td>107 (22.6)</td>
</tr>
<tr>
<td>Heart rate, bpm (Mean [SD])</td>
<td>81.5 [24.6]</td>
<td>79.4 [22.1]</td>
</tr>
<tr>
<td>SBP, mmHg (Mean [SD])</td>
<td>141.9 [24.6]</td>
<td>141.3 [23.9]</td>
</tr>
<tr>
<td>DBP, mmHg (Mean [SD])</td>
<td>81.6 [14.5]</td>
<td>79.9 [14.3]</td>
</tr>
<tr>
<td>Elevated cardiac troponin (according to local cut-off)</td>
<td>545 (94.1)</td>
<td>443 (93.5)</td>
</tr>
<tr>
<td>Medications at admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>240 (42.3)</td>
<td>168 (38.0)</td>
</tr>
<tr>
<td>A2 receptor blockers</td>
<td>60 (10.6)</td>
<td>45 (10.2)</td>
</tr>
<tr>
<td>Warfarin</td>
<td>22 (3.9)</td>
<td>20 (4.5)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>263 (46.1)</td>
<td>189 (42.7)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>71 (12.5)</td>
<td>46 (10.4)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>213 (37.8)</td>
<td>147 (33.2)</td>
</tr>
<tr>
<td>Calcium antagonists</td>
<td>99 (17.5)</td>
<td>87 (19.7)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>131 (23.2)</td>
<td>97 (22.0)</td>
</tr>
<tr>
<td>Statins</td>
<td>242 (42.6)</td>
<td>191 (43.4)</td>
</tr>
<tr>
<td>Discharge diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>400 (69.0)</td>
<td>333 (70.3)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>163 (28.1)</td>
<td>120 (25.3)</td>
</tr>
<tr>
<td>Death in-hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>7 (1.2)</td>
<td>7 (1.5)</td>
</tr>
</tbody>
</table>

*All values are N(%) unless otherwise indicated
2.3.3 Primary outcome measure

The primary outcome measure, a composite of eight recommended non-ST elevation ACS treatment strategies, was calculated from the difference in improvement between the two groups. The proportion of quality indicators fulfilled i.e. ACS treatments given after the QI training was compared to the proportion of indicators fulfilled during the baseline phase for each group.

Proportions of quality indicators fulfilled during the baseline and post-QI phases in the non-QI group were 77.6% and 78.6%, and for the QI group 74.4% and 83.1%, corresponding to a within group change of 1% and 8.7% respectively. The relative probability of fulfilling a quality indicator after the intervention in the QI versus non-QI group expressed as an odds ratio was 1.69 (95% confidence interval 1.45 to 1.97, p<0.001; Table 5 and Figure 8).

2.3.4 Individual indicators

The individual components of the composite outcome were analysed separately, although the study was not powered to detect a difference in these. With the exception of clopidogrel maintenance dose, each of the remaining 7 indicators showed a trend to improve more in the QI centres. Risk stratification and clopidogrel loading dose were statistically more likely to improve in the QI centres. Table 5 summarises the results for the composite outcome and each individual indicator.
### Quality Indicators

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Non-QI centres (indicators achieved/indicators possible (%))</th>
<th>QI centres (indicators achieved/indicators possible (%))</th>
<th>Odds ratio* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline phase</td>
<td>Post-QI phase</td>
<td>Baseline phase</td>
<td>Post-QI phase</td>
</tr>
<tr>
<td>Primary outcome</td>
<td>3128/4032 (77.6)</td>
<td>2557/3253 (78.6)</td>
<td>4158/5591 (74.4)</td>
<td>4106/4940 (83.1)</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>347/580 (59.8)</td>
<td>246/474 (51.9)</td>
<td>421/813 (51.8)</td>
<td>595/715 (83.2)</td>
</tr>
<tr>
<td>Coronary Angiography</td>
<td>327/578 (56.6)</td>
<td>275/474 (58.0)</td>
<td>442/811 (54.5)</td>
<td>427/715 (59.7)</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>525/579 (90.7)</td>
<td>437/470 (93.0)</td>
<td>729/811 (89.9)</td>
<td>660/709 (93.1)</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>162/196 (82.7)</td>
<td>110/124 (88.7)</td>
<td>190/226 (84.1)</td>
<td>188/212 (88.7)</td>
</tr>
<tr>
<td>Statins</td>
<td>535/571 (93.7)</td>
<td>440/464 (94.8)</td>
<td>717/791 (90.6)</td>
<td>668/699 (95.6)</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>355/433 (82.0)</td>
<td>288/348 (82.8)</td>
<td>499/598 (83.4)</td>
<td>463/534 (86.7)</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>463/574 (80.7)</td>
<td>387/463 (83.6)</td>
<td>591/805 (73.4)</td>
<td>591/706 (83.7)</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>414/521 (79.5)</td>
<td>374/436 (85.8)</td>
<td>569/736 (77.3)</td>
<td>514/650 (79.1)</td>
</tr>
</tbody>
</table>

* Relative odds of achieving QI indicator(s) in the QI group compared to the non-QI group in the post-QI intervention phase adjusted for country and ability to perform PCI on-site (stratification variables)

**Table 5. Primary outcome and key secondary outcomes**
Figure 8. Primary Outcome: The proportion of patients fulfilling the primary outcome (composite of 8 quality indicators) at centres before and after the QI intervention

2.3.5 Interpretation of Odds Ratio for ‘interaction term’

The Odds Ratios (ORs) presented in Table 5 are for outcomes in the QI group compared to the non-QI group, during the post-QI intervention phase. These ORs are for the ‘interaction term’ in each case which is a ratio of the odds ratios of each group. The interaction term is effectively estimating the difference in differences, i.e. comparing the improvement in the non-QI group to the improvement in the QI group over time. The OR of the interaction term is multiplicative as it takes the OR of each group compared to its baseline into account and should not be interpreted in the same manner as a traditional OR.

Although the OR for the composite outcome and two of the individual outcomes is statistically significant, it does not give an indication of clinical significance. The OR for risk stratification is 24.65, (95%CI: 14.39-42.22, p<0.001) and this is comparing a reduction in use of risk stratification in the non-QI group with an increase of more than 30% in the QI group.
The marginal effect observed for risk stratification in each group and time-period has been estimated using STATA® and used to plot Figure 9 below which shows that the marginal effects for each group go in opposite directions. (Maarten 2010; Williams 2012)

![Predictive Margins with 95% CIs](image)

Key: ‘treatment’ represents allocation where 0 is the non-QI and 1 is the QI group. ‘d_period’ represents the study phase where 1 is the baseline phase and 3 is the post-QI intervention phase.

**Figure 9. Predictive margins for Risk stratification in QI centres vs non-QI centres**

### 2.3.6 Subgroup analyses

The primary outcome was also analysed by key pre-specified subgroups to look for differences. The subgroups analysed were: gender, age (≤65 and >65 years), presence of PCI facilities and country. Improvement was found to be similar in both genders, both age groups and centres with or without PCI facilities. Four out of five countries showed an improvement with the QI intervention with two countries showing individually significant benefits although there is significant heterogeneity in the effect by country (Figure 10). These factors will be considered in more detail in a later chapter of this thesis.
Figure 10. Forest plot of primary outcome analysed by key subgroups: gender, age, ability to perform PCI on-site and country

2.3.7 Exploratory analyses for coronary angiography

Two exploratory analyses were performed to assess the coronary angiography results in more detail, as the proportion of patients receiving coronary angiography was lower than anticipated. For the first of these, the definition of intermediate to high risk was modified from the ESC guideline definition. Instead of including patients with positive troponin values according to local laboratory ranges (generally within the range 0.03-0.05 µg/L), a cut-off of >0.1 µg/L to indicate potentially clinically important myocardial damage was selected. Aside from this modification, the definition for intermediate to high risk was consistent with ESC guidelines and in line with that used for this indicator throughout the trial. The second exploratory analysis for this indicator included patients classified as intermediate or high risk by the centres only, irrespective of the method of risk stratification. These analyses are summarised in Table 6 below and it can be seen that these modifications did not alter the finding of a modest effect of the QI intervention on rate of coronary angiography. Results obtained from these additional exploratory analyses remained statistically non-significant.
<table>
<thead>
<tr>
<th>Method</th>
<th>Non-QI centres</th>
<th>QI Centres</th>
<th>OR (95%CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Proportion</td>
<td>Post-QI Proportion</td>
<td>Baseline Proportion</td>
<td>Post-QI Proportion</td>
</tr>
<tr>
<td>Modified ESC definition*</td>
<td>325/564 (57.6)</td>
<td>274/464 (59.1)</td>
<td>425/765 (55.6)</td>
<td>416/685 (60.7)</td>
</tr>
<tr>
<td>Intermediate/High risk</td>
<td>171/288 (59.4)</td>
<td>133/215 (61.9)</td>
<td>204/308 (66.2)</td>
<td>298/441 (67.6)</td>
</tr>
<tr>
<td>according to centres</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*ESC definition for intermediate to high risk, with positive troponin defined as >0.1µg/L

Table 6. Exploratory analyses for coronary angiography

2.4 Discussion

2.4.1 Summary of results

A randomised, multi-centre, multi-factorial QI programme was successfully implemented in 38 hospitals in 5 European countries. A measurable improvement was noted in the primary outcome of the study, which was a composite endpoint based on 8 guideline-recommended treatments for non-ST elevation ACS. The primary outcome was determined by comparing use of the 8 treatments before and after the QI intervention. The composite endpoint improved by 1% in the non-QI centres and 8.7% in the QI centres after the intervention. The difference between the groups of 7.7% was statistically significant (Odds ratio for achieving the composite outcome in the QI group versus the non-QI group: 1.69; 95% confidence interval: 1.45-1.97, p<0.001). The study was not powered to show improvements in individual components of the primary endpoint but 7 out of 8 treatments showed a trend to improve after the QI intervention and 2 of these, risk stratification and clopidogrel loading dose, improved statistically significantly. An improvement of 8.7% was observed for the QI centres which is consistent with the pre-specified difference of 8% that was considered clinically meaningful.

2.4.2 Comparison with results from other (non-randomised) QI trials

The improvement in use of ACS treatments observed in EQUIP-ACS is consistent with that reported for other quality improvement programmes which range from 5 to 15%. Results from key published quality improvement programmes are summarised below.

The QUIICC study, which used a similar QI intervention to EQUIP-ACS, (Carlhed et al. for the QUIICC study group 2006;Peterson et al. 2007) had a matched control design whereby management of acute MI at 19 QI hospitals was compared with 10 matched ‘control’
hospitals. All hospitals were selected from the network of Swedish hospitals submitting data onto the RIKS-HIA database on an ongoing basis. Improvements observed in the intervention group ranged from 7 to 16%, compared with improvements of 1 to 6% in the control group. The exception to this was clopidogrel which improved by over 40% in the QI group and more than 25% in the control group. This large increase was explained by the very low baseline rate for this treatment, which was less than 30% at all sites. Baseline rates of treatments in general were lower than those observed for EQUIP-ACS.

The CRUSADE initiative, which was a QI programme comprising a registry and educational programme for clinicians (Hoekstra et al. 2002; Mehta et al. 2006) showed similar improvements to EQUIP-ACS but there was no control group so changes due to temporal trends cannot be excluded. Similarly, the GAP programme (Mehta et al. 2002), which compared results before and after a QI intervention based on reminder tools and checklists, showed modest improvement in use of beta-blockers and aspirin but there was no comparison with a control group.

The DMACS study (Peterson et al. for the DMACS Project Group 2012) was a non-randomised QI study comparing discharge management for all ACS, before and after an educational QI intervention. Improvements in prescription of key discharge medications (ACE/ARB, beta-blockers, statins, antiplatelet) were observed, ranging from 2 to 6% for individual medications and approximately 12% when considered as a composite measure.

2.4.3 Comparison with other cluster-randomised QI programmes

There have been a few cluster-randomised trials of QI initiatives in ACS management reported in the literature which show similarities to the EQUIP-ACS project and these are summarised here.

The PROMIS study (Booth et al. 2006) included 38 centres in the UK and recruited approximately 1000 patients over the course of the study. Centres were allocated to receive an educational intervention or no intervention, using cluster randomisation. The educational intervention was delivered at the start of the study and consisted of a presentation on the ESC guidelines, pocket guidelines for the participating teams and a checklist of evidence-based treatments for the patient notes. As for EQUIP-ACS, the primary outcome was a composite endpoint based on 5 evidence-based ACS treatments and this was reported as a score out of 5. The score achieved in the QI group was 0.2 points higher that the control group but this was not statistically significant.
The BRIDGE-ACS trial,(Berwanger et al. for the BRIDGE-ACS Investigators 2012b) a cluster-randomised trial of a multi-factorial QI intervention that took place after EQUIP-ACS, assessed improvement in (a) acute treatments i.e. those given within 24 hours of admission and, (b) those given at discharge. Baseline performance at the Brazilian hospitals was lower than at the EQUIP-ACS centres, meaning that there was more scope for improvement. BRIDGE-ACS also included both STEMI and NSTEMI patients. The primary outcome was a composite outcome based on direct comparison of the control and intervention groups after the intervention, rather than a comparison of the change from baseline.

The QI intervention in the AFFECT trial,(Beck et al. 2005) consisted of a confidential report card summarising performance. No measurable improvements were noted in the pre-specified primary and secondary outcomes. The EFFECT trial(Tu et al. 2009) also used a public report card as the QI intervention and centres were randomised to receive this in an early or delayed manner. There was no measurable improvement noted for the key outcomes in this trial.

Another cluster-randomised QI project reported recently was the CPACS trial.(Du et al. 2014) The study implemented clinical pathways for risk stratification, STEMI and NSTEMI/Unstable Angina patients as the QI tool. Centres were allocated to receive this either ‘early’ i.e. at the start of the study (intervention group), or ‘late’ i.e. 12 months later (control group). The study was conducted in 75 centres in China from October 2007 to August 2010 recruiting a total of 3500 patients, i.e. approximately 50 cases per centre. A statistically significant improvement of 10% was observed for prescription of discharge medications 12 months after the intervention. No improvements were seen in the other pre-specified performance indicators including coronary angiography and functional testing for lower risk patients. Improvement in prescription of discharge medication was not accompanied by an improvement in clinical endpoints, but the study was not adequately powered to assess this. A companion qualitative study was conducted to identify barriers to optimal ACS management; this will be considered in the qualitative chapter of this thesis.

2.4.4 Individual indicators

2.4.4.1 Risk stratification

Although the trial was not powered to show differences in the individual ACS treatments, a large improvement was noted for risk stratification, corresponding to an increase of 31% in the QI centres versus a decrease of 8% in the non-QI centres. Risk stratification is a relatively new strategy for management of non-ST elevation ACS, compared to statins or
anticoagulation and its routine use was recommended in the ESC guidelines (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007), published shortly before the start of the study. There are a number of factors that could have led to the increase observed for this indicator. An important factor to consider is that baseline levels were lowest for this indicator with some centres not using risk models at all, which meant that this indicator had the greatest scope for improvement. Furthermore, the process of carrying out risk stratification is a relatively simple one entailing a hand or computer-based calculation which takes a few minutes once all the relevant results are available. A later chapter of this thesis will focus on this indicator in more depth.

2.4.4.2 Coronary angiography

Coronary angiography showed a modest improvement after implementation of the QI programme despite the relatively low baseline level. Rate of angiography in the Non-QI centres was 57% during the baseline phase, increasing to 58% after QI intervention compared to 55% in the QI centres during the baseline phase, increasing to 60% after QI intervention; OR 1.28 (0.88-1.86), p=0.2. A series of exploratory analyses using modified definitions for intermediate to high risk patients in the trial gave the same result for this indicator.

The algorithm for this indicator took timing into account due to the guideline recommendation that this should be delivered within 72 hours (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007) and it is likely that so soon after the publication of these guidelines, hospitals did not yet have systems in place to comply with this. In addition to this, a number of centres in the study did not have on-site angiography and PCI facilities, requiring transfer to a nearby site for the procedures. If patients did not return to the original centre after the angiography procedure, data on timing of angiography was not always available, resulting in these patients not being included in the analyses for this indicator.

This is the most organisationally complex of the eight indicators in that coronary angiography requires a number of steps and range of staff to be involved. It is possible that a different QI approach is needed for more complex treatment strategies such as this, or that more time is needed to allow the QI intervention to have an effect. Rates of angiography in both the QUICC and CPACS studies were approximately 10% higher than the control groups and the intervention phase in both studies lasted at least 6 months. Walshe has commented on the heterogeneity of treatment strategies and their responsiveness to QI (Walshe 2007; Walshe &
Freeman 2002) and it can be deduced that strategies involving multiple factors such as coronary angiography may not respond to the same QI intervention as simpler interventions e.g. prescription of discharge medications.

### 2.4.4.3 ACS medications

Improvements of 2-10% were noted for the 6 ACS medications assessed during the trial. Baseline prescription rates were over 75% for all with anticoagulation and statins starting at over 90%. This high baseline rate could explain the modest improvements observed. Clopidogrel loading dose improved the most and the improvement was statistically significant.

### 2.4.5 Limitations

The majority of the quality indicators assessed had high baseline rates, limiting the scope for improvement. The indicators were selected on the basis of guideline recommendations but it would have been useful to carry out a baseline survey or run-in phase to identify key areas for improvement prior to implementing the programme.

Patients were not followed up beyond discharge from hospital, so the effect of improved management during the in-hospital phase on clinical outcomes could not be assessed. In addition, centres were not followed up beyond the end of the study so it was not possible to establish whether the improvement observed during the study was maintained. Only two out of 38 centres agreed to collect data for one year following the end of the study and this data will be considered in a later chapter.

The QI intervention was delivered over a four-month period, which is shorter than some of the examples in the literature and may be too short a timeframe to effect a change in some of the more complex treatment strategies. This could be particularly important for coronary angiography as noted above, and it may be that a longer time period would have enabled the participating hospitals to streamline their processes for this quality indicator. The duration of the post-intervention phase is also important as QI work may continue throughout this phase and it is possible that further improvement would have been observed.

The QI intervention was not tailored to the individual treatments. Although the QI teams were encouraged to identify their own improvement tools to address local barriers, the same overall strategy was used for all indicators which may not be appropriate. It is possible that complex interventions such as coronary angiography require a different approach to ACS medications.
In addition to the complexity of quality indicators, QI itself is a multi-factorial intervention, the effects of which cannot be easily explained. Literature indicates that a range of factors could contribute to the effect of QI and these could be professional, financial or organisational, implying that one approach may not be adequate and certainly further work is required to elucidate the mechanisms involved. (Green et al. 2006; Grol 2001) The influence of a range of factors on the outcome of the QI intervention will be assessed in a later chapter.

Multiple statistical comparisons have been performed to assess the effect of the QI intervention on the individual ACS treatments. This should be taken into account in interpretation of results.

2.5 Conclusion

The QI intervention assessed by the EQUIP-ACS trial led to measurable improvements in the management of non-ST elevation ACS patients at a range of hospitals in 5 European countries. These findings support the use of QI strategies in routine management of non-ST elevation ACS but further work is needed to understand the long-term effects of this type of QI intervention.
CHAPTER 3. Secondary quantitative analysis of EQUIP-ACS: Use of risk stratification methods
3.1 Introduction

Risk stratification using a validated score was recommended by the ESC 2007 and 2011 guidelines for the management of non-ST elevation ACS (Hamm et al. 2011; Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007), highlighting the GRACE tool as the preferred method (Thomas and Giugliano 2012) but there is limited information available about the adoption of this score by cardiologists. The results of the EQUIP-ACS programme showed that formal risk assessment methods were not widely used prior to implementation of the programme and also that they improved considerably after delivery of the QI intervention. Use of risk stratification was the indicator that improved the most after implementation of the QI intervention but it is not known whether improved use of risk stratification was associated with an increase in use of the other guideline-recommended ACS treatments.

The EQUIP-ACS QI programme recommended the use of any formal, documented risk stratification method. Although any formal risk score could be used, emphasis was on the GRACE model, in line with ESC guideline recommendations at the time (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007).

This post-hoc analysis aims to evaluate the change in the use of risk scores by EQUIP-ACS centres and to assess whether an increase in use of these methods was accompanied by an improvement in the other indicators, deemed to be important quality markers of non-ST elevation ACS management.

3.2 Aims

- To evaluate the use of risk scores during the EQUIP-ACS programme
- To compare risk stratification performed by centres with a retrospective method using the GRACE score
- To assess whether improvement in use of risk scores is associated with an improvement in the other quality indicators

3.3 Method

Data for patients recruited during the baseline, QI implementation and post-QI phase were analysed for this evaluation. Patients that did not fulfil the EQUIP-ACS eligibility criteria were excluded from the analyses. (Flather et al. 2010)
The GRACE score was calculated retrospectively for all patients in the dataset, taking into account all components of the in-hospital risk model (Granger et al. 2003) as indicated below. On the basis of their GRACE score, patients were categorised as low, intermediate and high risk respectively, using the GRACE definitions for these categories. The GRACE definitions are based on tertiles of the scores from the population used to develop the score (Granger et al. 2003) See Table 7 and Table 8.

Patient characteristics were reported as number and percentage, N(%), in the case of categorical variables or for continuous variables as mean and standard deviation or median and interquartile range if they were not normally distributed. Statistical comparisons of characteristics were performed using analysis of variance (ANOVA) or chi-squared test as appropriate and in the case of outcome measures, using hierarchical logistic regression to take account of the clustered nature of the data. Analyses were performed using STATA version 12.1.
<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Value</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>&lt;=30</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>40-49</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>50-59</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>60-69</td>
<td>58</td>
</tr>
<tr>
<td></td>
<td>70-79</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>80-89</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>&gt;=90</td>
<td>100</td>
</tr>
<tr>
<td>Heart rate (bpm)</td>
<td>&lt;=50</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>50-69</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>70-89</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>90-109</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>110-149</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>150-199</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>&gt;=200</td>
<td>46</td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>&lt;=80</td>
<td>58</td>
</tr>
<tr>
<td></td>
<td>80-99</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>100-119</td>
<td>43</td>
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<tr>
<td></td>
<td>120-139</td>
<td>34</td>
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<td></td>
<td>160-199</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>&gt;=200</td>
<td>0</td>
</tr>
<tr>
<td>Creatinine (umol/L)</td>
<td>0 – 35.3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>35.4 - 70</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>71 - 105</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>106 - 140</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>141 - 176</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>177 - 353</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>&gt;=354</td>
<td>28</td>
</tr>
<tr>
<td>Killip Class</td>
<td>I (no CHF)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>II (lung rales)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>III (pulmonary oedema)</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>IV (cardiogenic shock)</td>
<td>59</td>
</tr>
<tr>
<td>Cardiac arrest at admission</td>
<td>Yes</td>
<td>39</td>
</tr>
<tr>
<td>ST segment deviation</td>
<td>Yes</td>
<td>28</td>
</tr>
<tr>
<td>Elevated cardiac enzymes</td>
<td>Yes</td>
<td>14</td>
</tr>
</tbody>
</table>

Table 7. GRACE in-hospital score

<table>
<thead>
<tr>
<th>RISK CATEGORY</th>
<th>GRACE RISK SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1-108</td>
</tr>
<tr>
<td>INTERMEDIATE</td>
<td>109-140</td>
</tr>
<tr>
<td>HIGH</td>
<td>141-372</td>
</tr>
</tbody>
</table>

Table 8. GRACE score categories (in-hospital mortality)
3.4 Results

The total number of patients included in this analysis was 4,448 corresponding to 1,393 during the baseline phase, 1,648 during the QI phase and 1,189 during the post-QI phase. The number of centres and patients in each phase and group are summarised in Figure 11.

![Flow chart summarising number of centres and patients in each phase of the EQUIP-ACS study](image)

**Figure 11. Flow chart summarising number of centres and patients in each phase of the EQUIP-ACS study**

3.4.1 Use of risk stratification during QI programme

Overall rates of formal risk stratification at baseline were 59.8% in the non-QI centres and 51.8% in the QI centres and after the QI intervention, rates were 51.9% and 83.2% respectively. Odds ratio [OR] corrected for cluster effect = 19.28 (95% CI 11.61 to 32.01; p<0.001). Use of the GRACE score increased more in the QI centres, from 7.1% to 37.8%, whilst use of the TIMI score remained approximately constant, from 25.7% to 25.9%. In the case of the non-QI centres, a moderate increase in use of the GRACE score was noted, from 9.7% to 16.7%, whilst use of the TIMI score decreased from 39.1% to 21.2%. The
overall adjusted Odds ratio [OR] for the GRACE score is 10.42 (95% CI 8.18 to 13.27, p<0.001) and for the TIMI score is 4.57 (95%CI 3.64 to 5.74, p<0.001).

### Table 9. Use of risk stratification by group and period

#### 3.4.2 Validation of risk stratification using retrospective GRACE score

The GRACE score was calculated retrospectively for all patients and they were classified as low, intermediate or high risk using the GRACE in-hospital definitions for these categories (Granger et al. 2003). The GRACE cut-offs for risk categories were selected as these are recognised and implemented in management of ACS but a comparison was also made with tertiles of GRACE score derived from the EQUIP-ACS dataset to ensure they are appropriate for the study population. See Table 10.

<table>
<thead>
<tr>
<th>Risk stratification</th>
<th>Non-QI centres</th>
<th>Odds ratio (95%CI) for BL vs PQI</th>
<th>QI centres</th>
<th>Odds ratio (95%CI) for BL vs PQI</th>
<th>Overall OR*</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>BL</td>
<td>QI</td>
<td>PQI</td>
<td>BL</td>
<td>QI</td>
</tr>
<tr>
<td>Using any method</td>
<td>59.8</td>
<td>49.5</td>
<td>51.9</td>
<td>0.66</td>
<td>(0.45-0.97)</td>
</tr>
<tr>
<td>GRACE</td>
<td>9.7</td>
<td>18.1</td>
<td>16.7</td>
<td>1.79</td>
<td>(1.48-2.18)</td>
</tr>
<tr>
<td>TIMI</td>
<td>39.1</td>
<td>21.2</td>
<td>19.2</td>
<td>0.25</td>
<td>(0.21-0.31)</td>
</tr>
</tbody>
</table>

Key: BL= Baseline phase, QI= QI implementation phase, PQI= Post-QI implementation phase

*adjusted for country and PCI-facilities

<table>
<thead>
<tr>
<th>RISK CATEGORY (TERTILES)</th>
<th>GRACE RISK SCORE</th>
<th>EQUIP-ACS DERIVED TERTILES</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW</td>
<td>1-108</td>
<td>25-111</td>
</tr>
<tr>
<td>INTERMEDIATE</td>
<td>109-140</td>
<td>112-142</td>
</tr>
<tr>
<td>HIGH</td>
<td>141-372</td>
<td>143-271</td>
</tr>
</tbody>
</table>

Table 10. Comparison of EQUIP-ACS tertiles with GRACE risk categories
3.4.2.1 Baseline characteristics

Baseline characteristics for patients in each of the risk categories are summarised in Table 11. The data in Table 11 demonstrate that the retrospective GRACE score has categorised patients appropriately as the following factors increase with risk: age, diabetes, hypertension, prior MI, ST depression on the ECG. Rates of angiography and percutaneous coronary intervention (PCI) performed in-hospital were lowest in the high risk category however and this will be explored further in later analyses.

The distribution of GRACE scores calculated for this population is shown in Figure 12.
<table>
<thead>
<tr>
<th>Description</th>
<th>GRACE Low risk</th>
<th>GRACE Intermediate risk</th>
<th>GRACE High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>1,259</td>
<td>1,623</td>
<td>1,566</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (mean [SD])</td>
<td>55.3 [9.6]</td>
<td>66.1 [8.6]</td>
<td>72.0 [6.6]</td>
</tr>
<tr>
<td>Male, N(%)</td>
<td>939 (74.6)</td>
<td>1,115 (68.7)</td>
<td>1,042 (66.5)</td>
</tr>
<tr>
<td>Female, N(%)</td>
<td>320 (25.4)</td>
<td>508 (31.3)</td>
<td>524 (33.5)</td>
</tr>
<tr>
<td>Diabetes, N(%)</td>
<td>199 (16.3)</td>
<td>389 (24.0)</td>
<td>527 (33.8)</td>
</tr>
<tr>
<td>Hypertension, N(%)</td>
<td>660 (54.4)</td>
<td>1,057 (65.6)</td>
<td>1,130 (72.9)</td>
</tr>
<tr>
<td>Smoker, N(%)</td>
<td>478 (40.8)</td>
<td>404 (26.0)</td>
<td>276 (18.9)</td>
</tr>
<tr>
<td>Prior MI, N(%)</td>
<td>252 (20.7)</td>
<td>412 (25.7)</td>
<td>546 (35.4)</td>
</tr>
<tr>
<td>ST-depression, N(%)</td>
<td>150 (12.4)</td>
<td>657 (40.6)</td>
<td>1,109 (71.0)</td>
</tr>
<tr>
<td>Pathological T-wave, N(%)</td>
<td>545 (44.9)</td>
<td>439 (27.1)</td>
<td>134 (8.6)</td>
</tr>
<tr>
<td>Cardiac marker positive (according to local cut-off), N(%)</td>
<td>923 (76.0)</td>
<td>1,364 (84.2)</td>
<td>1,450 (92.6)</td>
</tr>
<tr>
<td><strong>Admission medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel on admission, N(%)</td>
<td>107 (9.7)</td>
<td>168 (11.5)</td>
<td>213 (15.3)</td>
</tr>
<tr>
<td>Aspirin on admission, N(%)</td>
<td>342 (31.1)</td>
<td>606 (41.9)</td>
<td>731 (52.7)</td>
</tr>
<tr>
<td>Statin on admission, N(%)</td>
<td>346 (31.4)</td>
<td>615 (42.6)</td>
<td>692 (50.2)</td>
</tr>
<tr>
<td>ACE inhibitors /A2 receptor blockers on admission, N(%)</td>
<td>365 (31.0)</td>
<td>685 (44.2)</td>
<td>773 (51.4)</td>
</tr>
<tr>
<td><strong>In-hospital procedures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiography performed, N(%)</td>
<td>829 (68.2)</td>
<td>1,087 (67.1)</td>
<td>931 (59.5)</td>
</tr>
<tr>
<td>Yes at this hospital</td>
<td>32 (2.6)</td>
<td>40 (2.5)</td>
<td>38 (2.4)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>247 (20.3)</td>
<td>297 (18.3)</td>
<td>265 (16.9)</td>
</tr>
<tr>
<td>Total</td>
<td>1,108 (91.1)</td>
<td>1,424 (88.2)</td>
<td>1,234 (78.8)</td>
</tr>
<tr>
<td>PCI performed, N(%)</td>
<td>473 (39.7)</td>
<td>634 (40.3)</td>
<td>522 (34.6)</td>
</tr>
<tr>
<td>Yes at hospital</td>
<td>10 (0.8)</td>
<td>10 (0.6)</td>
<td>16 (1.0)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>152 (12.7)</td>
<td>167 (10.6)</td>
<td>112 (7.4)</td>
</tr>
<tr>
<td>Total</td>
<td>635 (53.2)</td>
<td>811 (51.5)</td>
<td>650 (43.0)</td>
</tr>
<tr>
<td>CABG performed, N(%)</td>
<td>43 (3.6)</td>
<td>61 (3.9)</td>
<td>58 (3.9)</td>
</tr>
<tr>
<td>Yes at hospital</td>
<td>43 (3.6)</td>
<td>105 (6.7)</td>
<td>100 (6.6)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>37 (3.1)</td>
<td>53 (3.4)</td>
<td>74 (4.9)</td>
</tr>
<tr>
<td>Death in-hospital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction, N(%)</td>
<td>706 (57.6)</td>
<td>1,022 (63.1)</td>
<td>1,117 (71.3)</td>
</tr>
<tr>
<td>Unstable angina, N(%)</td>
<td>429 (35.0)</td>
<td>523 (32.3)</td>
<td>381 (24.3)</td>
</tr>
<tr>
<td><strong>Death in-hospital</strong></td>
<td>4 (0.3)</td>
<td>9 (0.6)</td>
<td>69 (4.4)</td>
</tr>
</tbody>
</table>

Table 11. Baseline characteristics of patients, by GRACE risk category
3.4.3 Validation of risk scoring performed by centres

Risk stratification performed by centres during the study was compared with the retrospective method to assess whether methods were performed appropriately by the centres. Table 12 and Figure 13 show the comparison between risk stratification performed by centres using any method or the GRACE score only, and by the retrospective GRACE score for all patients and for those that were risk stratified only. Although the proportions for each risk category are similar across all groups, it can be seen that the proportion of patients classified as ‘intermediate risk’ is highest for the group risk stratified by centres using any method.

The Kappa statistic ($\kappa$) was calculated to assess agreement between the two methods. Comparison of risk stratification performed by centres using any method with the retrospective GRACE method showed ‘fair’ agreement, corresponding to a $\kappa$ of 0.23 and 49% agreement. Comparison of risk stratification performed by centres using the GRACE method only with the retrospective GRACE method showed slightly improved agreement, corresponding to a $\kappa$ of 0.37 and 59% agreement. The definition of ‘fair’ agreement is based
on a kappa value in the range of 0.21-0.40 as defined by Landis et al and Viera et al in their papers about comparing categorical variables using the kappa statistic. (Landis and Koch 1977; Viera and Garrett 2005)

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Risk stratification by any method</th>
<th>GRACE score (performed by centres)</th>
<th>GRACE score (determined retrospectively)</th>
<th>GRACE score (determined retrospectively)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>670 (23.6)</td>
<td>210 (21.6)</td>
<td>1,259 (28.3)</td>
<td>770 (27.2)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>1,283 (45.3)</td>
<td>404 (41.5)</td>
<td>1,623 (36.5)</td>
<td>1,063 (37.5)</td>
</tr>
<tr>
<td>High risk</td>
<td>882 (31.1)</td>
<td>359 (36.9)</td>
<td>1,259 (28.3)</td>
<td>1,002 (35.3)</td>
</tr>
</tbody>
</table>

*Risk category defined by any score

*Calculated for patients that were risk stratified only

Table 12. Use of risk stratification in EQUIP-ACS centres

![Figure 13. Comparison of centres' own risk stratification and retrospective method using GRACE score](image)

Mean and median GRACE scores were determined for each risk category and are shown in Table 13. The medians and interquartile ranges for each category are also shown graphically in Figure 14. The risk categories overlap but GRACE score increases with risk
and the scores determined for intermediate and high risk are in line with GRACE definitions. The scores determined for patients classified as low risk are at the higher end of the GRACE definition for low risk. The distribution of GRACE scores in each category is shown in Figure 15.

<table>
<thead>
<tr>
<th>GRACE score</th>
<th>Low risk</th>
<th>Intermediate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [SD]</td>
<td>111.4 [29.9]</td>
<td>126.5 [28.9]</td>
<td>145.9 [34.3]</td>
</tr>
</tbody>
</table>

Table 13. Comparison of Risk stratification performed by centres and retrospective validation

Figure 14. Box and whisker plots comparing GRACE scores in Low, Intermediate, and High risk categories determined by centres
Key baseline characteristics for risk categories assigned by the centres using any risk stratification method were also assessed, and these are summarised in Table 14. Comparing these data with the baseline characteristics presented in Table 11 for the retrospective risk scoring method, reveals some minor differences. Mean age increases more with each risk category calculated using the retrospective method. Similarly, ST depression on the admission ECG increases more for each category defined by the retrospective method, compared to the risk categories defined by centres. Differences are also observed for the rates of coronary angiography and PCI; data for the categories determined by the centres are similar across all groups whereas rates for patients categorised retrospectively decrease as risk increases.
<table>
<thead>
<tr>
<th>Description</th>
<th>Low risk</th>
<th>Intermediate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>670</td>
<td>1,283</td>
<td>882</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (mean [SD])</td>
<td>59.7 [10.8]</td>
<td>65.2 [10.0]</td>
<td>68.3 [9.5]</td>
</tr>
<tr>
<td>Male, N(%)</td>
<td>465 (69.4)</td>
<td>875 (68.2)</td>
<td>617 (70.0)</td>
</tr>
<tr>
<td>Female, N(%)</td>
<td>205 (30.6)</td>
<td>408 (31.8)</td>
<td>265 (30.1)</td>
</tr>
<tr>
<td>Diabetes, N(%)</td>
<td>82 (12.2)</td>
<td>294 (23.1)</td>
<td>319 (36.3)</td>
</tr>
<tr>
<td>Hypertension, N(%)</td>
<td>326 (49.0)</td>
<td>889 (70.4)</td>
<td>665 (75.9)</td>
</tr>
<tr>
<td>Smoker, N(%)</td>
<td>227 (35.6)</td>
<td>328 (27.1)</td>
<td>207 (25.1)</td>
</tr>
<tr>
<td>Prior MI, N(%)</td>
<td>81 (12.2)</td>
<td>349 (27.7)</td>
<td>357 (41.0)</td>
</tr>
<tr>
<td>ST-depression, N(%)</td>
<td>235 (35.1)</td>
<td>592 (46.3)</td>
<td>517 (58.8)</td>
</tr>
<tr>
<td>Pathological T-wave, N(%)</td>
<td>206 (30.8)</td>
<td>356 (27.8)</td>
<td>138 (15.7)</td>
</tr>
<tr>
<td>Cardiac marker positive (according to local cut-off), N(%)</td>
<td>503 (75.3)</td>
<td>1,040 (81.1)</td>
<td>820 (93.0)</td>
</tr>
<tr>
<td><strong>Admission medications</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clopidogrel on admission, N(%)</td>
<td>30 (4.9)</td>
<td>113 (10.8)</td>
<td>149 (18.9)</td>
</tr>
<tr>
<td>Aspirin on admission, N(%)</td>
<td>148 (24.3)</td>
<td>441 (42.6)</td>
<td>462 (58.5)</td>
</tr>
<tr>
<td>Statin on admission, N(%)</td>
<td>154 (25.3)</td>
<td>409 (39.6)</td>
<td>439 (55.9)</td>
</tr>
<tr>
<td>ACE inhibitors /A2 receptor blockers on admission, N(%)</td>
<td>178 (27.3)</td>
<td>510 (43.4)</td>
<td>450 (53.2)</td>
</tr>
<tr>
<td><strong>In-hospital procedures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiography performed, N(%)</td>
<td>432 (64.5)</td>
<td>856 (66.8)</td>
<td>564 (64.0)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>28 (4.2)</td>
<td>31 (2.4)</td>
<td>4 (1.6)</td>
</tr>
<tr>
<td>Yes transferred to another hospital</td>
<td>120 (17.9)</td>
<td>235 (18.3)</td>
<td>183 (20.8)</td>
</tr>
<tr>
<td>Total</td>
<td>580 (86.6)</td>
<td>1,122 (87.5)</td>
<td>751 (86.4)</td>
</tr>
<tr>
<td>PCI performed, N(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes at hospital</td>
<td>236 (36.0)</td>
<td>519 (42.0)</td>
<td>329 (38.7)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>5 (0.8)</td>
<td>8 (0.7)</td>
<td>12 (1.4)</td>
</tr>
<tr>
<td>Yes transferred to another hospital</td>
<td>62 (9.5)</td>
<td>101 (8.2)</td>
<td>89 (10.5)</td>
</tr>
<tr>
<td>Total</td>
<td>538 (46.3)</td>
<td>628 (50.9)</td>
<td>430 (50.6)</td>
</tr>
<tr>
<td>CABG performed, N(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes at hospital</td>
<td>21 (3.2)</td>
<td>57 (4.6)</td>
<td>32 (3.8)</td>
</tr>
<tr>
<td>Planned after discharge</td>
<td>26 (4.0)</td>
<td>90 (7.3)</td>
<td>53 (6.2)</td>
</tr>
<tr>
<td>Yes transferred to another hospital</td>
<td>21 (3.2)</td>
<td>47 (3.8)</td>
<td>50 (5.9)</td>
</tr>
<tr>
<td><strong>Discharge diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction, N(%)</td>
<td>386 (57.7)</td>
<td>791 (61.7)</td>
<td>648 (73.5)</td>
</tr>
<tr>
<td>Unstable angina, N(%)</td>
<td>232 (34.7)</td>
<td>440 (34.3)</td>
<td>208 (23.6)</td>
</tr>
<tr>
<td><strong>Death in-hospital</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death, N(%)</td>
<td>7 (1.1)</td>
<td>17 (1.3)</td>
<td>25 (2.8)</td>
</tr>
</tbody>
</table>

Table 14. Baseline characteristics for risk categories defined by centres
3.4.4 Assessment of whether risk scoring is associated with an improvement in quality indicators

Use of risk stratification methods showed the greatest improvement out of the eight quality indicators assessed during the EQUIP-ACS trial. The following analyses were performed to assess whether improved use of risk scores was associated with an improvement in any of the other indicators, i.e. whether assigning a risk score to patients led to improved use of other guideline recommended treatments for managing non-ST elevation ACS.

Since the composite outcome of all eight treatments includes use of risk stratification as one of its components, a new composite outcome which excludes use of risk stratification was generated to assess whether improvement in the remaining seven treatments is still observed.

Stratifying the risk categories by whether patients were risk scored or not showed an improvement in the composite outcome for all categories. Irrespective of patient risk, an odds ratio of 1.30-1.40 was observed for all categories, indicating that risk scoring a patient is associated with approximately 30% improvement in use of all ACS treatments assessed.

In terms of the individual indicators, there was a trend for all indicators to improve and this was observed for all risk categories. A significant improvement was noted in use of coronary angiography for intermediate and high risk patients with an OR for intermediate risk patients of 1.65 (95% confidence interval 1.21 – 2.24, p=0.001) and OR for high risk patients of 1.63 (95% confidence interval 1.20 – 2.22, p=0.002). Use of anticoagulation and ACE-inhibitors improved significantly for intermediate risk patients only, whereas use of statins showed significant improvement for low and high risk patients. Clopidogrel loading dose improved for all risk categories with ORs indicating at least a two-fold statistically significant improvement. These results are summarised in Table 15.

The results were also analysed taking allocation to the QI programme into account as shown in Table 16. It can be seen that the composite outcome, coronary angiography, clopidogrel loading dose and clopidogrel as a maintenance dose improved more in the QI centres compared to the non-QI centres.

These results are summarised in Table 15, Table 16 and Figure 16 to Figure 19. Figure 19 is a Forest plot comparing the effect of allocation to QI, time-period and risk stratification on the composite outcome of all 8 ACS treatments by GRACE risk category. The Forest plot
demonstrates that improvement in the composite outcome is observed in all cases, irrespective of risk category.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>GRACE Low risk</th>
<th>GRACE Intermediate risk</th>
<th>GRACE High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Risk stratified?</td>
<td>Risk stratified?</td>
<td>Risk stratified?</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>Y</td>
<td>OR (95%CI) p-value</td>
</tr>
<tr>
<td>Composite outcome</td>
<td>79.2</td>
<td>83.5</td>
<td>1.39 (1.20-1.61) p&lt;0.001</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>59.9</td>
<td>62.5</td>
<td>1.23 (0.88-1.73) p=0.229</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>93.0</td>
<td>93.2</td>
<td>1.85 (1.00-3.45) p=0.051</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>78.9</td>
<td>82.6</td>
<td>1.18 (0.83-1.69) P=0.355</td>
</tr>
<tr>
<td>Statins</td>
<td>93.2</td>
<td>95.2</td>
<td>2.01 (1.07-3.76) P=0.029</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>73.4</td>
<td>80.3</td>
<td>1.19 (0.84-1.70) P=0.326</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>77.7</td>
<td>88.4</td>
<td>3.20 (2.06-4.96) P&lt;0.001</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>78.5</td>
<td>82.1</td>
<td>1.19 (0.85-1.66) P= 0.31</td>
</tr>
</tbody>
</table>

Table 15. Effect of patient risk on outcome, by risk stratification performed (composite and individual outcomes)
Table 16. Effect of patient risk on outcome, by risk stratification performed and allocation to QI programme

<table>
<thead>
<tr>
<th>Outcome (%)</th>
<th>Non-QI</th>
<th>QI</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not risk stratified</td>
<td>Risk stratified</td>
<td>Not risk stratified</td>
<td>Risk stratified</td>
</tr>
<tr>
<td>Composite outcome</td>
<td>80.4</td>
<td>82.0</td>
<td>74.5</td>
<td>83.0</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>59.7</td>
<td>63.2</td>
<td>44.1</td>
<td>59.7</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>93.2</td>
<td>93.4</td>
<td>91.6</td>
<td>92.7</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>78.1</td>
<td>82.7</td>
<td>78.4</td>
<td>83.0</td>
</tr>
<tr>
<td>Statins</td>
<td>94.0</td>
<td>94.9</td>
<td>91.1</td>
<td>94.9</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>73.7</td>
<td>76.9</td>
<td>73.4</td>
<td>83.3</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>82.1</td>
<td>85.7</td>
<td>69.3</td>
<td>87.7</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>81.8</td>
<td>77.3</td>
<td>74.1</td>
<td>80.1</td>
</tr>
</tbody>
</table>

* Statistically significant difference

Figure 16. Quality indicators for low risk patients, comparison of those risk stratified with those that were not
* Statistically significant difference

Figure 17. Quality indicators for intermediate risk patients, comparison of those risk stratified with those that were not
Figure 18. Quality indicators for high risk patients, comparison of those risk stratified with those that were not

Figure 19. Forest plot showing effect of performing risk stratification, time-period and allocation to QI on the composite outcome of all ACS treatments, for each of the three risk categories
3.5 Discussion

3.5.1 Summary of results

The results of the analyses reported in this chapter show that use of risk stratification improved after implementation of the QI programme, largely driven by an improvement in use of the GRACE score. After implementation of the QI intervention, centres allocated to QI were risk scoring more than 80% of non-ST elevation ACS patients compared to 50% at the non-QI centres.

Validation of risk scoring performed by centres using a retrospective method showed fair agreement, as determined by the kappa statistic. Comparison of risk scoring performed by centres with the retrospective method showed some minor differences in patient characteristics which could be explained by the overlap seen between categories. It is possible that centres were either over-estimating risk for low risk patients or under-estimating risk for high risk patients, or both, since the intermediate risk category was the largest at about 45% of the total.

Median GRACE scores per risk category determined by the centres were calculated, showing appropriate scores for each category although in the case of the low risk category, these were at the higher end of the GRACE definition. This could be explained by the fact that the EQUIP-ACS eligibility criteria were mainly focussed on intermediate to high risk patients as defined by GRACE and patients with low GRACE scores would not have been eligible for the study.

An assessment of the effect of risk scoring on the remaining ACS treatments demonstrated a trend for management to improve if risk stratification was performed. The composite measure improved significantly for all three categories when risk stratification was performed but improved management was also noted for each of the individual measures, notably for coronary angiography and use of clopidogrel as a loading dose. It is encouraging to see that use of risk stratification is associated with an improvement in referral for coronary angiography as this measure demonstrated the lowest rates in the main study results. The greatest difference was observed for high risk patients, 58% of risk stratified high risk patients received angiography compared to 44% of those that had not been risk stratified.

A comparison of data for the three risk categories to look at the effect of allocation to QI, time-period and whether patients were risk stratified or not, showed that the composite of all
eight ACS treatments improved irrespective of risk. This implies that the QI intervention targeted all patients irrespective of risk.

3.5.2 Comparison with literature

Oliveira et al (Oliveira et al. 2007) observed that better use of the GRACE score did not lead to improved management of high risk patients. The analyses presented in this chapter however, provide evidence that improved risk scoring using validated scores such as GRACE and TIMI, as a result of a QI intervention, led to a meaningful improvement in management of non-ST elevation ACS patients. A three-fold improvement was observed in the composite outcome and importantly, improved rates of coronary angiography were seen for intermediate and high risk patients corresponding to a statistically significant difference of at least 10% in both cases, when comparing patients that were risk stratified to those that were not. This encouraging data supports early risk scoring of patients to ensure appropriate referral for angiography.

Validated risk stratification methods were used in approximately 50% of cases prior to delivery of the EQUIP-ACS QI programme and this increased to more than 80% in the QI centres after the programme was implemented. In the remainder of cases, a decision to manage patients with an early invasive strategy was reached on the basis of global clinical evaluation. It has been reported that risk stratification based on clinical evaluation only can lead to under-estimating the true risk as important risk factors are frequently ignored. In some instances clinicians may react to extremes of one risk factor and ignore the overall picture, and risk factors are sometimes assigned the same weight even though some e.g. age, are known to drive risk more than others (Fox & Langrish 2010; Henderson 2013; Scirica 2010; Steg 2009)

Risk-guided angiography and revascularisation where risk is determined by clinical evaluation has been assessed in a range of studies, but retrospective analyses using validated scores showed that clinicians were underestimating risk and due to a misperception that patients were not high risk enough, were not referring them adequately for invasive strategies (Bagnall et al. 2010; Lee et al. 2008; Yan et al. 2007a; Yan et al. 2009) Results of risk stratification using validated scores identified intermediate and high risk patients that had been categorised as low risk by clinicians leading to sub-optimal treatment in all areas.
3.5.3 Limitations

The analyses reported in this chapter were performed retrospectively and are exploratory. Use of risk scores by centres has been validated via a retrospective method, validation of the method was not performed by monitoring medical records of each patient to ensure scores were calculated in accordance with the formal methods. It was also not possible to verify the score determined for each patient as the database only captured risk category as low, intermediate or high, rather than as an absolute score.

It would also have been interesting to collect data on whether the outcome of risk stratification was used to determine further decisions on management of the patient, rather than just to satisfy the data collection requirements of the trial.

The eligibility criteria for the EQUIP-ACS trial specified that, in addition to a clinical history of ACS, patients must have either ST or T wave changes on the admission ECG or a troponin rise indicative of myocardial necrosis. Presence of either of these criteria mean that true low risk patients may not have been included in the trial and therefore management of low risk patients cannot be fully assessed.

The GRACE definitions for risk category are based on data-driven tertiles rather than clinical factors. The EQUIP-ACS database prompted participating centres to categorise patients into one of three categories i.e. ‘low’, ‘intermediate’ or ‘high’, rather than to specify an absolute score. While it is practical to assign a risk category to guide further management decisions, it should be acknowledged that risk is in fact continuous and the cut-offs selected may not be clinically meaningful.

Rate of risk stratification for the Non-QI centres using any method remained approximately the same after the QI intervention. Assessment of the results by individual risk scores however showed that there was a reduction in use of TIMI and an increase in use of the GRACE score. This change in use of scores could be attributed to the release of the ESC guidelines which recommended GRACE over other methods.

As for the primary analysis of the trial, data on outcome measures after discharge from hospital are not available so it was not possible to assess the effect of risk scoring in-hospital on clinical outcomes.
3.6 Conclusion

Risk stratification using validated scores improved considerably after delivery of the QI intervention and a retrospective validation demonstrated that the scores were used appropriately by centres. Importantly, this improvement in use of risk scores translated to higher rates of ACS treatments for all patients and the most important change observed was a higher rate of angiography for intermediate and high risk patients. Whilst the current guidelines recommend use of validated risk scores to ensure appropriate management of ACS patients, these data provide documented evidence that in-hospital management can improve as a result of formal risk scoring. These data could help to convince clinicians who are sceptical of these methods that risk stratification is central to ACS management and should be performed as a matter of routine.
CHAPTER 4. The effect of patient and centre characteristics on outcome of the QI programme
4.1 Introduction

The outcome of a QI intervention may be influenced by the characteristics of the hospitals implementing QI work. The hospitals that took part in EQUIP-ACS varied in size and included district general hospitals and teaching hospitals. It is possible that these differences could have led to variation in the way QI work was carried out.

There is evidence (Roe et al. 2006) that high risk patients, whether this is assessed by a formal risk score or a global clinical evaluation, are treated sub-optimally with respect to guideline recommendations. The literature indicates that all patients are treated sub-optimally but the standard of care is even lower in specific populations such as the elderly or those with comorbidities. The QI intervention implemented during EQUIP-ACS targeted all non-ST elevation ACS patients according to the ESC guidelines (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology et al. 2007) irrespective of risk, but it is not known whether the improvement observed was affected by patient characteristics.

The aim of this chapter is to assess whether management of patients admitted to hospitals participating in the EQUIP-ACS project was affected by the patients’ characteristics and the characteristics of the hospitals they were treated at.

4.2 Methods

Data for patients recruited during the baseline, QI-intervention and post-intervention phase were included in this evaluation. Patients that did not fulfil the EQUIP-ACS eligibility criteria were excluded from the analyses. (Flather et al. 2010)

Patient characteristics were reported as number and percentage, N(%), in the case of categorical variables or for continuous variables as mean and standard deviation or median and interquartile range if they were not normally distributed. Statistical testing of outcome measures was performed using hierarchical logistic regression to take account of clustered nature of data. The multivariate regression was performed using a mixed effects model to account for fixed and random effects at the patient and centre level. Analyses were performed using STATA version 12.1.
4.3 Results

4.3.1 Baseline characteristics

Table 17 below summarises patient characteristics that may have influenced the outcome of the QI intervention, split by allocation. These are the characteristics that will be assessed individually in order to evaluate their effect on use of guideline recommended treatments during the EQUIP-ACS programme.

The hospital characteristics to be considered are summarised in Table 18, presented by allocation. Both patient and hospital characteristics will be included in the multivariate model at the end of the results section.

<table>
<thead>
<tr>
<th>Description</th>
<th>Units</th>
<th>Non-QI centres</th>
<th>QI centres</th>
<th>All centres</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td></td>
<td>1054</td>
<td>1528</td>
<td>2582</td>
</tr>
<tr>
<td>Age</td>
<td>mean [SD]</td>
<td>65.9 [10.4]</td>
<td>65.3 [10.8]</td>
<td>65.6 [10.6]</td>
</tr>
<tr>
<td>Female</td>
<td>N (%)</td>
<td>294 (27.9)</td>
<td>493 (32.3)</td>
<td>787 (30.5)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>N (%)</td>
<td>298 (28.4)</td>
<td>387 (25.4)</td>
<td>685 (26.6)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>N (%)</td>
<td>300 (28.7)</td>
<td>431 (28.6)</td>
<td>731 (28.7)</td>
</tr>
<tr>
<td>ST depression on admission ECG</td>
<td>N (%)</td>
<td>476 (45.3)</td>
<td>670 (43.9)</td>
<td>1,146 (44.5)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>N (%)</td>
<td>59 (5.6)</td>
<td>96 (6.3)</td>
<td>155 (6.0)</td>
</tr>
<tr>
<td>History of HF</td>
<td>N (%)</td>
<td>134 (12.7)</td>
<td>154 (10.3)</td>
<td>288 (11.3)</td>
</tr>
</tbody>
</table>

GRACE risk score

| Low (1-108)                        | N (%)   | 249 (23.6)     | 425 (27.8) | 674 (26.1)  |
| Intermediate (109-140)             | N (%)   | 392 (37.2)     | 571 (37.4) | 963 (37.3)  |
| High (141-372)                     | N (%)   | 413 (39.2)     | 532 (34.8) | 945 (36.6)  |
| Mean score                         | Mean [SD]| 133.1 [33.6]   | 128.2 [33.2]| 130.2 [33.5]|

Table 17. Patient characteristics (data for baseline, QI-intervention and post-QI phase combined)
<table>
<thead>
<tr>
<th>Description</th>
<th>Units</th>
<th>Non-QI centres</th>
<th>QI centres</th>
<th>All centres</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>19</td>
<td>19</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Population served for acute coronary admissions</td>
<td>mean [SD] 432248.7 [237821]</td>
<td>328284.9 [222023.2]</td>
<td>378780 [266599.9]</td>
<td></td>
</tr>
<tr>
<td>Angiography on site</td>
<td>N (%) 13 (68.4)</td>
<td>13 (68.4)</td>
<td>26 (68.4)</td>
<td></td>
</tr>
<tr>
<td>PCI facilities on-site</td>
<td>N (%) 11 (57.9)</td>
<td>10 (52.6)</td>
<td>21 (55.3)</td>
<td></td>
</tr>
<tr>
<td>CABG facilities on-site</td>
<td>N (%) 4 (21.1)</td>
<td>6 (31.6)</td>
<td>10 (26.3)</td>
<td></td>
</tr>
<tr>
<td>Number of cardiology beds (including CCU if applicable)</td>
<td>mean [SD] 45.2 [36.5]</td>
<td>37.7 [27.0]</td>
<td>41.2 [31.6]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median [IQR] 36.5 [25.5,52]</td>
<td>31 [20,55]</td>
<td>32.5 [21,55]</td>
<td></td>
</tr>
<tr>
<td>Number of ACS admissions per year</td>
<td>mean [SD] 597.7 [430.3]</td>
<td>645.2 [496.7]</td>
<td>622.8 [460.3]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median [IQR] 494.5 [308,696]</td>
<td>490 [400,750]</td>
<td>492.5 [320,742]</td>
<td></td>
</tr>
<tr>
<td>Number of cardiologists (full time equivalents)</td>
<td>mean [SD] 7.8 [4.9]</td>
<td>9.1 [8]</td>
<td>8.5 [6.7]</td>
<td></td>
</tr>
<tr>
<td>Hospital with routine undergraduate teaching programme</td>
<td>N (%) 12 (75)</td>
<td>14 (77.8)</td>
<td>26 (76.5)</td>
<td></td>
</tr>
<tr>
<td>Baseline performance (proportion of composite outcome fulfilled during baseline phase)</td>
<td>Median proportion 76.9 [70.9, 82.6]</td>
<td>76.7 [60.3, 82.3]</td>
<td>76.8 [70.9, 82.3]</td>
<td></td>
</tr>
<tr>
<td>&lt;70%</td>
<td>N (%) 4 (21.1)</td>
<td>5 (26.3)</td>
<td>9 (23.7)</td>
<td></td>
</tr>
<tr>
<td>≥70% &amp; &lt;90%</td>
<td>N (%) 12 (63.2)</td>
<td>13 (68.4)</td>
<td>25 (65.8)</td>
<td></td>
</tr>
<tr>
<td>≥ 90%</td>
<td>N (%) 3 (15.8)</td>
<td>1 (5.3)</td>
<td>4 (10.5)</td>
<td></td>
</tr>
</tbody>
</table>

Table 18. Hospital characteristics (data for baseline, QI-intervention and post-QI phases combined)
4.3.2 Effect of patient characteristics

A series of unadjusted analyses were performed to assess the effect of individual patient characteristics on use of guideline recommended treatments as a composite and individual outcomes. The individual unadjusted analyses will be included in a multivariable regression model later in this chapter.

4.3.2.1 Age

Patients aged over 65 years were less likely to receive all recommended treatments. The proportion of patients aged over 65 years receiving all treatments was 75.7% compared to 79.7% of those aged less than 65 years. The unadjusted odds ratio for this comparison is 0.84, 95% confidence interval (0.78-0.90), p<0.001, favouring the lower age group. The rates of coronary angiography, statins and clopidogrel as a loading and maintenance dose were also significantly lower for the higher age group as shown in Table 19.

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Age =&lt;65</th>
<th>Age &gt;65</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>79.7</td>
<td>75.7</td>
<td>0.84 (0.78-0.90)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>63.0</td>
<td>61.8</td>
<td>0.96 (0.78-1.19)</td>
<td>0.734</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>63.1</td>
<td>52.4</td>
<td>0.63 (0.52-0.75)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>92.4</td>
<td>90.9</td>
<td>0.81 (0.60-1.09)</td>
<td>0.161</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>83.3</td>
<td>79.3</td>
<td>0.82 (0.67-1.02)</td>
<td>0.071</td>
</tr>
<tr>
<td>Statins</td>
<td>94.8</td>
<td>91.9</td>
<td>0.67 (0.48-0.93)</td>
<td>0.017</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>78.2</td>
<td>78.9</td>
<td>1.12 (0.91-1.37)</td>
<td>0.272</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>83.1</td>
<td>77.2</td>
<td>0.76 (0.61-0.94)</td>
<td>0.013</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>80.2</td>
<td>73.3</td>
<td>0.70 (0.57-0.85)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table 19. Effect of age on outcome measures of QI programme

4.3.2.2 Gender

Female patients were less likely to receive all ACS treatments, 77.9% of male patients achieved the composite outcome of all eight treatments compared to 76.4% of female patients. This difference was statistically significant with an unadjusted OR of 0.88 (95%CI=0.82 – 0.95, p=0.001) but a difference of 1.5% is unlikely to be clinically significant. There was a trend for all individual treatments to be prescribed less for female patients, although only clopidogrel at discharge achieved a statistically significant difference.
<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Male</th>
<th>Female</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>77.9</td>
<td>76.4</td>
<td>0.88 (0.82-0.95)</td>
<td>0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>61.9</td>
<td>63.3</td>
<td>0.93 (0.74-1.17)</td>
<td>0.542</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>57.3</td>
<td>56.4</td>
<td>0.90 (0.74-1.09)</td>
<td>0.270</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>92.4</td>
<td>89.4</td>
<td>0.75 (0.56-1.02)</td>
<td>0.063</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>81.4</td>
<td>80.1</td>
<td>0.88 (0.71-1.10)</td>
<td>0.265</td>
</tr>
<tr>
<td>Statins</td>
<td>93.6</td>
<td>92.1</td>
<td>0.81 (0.58-1.13)</td>
<td>0.223</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>78.7</td>
<td>78.2</td>
<td>0.87 (0.70-1.08)</td>
<td>0.214</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>80.3</td>
<td>78.6</td>
<td>0.88 (0.70-1.10)</td>
<td>0.272</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>77.5</td>
<td>73.5</td>
<td>0.76 (0.62-0.93)</td>
<td>0.007</td>
</tr>
</tbody>
</table>

Table 20. Effect of gender on outcome measures of QI programme

4.3.2.3 Diabetes

There was no statistically significant difference observed for the composite of eight treatments between patients with and without diabetes. The composite outcome measure was achieved in 77.5% of non-diabetic patients compared with 77.4% of diabetic patients (OR (95%CI) = 1.01 (0.93-1.09), p=0.835). Rate of coronary angiography was statistically lower for diabetic patients however, corresponding to 58.8% in non-diabetic patients compared to 52.1% in diabetic patients (OR (95%CI)= 0.69 (0.57-0.84), p<0.001). Rates of prescription of beta blockers and ACE-inhibitors were statistically higher for diabetic patients.

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>No diabetes</th>
<th>Diabetes</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>77.5</td>
<td>77.4</td>
<td>1.01 (0.93-1.09)</td>
<td>0.835</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>62.5</td>
<td>61.9</td>
<td>0.88 (0.69-1.12)</td>
<td>0.300</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>58.8</td>
<td>52.1</td>
<td>0.69 (0.57-0.84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>91.4</td>
<td>91.8</td>
<td>1.02 (0.73-1.42)</td>
<td>0.901</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>80.3</td>
<td>83.1</td>
<td>1.28 (1.01-1.63)</td>
<td>0.045</td>
</tr>
<tr>
<td>Statins</td>
<td>92.8</td>
<td>94.1</td>
<td>1.26 (0.87-1.84)</td>
<td>0.225</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>76.7</td>
<td>84.0</td>
<td>1.80 (1.41-2.31)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>80.3</td>
<td>78.3</td>
<td>0.90 (0.71-1.14)</td>
<td>0.363</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>77.1</td>
<td>73.9</td>
<td>0.88 (0.71-1.08)</td>
<td>0.220</td>
</tr>
</tbody>
</table>

Table 21. Effect of diabetes on outcome measures of QI programme

4.3.2.4 Prior Myocardial Infarction (MI)

Patients with prior MI at presentation were less likely to have coronary angiography and anticoagulation but more likely to receive statins, ACE-inhibitors and clopidogrel as a maintenance dose. Rates of discharge medications tended to be higher for patients with prior MI.

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>No prior MI</th>
<th>Prior MI</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>76.8</td>
<td>78.8</td>
<td>1.08 (1.00-1.16)</td>
<td>0.061</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>61.0</td>
<td>64.7</td>
<td>1.03 (0.81-1.30)</td>
<td>0.820</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>58.3</td>
<td>53.9</td>
<td>0.74 (0.61-0.90)</td>
<td>0.003</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>92.4</td>
<td>89.4</td>
<td>0.74 (0.55-1.00)</td>
<td>0.011</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>80.0</td>
<td>83.6</td>
<td>1.23 (0.97-1.56)</td>
<td>0.084</td>
</tr>
<tr>
<td>Statins</td>
<td>92.3</td>
<td>96.0</td>
<td>2.06 (1.36-3.14)</td>
<td>0.001</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>76.4</td>
<td>83.2</td>
<td>1.43 (1.13-1.81)</td>
<td>0.003</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>79.0</td>
<td>81.0</td>
<td>1.16 (0.91-1.47)</td>
<td>0.220</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>75.3</td>
<td>78.8</td>
<td>1.26 (1.02-1.56)</td>
<td>0.034</td>
</tr>
</tbody>
</table>

Table 22. Effect of prior MI on outcome measures of QI programme

4.3.2.5 Chronic Kidney Disease

Patients with chronic kidney disease (CKD) received fewer ACS treatments than those without chronic kidney disease. This was observed for the composite outcome measure which was 71.7% for patients with CKD compared with 78.0% for patients with no CKD (OR 95%CI; 0.68 (0.60-0.76), p<0.001). Lower rates were noted for all the individual factors, with statistical significance achieved for coronary angiography, ACE-inhibitors and clopidogrel loading dose.
Table 23. Effect of chronic kidney disease on outcome measures of QI programme

4.3.2.6 ST depression

There was no difference observed for the composite outcome measure between patients with ST depression on their admission ECG and those with no ST depression on the admission ECG. No statistically significant differences were observed for any of the individual treatments.

Table 24. Effect of ST depression on the ECG on outcome measures of QI programme
4.3.2.7 Prior stroke

Patients with prior stroke were less likely to receive recommended ACS treatments. The composite outcome of all treatments was lower for patients with prior stroke, 73.3% compared with 77.7% for those with no prior stroke (OR 95%CI = 0.80 (0.70-0.91), p=0.001) and statistically significantly lower values were also observed for coronary angiography and anticoagulation.

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>No prior stroke</th>
<th>Prior stroke</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>77.7</td>
<td>73.3</td>
<td>0.80 (0.70-0.91)</td>
<td>0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>62.4</td>
<td>60.7</td>
<td>0.80 (0.52-1.25)</td>
<td>0.331</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>58.4</td>
<td>37.4</td>
<td>0.39 (0.27-0.56)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>91.8</td>
<td>87.1</td>
<td>0.55 (0.33-0.93)</td>
<td>0.025</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>81.3</td>
<td>77.5</td>
<td>0.82 (0.55-1.24)</td>
<td>0.358</td>
</tr>
<tr>
<td>Statins</td>
<td>93.3</td>
<td>91.6</td>
<td>0.77 (0.41-1.41)</td>
<td>0.393</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>78.6</td>
<td>77.5</td>
<td>0.92 (0.61-1.40)</td>
<td>0.704</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>80.0</td>
<td>76.3</td>
<td>0.87 (0.56-1.33)</td>
<td>0.515</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>76.1</td>
<td>78.8</td>
<td>1.24 (0.82-1.88)</td>
<td>0.303</td>
</tr>
</tbody>
</table>

Table 25. Effect of prior stroke on outcome measures of QI programme

4.3.2.8 History of heart failure

The proportion of patients with a history of heart failure receiving all eight treatments was statistically lower than the proportion of patients without a history of heart failure. This result was not clinically significant as the difference observed between the two groups was only 0.2%. As the dataset for EQUIP-ACS is large, in this case over 4,000 patients, very small effect sizes can be statistically significant.

Coronary angiography and prescription of clopidogrel loading dose were significantly lower for patients with a history of heart failure.
<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>No Heart Failure</th>
<th>Heart Failure</th>
<th>OR (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>77.5</td>
<td>77.3</td>
<td>0.75 (0.65-0.85)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>61.4</td>
<td>68.1</td>
<td>0.56 (0.28-1.09)</td>
<td>0.087</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>58.1</td>
<td>49.5</td>
<td>0.38 (0.16-0.88)</td>
<td>0.024</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>92.1</td>
<td>87.9</td>
<td>0.86 (0.56-1.30)</td>
<td>0.464</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>80.3</td>
<td>86.6</td>
<td>1.41 (0.67-2.99)</td>
<td>0.364</td>
</tr>
<tr>
<td>Statins</td>
<td>93.2</td>
<td>94.1</td>
<td>1.25 (0.72-2.17)</td>
<td>0.419</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>77.5</td>
<td>86.6</td>
<td>1.19 (0.67-2.12)</td>
<td>0.545</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>80.7</td>
<td>72.0</td>
<td>0.35 (0.14-0.92)</td>
<td>0.033</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>76.6</td>
<td>73.8</td>
<td>0.76 (0.56-1.04)</td>
<td>0.082</td>
</tr>
</tbody>
</table>

Table 26. Effect of history of heart failure on outcome measures of QI programme

4.3.2.9 Individual risk factors at presentation

The individual factors assessed in sections 4.3.2.1 to 4.3.2.8 were combined so that patients could be analysed according to the number of ‘risk factors’ or comorbidities present. Patients were given a score of zero to seven and Table 27 and Figure 20 summarise the proportion of indicators achieved in each group. Data for a score of seven were omitted due to low numbers of patients.

The proportion of indicators achieved for the composite outcome of all eight treatments decreased as the number of risk factors increased, and this pattern was also noted for coronary angiography, anticoagulation and ACE-inhibitors. Use of risk stratification however, tended to increase as the number of risk factors increased.
<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Primary outcome</td>
<td>80.8</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>62.7</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>61.6</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>95.2</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>87.6</td>
</tr>
<tr>
<td>Statins</td>
<td>94.4</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>85.0</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>85.5</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>82.9</td>
</tr>
</tbody>
</table>

Table 27. Effect of number of risk factors/comorbidities on outcome

Figure 20. Rates of treatments for patients with 0-6 risk factors at baseline
4.3.2.10 Effect of patient risk category determined by GRACE on QI measures

The primary (composite) outcome and individual treatments were evaluated for each of the three risk categories and the results are summarised in Table 28. There was a trend for rate of use of treatments to be highest in the low risk group and lowest in the high risk group.

The composite outcome measure was significantly higher in the low risk group (78.6%) when compared with the high risk group (75.2%), with an OR of 0.79 (95% CI: 0.72-0.86, p<0.001), favouring the low risk category. A statistically significantly higher rate was also observed for the following individual quality indicators in the case of the low risk category: Coronary angiography, beta-blockers at discharge and clopidogrel maintenance dose.

Significantly higher rates were also observed for the intermediate group compared with the high risk group for the majority of the indicators: the composite outcome measure, coronary angiography, beta-blockers at discharge, ACE-inhibitors at discharge and clopidogrel as a maintenance dose.

Only one of the comparisons between the low and intermediate risk categories was statistically significant and that was coronary angiography at 61.5% in the low and 59.2% in the intermediate risk category.
<table>
<thead>
<tr>
<th>Outcome %</th>
<th>GRACE Low risk</th>
<th>GRACE Intermediate risk</th>
<th>GRACE High risk</th>
<th>OR for inter vs low</th>
<th>OR for high vs inter</th>
<th>OR for high vs low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcome</td>
<td>78.6</td>
<td>78.8</td>
<td>75.2</td>
<td>0.98 (0.90-1.07) p=0.657</td>
<td>0.81 (0.75-0.87) p&lt;0.001</td>
<td>0.79 (0.72-0.86) p=0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>61.3</td>
<td>63.9</td>
<td>61.5</td>
<td>1.05 (0.80-1.38) p=0.708</td>
<td>0.80 (0.62-1.02) p=0.076</td>
<td>0.84 (0.64-1.10) P=0.199</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>62.4</td>
<td>58.1</td>
<td>52.2</td>
<td>0.77 (0.61-0.97) p=0.028</td>
<td>0.73 (0.59-0.89) p=0.002</td>
<td>0.56 (0.44-0.70) P&lt;0.001</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>92.5</td>
<td>90.6</td>
<td>91.7</td>
<td>0.79 (0.54-1.14) p=0.210</td>
<td>1.14 (0.82-1.58) p=0.432</td>
<td>0.89 (0.61-1.31) p=0.558</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>81.9</td>
<td>82.6</td>
<td>78.7</td>
<td>0.99 (0.76-1.29) p=0.943</td>
<td>0.76 (0.60-0.96) p=0.023</td>
<td>0.75 (0.57-0.97) p=0.031</td>
</tr>
<tr>
<td>Statins</td>
<td>94.2</td>
<td>93.6</td>
<td>91.9</td>
<td>0.88 (0.58-1.35) p=0.563</td>
<td>0.79 (0.55-1.13) p=0.197</td>
<td>0.70 (0.46-1.06) p=0.091</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>78.0</td>
<td>81.1</td>
<td>76.4</td>
<td>1.15 (0.89-1.49) p=0.277</td>
<td>0.75 (0.59-0.94) p=0.015</td>
<td>0.86 (0.66-1.11) p=0.237</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>81.0</td>
<td>81.2</td>
<td>77.3</td>
<td>1.02 (0.78-1.34) p=0.899</td>
<td>0.79 (0.62-1.01) p=0.06</td>
<td>0.80 (0.61-1.05) P=0.110</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>77.6</td>
<td>79.3</td>
<td>72.2</td>
<td>1.11 (0.87-1.42) p=0.400</td>
<td>0.66 (0.53-0.82) P&lt;0.001</td>
<td>0.74 (0.58-0.94) p=0.013</td>
</tr>
</tbody>
</table>

Table 28. Effect of patient risk on outcome for whole group (primary and secondary outcomes)

4.3.2.11 Effect of risk category on treatment, taking time-period into account

The effect of patient risk on treatment was also evaluated by time-period and the results are summarised in Table 29. The composite outcome improved for all categories after delivery of the QI intervention and the improvement was statistically significant in all cases. The only indicator which showed significant improvement for all risk categories after implementation of the QI programme was use of risk stratification.

Anticoagulation and ACE-inhibitors showed significant improvement for patients classified as intermediate risk whilst use of clopidogrel loading dose improved significantly for both low and intermediate risk patients. Prescription of statins increased significantly for intermediate and high risk patients but the improvement noted for low risk patients was not statistically significant.
<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>GRACE Low risk</th>
<th></th>
<th>GRACE Intermediate risk</th>
<th></th>
<th>GRACE High risk</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL</td>
<td>PQI</td>
<td>OR 95%CI</td>
<td>BL</td>
<td>PQI</td>
<td>OR 95%CI</td>
</tr>
<tr>
<td>Primary outcome</td>
<td>76.7</td>
<td>82.6</td>
<td>1.49 (1.28-1.74) p&lt;0.001</td>
<td>76.6</td>
<td>83.0</td>
<td>1.59 (1.39-1.82) p&lt;0.001</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>51.8</td>
<td>71.7</td>
<td>4.66 (2.95-7.37) p&lt;0.001</td>
<td>57.4</td>
<td>71.5</td>
<td>3.88 (2.64-5.70) p&lt;0.001</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>63.4</td>
<td>61.4</td>
<td>1.02 (0.71-1.47) p=0.528</td>
<td>54.2</td>
<td>62.6</td>
<td>1.88 (1.08-3.44) p=0.254</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>91.7</td>
<td>93.4</td>
<td>1.22 (0.66-2.26) p=0.909</td>
<td>88.4</td>
<td>93.4</td>
<td>1.73 (1.07-2.78) p=0.025</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>87.7</td>
<td>96.2</td>
<td>2.76 (0.48-15.98) p=0.257</td>
<td>87.6</td>
<td>89.9</td>
<td>1.32 (0.57-3.04) p=0.512</td>
</tr>
<tr>
<td>Statins</td>
<td>93.4</td>
<td>95.0</td>
<td>1.43 (0.72-2.86) p=0.304</td>
<td>91.9</td>
<td>96.1</td>
<td>2.28 (1.25-4.13) p=0.007</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>84.6</td>
<td>86.9</td>
<td>1.16 (0.65-2.08) p=0.618</td>
<td>84.8</td>
<td>90.1</td>
<td>2.08 (1.28-3.38) p=0.003</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>75.3</td>
<td>87.6</td>
<td>2.70 (1.71-4.27) p=0.001</td>
<td>78.7</td>
<td>84.3</td>
<td>1.66 (1.15-2.39) p=0.007</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>78.3</td>
<td>81.7</td>
<td>1.31 (0.87-1.97) p=0.194</td>
<td>80.8</td>
<td>83.2</td>
<td>1.27 (0.89-1.82) p=0.184</td>
</tr>
</tbody>
</table>

Table 29. Effect of patient risk on outcome by time period (primary and secondary outcomes). Data from baseline and post-QI intervention phase

4.3.2.12 Effect of risk category on outcome, by allocation to QI intervention

The outcomes were also evaluated by risk category and allocation to the QI intervention and the result are summarised in Table 30. Modest improvements were noted in all cases for the composite outcome but this did not achieve statistical significance. Use of risk stratification improved for all categories but again, this was not statistically significant. The remaining quality indicators showed either limited or no improvement.
Table 30. Effect of patient risk on outcome by allocation (primary and secondary outcomes)

4.3.3 Effect of centre characteristics on outcome of QI programme

4.3.3.1 Baseline performance

The effect of baseline centre performance on the outcome of the QI intervention was assessed, taking time-period into account and the results are summarised in Table 31. Baseline performance was defined as the proportion of patients achieving the composite endpoint of all eight treatments at a centre during the baseline phase. Centres were split into two groups for this comparison; those below median baseline performance and those above the median, where median performance at baseline was 76.8%. The proportion of patients receiving all treatments increased by almost 10% in the low baseline performance group whereas in the high baseline performance group, this decreased by about 1%. Each of the individual treatments also increased more for the low baseline performance group, with four out of eight showing statistically significant improvements.
### Table 31. Effect of baseline performance (composite outcome) on outcome

#### 4.3.3.2 Country effect

Analyses were performed to assess the effect of country on the outcome measures of the QI programme. Statistical tests have been omitted because the subgroups are small in each case. It can be seen in Table 32 that the composite outcome increased for all countries but the greatest improvement was observed for Spain. The lowest improvement occurred for the Polish centres which increased from 82% during the baseline phase to 85% after the QI intervention.

Regarding the individual treatments, the largest improvements were observed for the Spanish centres which ranged from no change to an improvement of 45%, whereas the lowest changes occurred for the Polish centres which ranged from a decrease of 3% to an increase of 7%.
### Table 32. Country effect

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Spain</th>
<th>Poland</th>
<th>Italy</th>
<th>UK</th>
<th>France</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL</td>
<td>PQI</td>
<td>BL</td>
<td>PQI</td>
<td>BL</td>
</tr>
<tr>
<td>Composite outcome</td>
<td>66.2</td>
<td>79.2</td>
<td>82.2</td>
<td>84.7</td>
<td>75.3</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>24.4</td>
<td>70.5</td>
<td>76.6</td>
<td>73.8</td>
<td>69.6</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>52.6</td>
<td>58.0</td>
<td>65.7</td>
<td>73.3</td>
<td>62.6</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>94.6</td>
<td>93.5</td>
<td>83.7</td>
<td>89.6</td>
<td>87.7</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>75.9</td>
<td>77.8</td>
<td>95.7</td>
<td>92.7</td>
<td>65.5</td>
</tr>
<tr>
<td>Statins</td>
<td>86.8</td>
<td>96.9</td>
<td>92.4</td>
<td>93.7</td>
<td>94.1</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>72.5</td>
<td>84.0</td>
<td>95.8</td>
<td>94.9</td>
<td>70.7</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>61.8</td>
<td>78.1</td>
<td>78.6</td>
<td>82.3</td>
<td>67.7</td>
</tr>
<tr>
<td>Clopidogrel maintenance</td>
<td>69.4</td>
<td>74.8</td>
<td>79.9</td>
<td>85.2</td>
<td>77.4</td>
</tr>
</tbody>
</table>

Key: BL=Baseline phase; PQI=Post-QI implementation phase

#### 4.3.3.3 Teaching hospital

The effect of being admitted to a teaching hospital compared to a non-teaching hospital was also assessed. A teaching hospital was defined as any hospital with a routine undergraduate teaching programme. The results in Table 33 indicate that admission to a teaching hospital did not lead to improved management of non-ST elevation ACS as there is no difference observed between the two types of hospitals.

The results for the two hospital types were also evaluated by comparing the pre and post-intervention phases and it can be seen in Table 34 that the differences are similar in both groups.
<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Not a teaching hospital</th>
<th>Teaching hospital</th>
<th>OR for non-teaching vs teaching (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite outcome</td>
<td>78.1</td>
<td>77.4</td>
<td>1.09 (0.73-1.62)</td>
<td>0.686</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>64.9</td>
<td>59.1</td>
<td>1.46 (0.18-12.19)</td>
<td>0.725</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>59.4</td>
<td>57.0</td>
<td>0.77 (0.28-2.11)</td>
<td>0.606</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>93.1</td>
<td>91.2</td>
<td>1.22 (0.58-2.57)</td>
<td>0.599</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>79.6</td>
<td>81.7</td>
<td>1.19 (0.65-2.19)</td>
<td>0.572</td>
</tr>
<tr>
<td>Statins</td>
<td>91.9</td>
<td>93.4</td>
<td>1.65 (0.70-3.89)</td>
<td>0.250</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>78.5</td>
<td>79.9</td>
<td>1.11 (0.55-2.24)</td>
<td>0.779</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>83.3</td>
<td>80.2</td>
<td>1.06 (0.45-2.50)</td>
<td>0.900</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>73.9</td>
<td>77.4</td>
<td>1.10 (0.67-1.81)</td>
<td>0.710</td>
</tr>
</tbody>
</table>

**Table 33. Effect of teaching hospital**

<table>
<thead>
<tr>
<th>Outcome, %</th>
<th>Baseline phase</th>
<th>Post-QI phase</th>
<th>Baseline phase</th>
<th>Post-QI phase</th>
<th>OR for non-teaching vs teaching (95%CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite outcome</td>
<td>75.3</td>
<td>82.8</td>
<td>75.8</td>
<td>80.8</td>
<td>0.94 (0.77-1.15)</td>
<td>0.562</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>56.0</td>
<td>73.0</td>
<td>50.9</td>
<td>68.8</td>
<td>0.99 (0.47-2.06)</td>
<td>0.974</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>56.5</td>
<td>62.0</td>
<td>55.2</td>
<td>59.0</td>
<td>0.96 (0.60-1.53)</td>
<td>0.852</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>90.8</td>
<td>95.1</td>
<td>90.3</td>
<td>92.2</td>
<td>0.55 (0.23-1.28)</td>
<td>0.165</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>82.1</td>
<td>90.2</td>
<td>85.5</td>
<td>87.8</td>
<td>0.90 (0.21-3.85)</td>
<td>0.889</td>
</tr>
<tr>
<td>Statins</td>
<td>93.1</td>
<td>91.0</td>
<td>91.5</td>
<td>96.5</td>
<td>3.46 (1.46-8.20)</td>
<td>0.005</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>82.1</td>
<td>86.1</td>
<td>84.5</td>
<td>84.9</td>
<td>1.03 (0.51-2.12)</td>
<td>0.926</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>76.7</td>
<td>89.4</td>
<td>77.9</td>
<td>82.8</td>
<td>0.53 (0.28-1.00)</td>
<td>0.05</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>73.1</td>
<td>82.5</td>
<td>80.0</td>
<td>81.2</td>
<td>0.66 (0.38-1.17)</td>
<td>0.156</td>
</tr>
</tbody>
</table>

**Table 34. Effect of teaching hospital, taking time-period into account**
4.3.3.4 Composite outcome by centres

Individual centres were ranked in order of highest improvement to lowest to look for common factors which may influence the outcome of the QI intervention. The ranking of centres is summarised in Table 35 below which includes allocation, country and performance during the baseline and post-intervention phases respectively. The change from baseline to post-intervention phase ranged from a decrease of 11% to an increase of 28%. 26 out of 38 centres improved after the intervention, 10 centres showed a decrease in performance, one remained at the same level and one collected no data during the post-intervention phase. Fifteen out of the 26 centres that improved were allocated to receive the QI intervention whereas 6 out of 10 centres that decreased were non-QI centres. Three of the top five centres were Spanish hospitals.

These results are also presented graphically in Figure 21 and Figure 22, split by allocation to QI. It can be seen that there is a trend for the QI centres to maintain or increase performance, whereas the majority of the non-QI centres either maintain or decrease performance.

<table>
<thead>
<tr>
<th>Centre rank</th>
<th>Allocation</th>
<th>Centre name</th>
<th>Country</th>
<th>Baseline phase (BL) Indicators achieved/Indicators possible (%)</th>
<th>Post-QI phase (PQI) Indicators achieved/Indicators possible (%)</th>
<th>Absolute change (PQI – BL) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QI</td>
<td>Hospital Universitario Joan XXIII de Tarragona</td>
<td>Spain</td>
<td>179/297 (60.3)</td>
<td>284/321 (88.5)</td>
<td>28.2</td>
</tr>
<tr>
<td>2</td>
<td>QI</td>
<td>Hospital de Terrassa</td>
<td>Spain</td>
<td>80/143 (55.9)</td>
<td>89/109 (81.7)</td>
<td>25.8</td>
</tr>
<tr>
<td>3</td>
<td>QI</td>
<td>Szpital w Grojcu</td>
<td>Poland</td>
<td>117/204 (57.4)</td>
<td>179/223 (80.3)</td>
<td>22.9</td>
</tr>
<tr>
<td>4</td>
<td>QI</td>
<td>Hospital Universitario Valle d’Hebron</td>
<td>Spain</td>
<td>404/711 (56.8)</td>
<td>518/678 (76.4)</td>
<td>19.6</td>
</tr>
<tr>
<td>5</td>
<td>Non-QI</td>
<td>Ospedale Livorno</td>
<td>Italy</td>
<td>343/458 (74.9)</td>
<td>136/154 (88.3)</td>
<td>13.4</td>
</tr>
<tr>
<td>6</td>
<td>QI</td>
<td>Antrim Area Hospital</td>
<td>UK</td>
<td>113/196 (57.7)</td>
<td>171/241 (71.0)</td>
<td>13.3</td>
</tr>
<tr>
<td>7</td>
<td>QI</td>
<td>Swietokrzyskie Centrum Chorob Serca</td>
<td>Poland</td>
<td>844/1107 (76.2)</td>
<td>566/653 (86.7)</td>
<td>10.5</td>
</tr>
<tr>
<td>8</td>
<td>QI</td>
<td>CHU de Grenoble</td>
<td>France</td>
<td>170/216 (78.7)</td>
<td>156/177 (88.1)</td>
<td>9.4</td>
</tr>
<tr>
<td>Centre rank</td>
<td>Allocation</td>
<td>Centre name</td>
<td>Country</td>
<td>Baseline phase (BL)</td>
<td>Post-QI phase (PQI)</td>
<td>Absolute change (PQI – BL) %</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>-------------</td>
<td>---------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>9</td>
<td>QI</td>
<td>SPZOZ w Radomiu</td>
<td>Poland</td>
<td>150/183 (82.0)</td>
<td>202/222 (91.0)</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td>Non-QI</td>
<td>Hopitaux Drome de Romans-sur-Isere</td>
<td>France</td>
<td>70/92 (76.1)</td>
<td>84/99 (84.9)</td>
<td>8.8</td>
</tr>
<tr>
<td>11</td>
<td>QI</td>
<td>Centre Hospitalier Guy Thomas de Riom</td>
<td>France</td>
<td>46/60 (76.7)</td>
<td>40/47 (85.1)</td>
<td>8.4</td>
</tr>
<tr>
<td>12</td>
<td>Non-QI</td>
<td>Ospedale Civile di Mirano</td>
<td>Italy</td>
<td>156/220 (70.9)</td>
<td>167/214 (78.0)</td>
<td>7.1</td>
</tr>
<tr>
<td>13</td>
<td>Non-QI</td>
<td>Hospital Universitario Germans Trias</td>
<td>Spain</td>
<td>120/186 (64.5)</td>
<td>174/245 (71.0)</td>
<td>6.5</td>
</tr>
<tr>
<td>14</td>
<td>Non-QI</td>
<td>York District Hospital</td>
<td>UK</td>
<td>318/490 (64.9)</td>
<td>251/355 (70.7)</td>
<td>5.8</td>
</tr>
<tr>
<td>15</td>
<td>Non-QI</td>
<td>Ospedale Generale Provinciale di Macerata</td>
<td>Italy</td>
<td>146/209 (69.9)</td>
<td>126/169 (74.6)</td>
<td>4.7</td>
</tr>
<tr>
<td>16</td>
<td>QI</td>
<td>Barnet General Hospital</td>
<td>UK</td>
<td>402/489 (82.2)</td>
<td>465/538 (86.4)</td>
<td>4.2</td>
</tr>
<tr>
<td>17</td>
<td>QI</td>
<td>Basildon Hospital</td>
<td>UK</td>
<td>297/393 (75.6)</td>
<td>244/307 (79.5)</td>
<td>3.9</td>
</tr>
<tr>
<td>18</td>
<td>Non-QI</td>
<td>Centre Hospitalier d’Ussel</td>
<td>France</td>
<td>10/13 (76.9)</td>
<td>19/24 (79.2)</td>
<td>2.3</td>
</tr>
<tr>
<td>19</td>
<td>QI</td>
<td>Ospedale Morgagni-Pierantoni, Forli</td>
<td>Italy</td>
<td>187/226 (82.7)</td>
<td>133/157 (84.7)</td>
<td>2.0</td>
</tr>
<tr>
<td>19</td>
<td>Non-QI</td>
<td>Hospital del Mar IMAS</td>
<td>Spain</td>
<td>162/200 (81.0)</td>
<td>151/182 (83.0)</td>
<td>2.0</td>
</tr>
<tr>
<td>20</td>
<td>Non-QI</td>
<td>Hospital Josep Trueta Girona</td>
<td>Spain</td>
<td>290/356 (81.5)</td>
<td>346/415 (83.4)</td>
<td>1.9</td>
</tr>
<tr>
<td>21</td>
<td>QI</td>
<td>Ospedale M. Bufalini - Cesena</td>
<td>Italy</td>
<td>52/61 (82.3)</td>
<td>291/347 (83.9)</td>
<td>1.6</td>
</tr>
<tr>
<td>21</td>
<td>Non-QI</td>
<td>Szpital w Ciechanowie</td>
<td>Poland</td>
<td>174/217 (80.2)</td>
<td>117/143 (81.8)</td>
<td>1.6</td>
</tr>
<tr>
<td>21</td>
<td>Non-QI</td>
<td>Szpital Zachodni</td>
<td>Poland</td>
<td>84/101 (83.2)</td>
<td>212/250 (84.8)</td>
<td>1.6</td>
</tr>
<tr>
<td>22</td>
<td>QI</td>
<td>Medical Academy of Warsaw</td>
<td>Poland</td>
<td>545/588 (92.7)</td>
<td>330/352 (93.8)</td>
<td>1.1</td>
</tr>
<tr>
<td>Centre rank</td>
<td>Allocation</td>
<td>Centre name</td>
<td>Country</td>
<td>Baseline phase (BL) Indicators achieved/Indicators possible (%)</td>
<td>Post-QI phase (PQI) Indicators achieved/Indicators possible (%)</td>
<td>Absolute change (PQI – BL) %</td>
</tr>
<tr>
<td>-------------</td>
<td>------------</td>
<td>------------------------------</td>
<td>---------</td>
<td>----------------------------------------------------------------</td>
<td>----------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>23</td>
<td>QI</td>
<td>Centre Hospitalier Pierre Bazin, Voiron</td>
<td>France</td>
<td>45/59 (76.3)</td>
<td>34/44 (77.3)</td>
<td>1.0</td>
</tr>
<tr>
<td>24</td>
<td>Non-QI</td>
<td>Yeovil District Hospital</td>
<td>UK</td>
<td>116/183 (63.4)</td>
<td>97/153 (63.4)</td>
<td>0.0</td>
</tr>
<tr>
<td>25</td>
<td>Non-QI</td>
<td>Szpital w Siedlcach</td>
<td>Poland</td>
<td>120/156 (76.9)</td>
<td>116/151 (76.8)</td>
<td>-0.1</td>
</tr>
<tr>
<td>26</td>
<td>Non-QI</td>
<td>Hopital G Montpied 2</td>
<td>France</td>
<td>38/46 (82.6)</td>
<td>112/136 (82.4)</td>
<td>-0.2</td>
</tr>
<tr>
<td>27</td>
<td>QI</td>
<td>Royal Albert Edward Infirmary Wigan</td>
<td>UK</td>
<td>174/238 (73.1)</td>
<td>89/123 (72.4)</td>
<td>-0.7</td>
</tr>
<tr>
<td>28</td>
<td>QI</td>
<td>Centre Hospitalier de Chambery</td>
<td>France</td>
<td>163/190 (85.8)</td>
<td>54/64 (84.4)</td>
<td>-1.4</td>
</tr>
<tr>
<td>29</td>
<td>Non-QI</td>
<td>Dept A’ CHU G. Montpied</td>
<td>France</td>
<td>79/82 (96.3)</td>
<td>46/49 (93.9)</td>
<td>-2.4</td>
</tr>
<tr>
<td>30</td>
<td>QI</td>
<td>Centre Hospitalier d’Annecy</td>
<td>France</td>
<td>113/135 (83.7)</td>
<td>108/133 (81.2)</td>
<td>-2.5</td>
</tr>
<tr>
<td>31</td>
<td>Non-QI</td>
<td>Radomski Szpital Specjalistycny</td>
<td>Poland</td>
<td>157/173 (90.8)</td>
<td>85/97 (87.6)</td>
<td>-3.2</td>
</tr>
<tr>
<td>32</td>
<td>QI</td>
<td>Szpital w Plocku</td>
<td>Poland</td>
<td>93/116 (80.2)</td>
<td>189/251 (75.3)</td>
<td>-4.9</td>
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<tr>
<td>33</td>
<td>Non-QI</td>
<td>Szpital we Wloclawku</td>
<td>Poland</td>
<td>605/669 (90.4)</td>
<td>259/317 (81.7)</td>
<td>-8.7</td>
</tr>
<tr>
<td>34</td>
<td>Non-QI</td>
<td>Hospital de Tortosa Virgen de la Cinta</td>
<td>Spain</td>
<td>134/175 (76.6)</td>
<td>86/133 (64.7)</td>
<td>-11.9</td>
</tr>
<tr>
<td>N/A</td>
<td>Non-QI</td>
<td>Warwick Hospital</td>
<td>UK</td>
<td>39/53 (73.6)</td>
<td>0/0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 35. Composite outcome by centre
Figure 21. QI centres during baseline and post-QI phase

Figure 22. Non-QI centres during baseline and post-QI phase
4.3.4 Multilevel mixed effects hierarchical model

The influence of patient and centre characteristics on outcome of the QI intervention were considered in a mixed effects multivariate model. The model had two levels to account for factors at the patient and centre level. Allocation to QI, time-period and the interaction term for allocation and time-period were included as co-variates. Two versions of the model were performed, the first using the composite of all eight ACS treatments as an outcome measure and the second using a composite of all ACS treatments except for risk stratification as the outcome measure.

The results of the multivariate model assessing the composite of eight ACS treatments are summarised in Table 36. The factors associated with improved management, represented by the composite of eight treatments, were the interaction term of allocation to QI and post-QI intervention phase, prior MI and number of cardiologists at a site. The factors associated with poorer outcome were female gender, prior stroke, CKD, history of heart failure and admission at a centre in the UK, Spain or Italy. Patients admitted to a QI hospital during the post-intervention phase were 84% more likely to receive all ACS treatments and those with a previous MI were 12% more likely to receive all eight treatments. Female patients were 8% less likely to receive all treatments and patients with a history of heart failure, CKD or prior stroke were 13-24% less likely to receive all eight guideline-recommended treatments.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>95%CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQI phase</td>
<td>0.96</td>
<td>0.85-1.09</td>
<td>0.535</td>
</tr>
<tr>
<td>Allocation to QI</td>
<td>0.93</td>
<td>0.79-1.09</td>
<td>0.374</td>
</tr>
<tr>
<td>PQIxQI*</td>
<td>1.84</td>
<td>1.57-2.16</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>0.92</td>
<td>0.84-0.99</td>
<td>0.046</td>
</tr>
<tr>
<td>Age</td>
<td>1.00</td>
<td>0.99-1.01</td>
<td>0.939</td>
</tr>
<tr>
<td>Age&gt;65</td>
<td>0.94</td>
<td>0.81-1.09</td>
<td>0.442</td>
</tr>
<tr>
<td>Prior MI</td>
<td>1.12</td>
<td>1.03-1.23</td>
<td>0.011</td>
</tr>
<tr>
<td>Chronic Kidney disease</td>
<td>0.76</td>
<td>0.66-0.88</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>0.82</td>
<td>0.70-0.96</td>
<td>0.012</td>
</tr>
<tr>
<td>History of HF</td>
<td>0.87</td>
<td>0.75-0.99</td>
<td>0.047</td>
</tr>
<tr>
<td>Intermediate GRACE risk</td>
<td>1.15</td>
<td>0.98-1.27</td>
<td>0.109</td>
</tr>
<tr>
<td>High GRACE risk</td>
<td>1.12</td>
<td>0.91-1.38</td>
<td>0.295</td>
</tr>
<tr>
<td>Country 2 (France)</td>
<td>0.80</td>
<td>0.64-1.01</td>
<td>0.066</td>
</tr>
<tr>
<td>Country 3 (Italy)</td>
<td>0.54</td>
<td>0.39-0.75</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Country 4 (Spain)</td>
<td>0.63</td>
<td>0.48-0.82</td>
<td>0.001</td>
</tr>
<tr>
<td>Country 5 (UK)</td>
<td>0.65</td>
<td>0.51-0.83</td>
<td>0.001</td>
</tr>
<tr>
<td>Population served</td>
<td>1.00</td>
<td>1.00-1.00</td>
<td>0.012</td>
</tr>
<tr>
<td>ACS admissions</td>
<td>1.00</td>
<td>1.00-1.00</td>
<td>0.749</td>
</tr>
<tr>
<td>Cardiology beds</td>
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<td>0.99-1.00</td>
<td>0.004</td>
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<tr>
<td>Cardiologists</td>
<td>1.03</td>
<td>1.01-1.04</td>
<td>0.002</td>
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<tr>
<td>PCI Facilities</td>
<td>0.97</td>
<td>0.80-1.17</td>
<td>0.751</td>
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<tr>
<td>Baseline performance &lt; median</td>
<td>0.94</td>
<td>0.73-1.22</td>
<td>0.645</td>
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</tbody>
</table>

*PQIxQI: Interaction of allocation to QI and post-QI intervention phase

Table 36. Multivariate model to assess effect of patient and centre characteristics on composite outcome of eight ACS treatments
The results of the multivariate model assessing the composite of all ACS treatments except risk stratification are summarised in Table 37. The factors associated with improved management, represented by the composite of seven treatments, were the interaction term of allocation to QI and post-QI intervention phase, prior MI, risk stratification and on-site PCI facilities. The factors associated with poorer outcome were female gender, prior stroke, CKD and admission to a centre in Spain. Patients that were risk stratified were 22% more likely to receive the other seven ACS treatments. Patients admitted to a QI hospital during the post-intervention phase were 26% more likely to receive all seven ACS treatments and those with a previous MI were 14% more likely to receive all seven treatments. Female patients were 9% less likely to receive all treatments, patients with CKD were 30% less likely and those with prior stroke were 19% less likely to receive all seven guideline-recommended treatments.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
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<td>PQI phase</td>
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<td>0.87-1.16</td>
<td>0.979</td>
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<td>Allocation to QI</td>
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<td>0.66-1.02</td>
<td>0.071</td>
</tr>
<tr>
<td>PQIxQI*</td>
<td>1.26</td>
<td>1.04-1.52</td>
<td>0.02</td>
</tr>
<tr>
<td>Female</td>
<td>0.91</td>
<td>0.82-0.99</td>
<td>0.044</td>
</tr>
<tr>
<td>Age</td>
<td>1.00</td>
<td>0.99-1.01</td>
<td>0.869</td>
</tr>
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<td>Age&gt;65</td>
<td>0.92</td>
<td>0.78-1.09</td>
<td>0.348</td>
</tr>
<tr>
<td>Prior MI</td>
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<td>1.03-1.26</td>
<td>0.013</td>
</tr>
<tr>
<td>Chronic Kidney disease</td>
<td>0.70</td>
<td>0.60-0.82</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>0.81</td>
<td>0.68-0.97</td>
<td>0.02</td>
</tr>
<tr>
<td>History of HF</td>
<td>0.87</td>
<td>0.74-1.02</td>
<td>0.08</td>
</tr>
<tr>
<td>Risk stratified</td>
<td>1.22</td>
<td>1.08-1.38</td>
<td>0.001</td>
</tr>
<tr>
<td>Intermediate GRACE risk</td>
<td>1.11</td>
<td>0.95-1.29</td>
<td>0.181</td>
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<td>High GRACE risk</td>
<td>1.12</td>
<td>0.89-1.42</td>
<td>0.331</td>
</tr>
<tr>
<td>Country 2 (France)</td>
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<td>0.74-1.40</td>
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<td>Country 3 (Italy)</td>
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<td>Country 4 (Spain)</td>
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<td>Country 5 (UK)</td>
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<td>0.55-1.10</td>
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<td>Population served</td>
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<td>ACS admissions</td>
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<td>Cardiology beds</td>
<td>0.99</td>
<td>0.98-1.00</td>
<td>0.036</td>
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<td>Cardiologists</td>
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<td>0.99-1.04</td>
<td>0.193</td>
</tr>
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<td>PCI Facilities</td>
<td>1.44</td>
<td>1.10-1.89</td>
<td>0.007</td>
</tr>
<tr>
<td>Baseline performance &lt; median</td>
<td>1.29</td>
<td>0.91-1.83</td>
<td>0.148</td>
</tr>
</tbody>
</table>

*PQIxQI: Interaction of allocation to QI and post-QI intervention phase

Table 37. Multivariate model to assess effect of patient and centre characteristics on the composite of seven treatments
4.4 Discussion

4.4.1 Summary of results

A series of univariate analyses indicated that management of non-ST elevation ACS patients admitted to hospitals participating in the EQUIP-ACS programme, where management is represented by the use of eight guideline-recommended treatments for ACS, was worse for patients that were aged over 65 years, females, patients with diabetes, CKD, previous stroke and a history of heart failure. The presence of each of these factors individually led to poorer treatment considered both as a composite outcome and individual treatments. The effect of number of risk factors on management was also assessed, indicating that as the number of risk factors increases, management deteriorates.

Rate of angiography was statistically lower for patients aged over 65, diabetics and patients with previous MI, previous stroke, CKD and heart failure. Rate of prescription of discharge medications was generally lower in the presence of these risk factors, especially in the case of patients with renal failure who received much lower rates of ACE inhibitors and clopidogrel. The exceptions were patients with ST depression on the admission ECG who were risk stratified more often and patients with prior MI who tended to receive higher rates of discharge medications.

Patients were categorised into low, intermediate and high risk using the GRACE risk score in order to assess the effect of risk category on management. Higher GRACE score was associated with worse management as demonstrated by the composite measure as well as the individual treatments, with the effect being most pronounced for coronary angiography.

Improvement in management was noted for all risk categories when time-period or allocation were taken into account, indicating that the QI intervention targeted management of all patients irrespective of risk. It was also noted that an increase in use of risk stratification led to an improvement in use of individual treatments and the greatest improvement was observed for angiography in high risk patients.

In terms of hospital characteristics, lower performance at baseline was associated with better management after delivery of the QI intervention. There was no difference observed between hospitals with an undergraduate teaching programme and non-teaching hospitals. Change in performance within countries varied, with Spain achieving the greatest improvement and Poland the lowest. An exploratory ranking of centres to compare
performance before and after the intervention indicated that centres allocated to the QI intervention showed, on average, greater improvement in the post-intervention phase.

The influence of patient and centre characteristics on use of ACS treatments was assessed in two multi-level multivariate mixed effects models accounting for patient and centre effects. The multivariate model assessing a composite outcome of eight ACS treatments showed that management of females, patients with CKD, a history of heart failure or prior stroke tended to be worse. Admission to hospitals in the UK, Spain or Italy was also associated with worse outcome. Patients admitted to a QI hospital during the post-QI intervention phase and those with a prior MI were more likely to receive all eight guideline-recommended treatments. The number of cardiologists at site was also associated with a small improvement in management. None of the other centre characteristics included in the multivariate model remained significant after adjusting for all covariates. It is reassuring that the effect of post-intervention phase and allocation to QI continues to be significant when adjusting for patient and centre characteristics. This suggests that the QI intervention was associated with improved management of non-ST elevation ACS patients irrespective of the type of hospital they were admitted to and the level of care before the intervention was delivered.

A second multivariate model to assess the effect of patient and centre characteristics on a composite outcome measure of all ACS treatments excluding risk assessment showed that management of females, patients with CKD, prior stroke and those admitted to hospitals in Spain tended to be worse. Patients admitted to a QI hospital during the post-QI phase, those with a previous episode of MI, patients that have been risk stratified and those admitted to hospitals with on-site PCI facilities were more likely to receive all seven treatments.

Comparison of the two multivariate models indicates that access to on-site PCI facilities may not be relevant for use of risk stratification but that this influences the composite of prescription of ACS treatments and use of coronary angiography. The effect of country is important when the endpoint considered includes risk stratification and this could be explained by the fact that risk stratification was low in each of Italy, Spain and the UK prior to implementation of the QI programme. When the outcome measure excludes risk stratification however, only Spain is associated with worse outcome. Importantly, use of risk stratification was independently associated with improved use of all other ACS treatments, indicating that appropriate risk scoring may lead to improved management of this group of patients.
4.4.2 Comparison with literature

The paradox of higher patient risk and presence of co-morbidities corresponding to poorer management, observed in the univariate analyses performed in this chapter, is well-documented in the literature. (Bhatt et al. 2004; Cohen et al. 2009; Fox et al. 2007b; Grabowski et al. 2011) Bhatt et al observed that patients with documented comorbidities or aged more than 75 years are less likely to be revascularised or managed with an early invasive strategy. Similarly, Fox et al noted that high risk patients were less likely to have angiography and PCI, irrespective of hospital or geography. Data from the CRUSADE study (Cohen et al. 2009; Tricoci et al. 2006) showed that high risk patients, defined as those with additional risk factors at presentation, receive less angiography and revascularisation but also reported that this leads to poorer prescription of ACS medications at discharge.

Data published from the GRACE registry are consistent with the findings reported here, indicating that management of ACS patients with a history of heart failure is worse despite the fact that these patients have a poorer prognosis. (Steg et al. 2004) The literature also reports inferior use of guideline recommended treatments in the presence of chronic kidney disease, in line with the analyses presented in this chapter. Despite increased risk of MI and death patients with CKD are under-treated, receiving less angiography and lower rates of medications at discharge. (Asim and Jeffrey 2011; Department of Health 2013; Fox et al. 2010a; Hanna, Chen, Roe, Wiviott, Fox, & Saucedo 2011; Patel et al. 2009; Tricoci, Peterson, & Roe 2006)

It is possible that clinicians use a more conservative approach if co-morbidities are present but it is important to note that the ESC guidelines, which the goals of the QI programme were based on, recommend these treatments for all patients, except in the presence of contra-indications. (Hamm et al. 2011; Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology 2007) Both the 2007 guidelines and the update in 2011, specify that elderly patients, diabetic patients and those with chronic kidney disease, should receive the same first-line treatment as ACS patients without these risk factors.

The fact that management of non-ST elevation in female patients is worse is also well documented in the literature, with data from the CRUSADE initiative demonstrating this in the case of catheterisation and medical treatment. (Blomkalns et al. 2005; Tavris et al. 2010; Willingham and Kilpatrick 2005) The difference observed in the composite endpoint for the EQUIP-ACS study was small, at approximately 1%, but this remained statistically significant in both multivariate models.
In contrast with the findings reported in this chapter, data from other quality improvement programmes indicate that hospital characteristics may influence management of ACS. Data from the Get-with-the-Guidelines Coronary Artery Disease (GTWG-CAD) programme (Lewis, Peterson, Cannon, Super, LaBresh, Quealy, Liang, & Fonarow 2008) indicated that teaching hospitals, volume and number of beds were associated with improved management. This QI programme is non-randomised which could account for the difference in findings between EQUIP-ACS and GWTG-CAD. In addition, the number of centres assessed is much higher than for EQUIP-ACS, so it is possible that EQUIP-ACS was not adequately powered to assess the effect of these hospital characteristics.

A retrospective study of AMI care conducted in Japan also reported that a range of hospital characteristics are associated with variation in management. Volume of AMI admissions, number of cardiovascular specialists per case and whether a patient was treated in a private or public hospital were associated with improved management, whereas high performance at baseline was associated with poorer management. (Ukawa et al. 2014) Pooled data from three German AMI registries demonstrated that patients admitted to hospitals with cardiology departments received higher rates of recommended treatments than those admitted to hospitals without cardiology departments. (Gottwik et al. 2001)

The BRIDGE-ACS trial, a randomised QI programme for ACS which took place in hospitals in Brazil, reported that presence of on-site PCI facilities was associated with improved management in a subgroup analysis. (Berwanger et al. for the BRIDGE-ACS Investigators 2012b) This is consistent with the findings reported here for the composite outcome excluding risk stratification.

It is possible that hospital characteristics explain some of the factors that facilitate improved management and guideline-adherence and that the EQUIP-ACS study was not adequately powered to demonstrate this, but there may also be other factors that have not been considered in the literature cited above. Bradley et al have shown that a range of hospital characteristics may explain improved prescription of beta-blockers for post-MI management but the effects observed are modest and the authors believe there must be other factors that drive improvement. (Bradley et al. 2004) In a separate study of AMI management, the same authors found a modest effect of hospital characteristics such as teaching status, number of hospital beds, volume of AMI admissions and location on mortality data. These characteristics provided a partial explanation for variation in mortality rates across hospitals.
but the effect was limited and further factors were likely to explain the differences observed.(Bradley et al. 2010)

Data from the CRUSADE study highlighted minor differences in management at teaching and non-teaching hospitals, with a trend for this to be superior at teaching hospitals. Management of ACS at both types of hospitals remained sub-optimal however and the effect was not consistent across all ACS treatments, i.e. prescription of medications was higher at academic hospitals whereas rates of invasive procedures were higher at non-teaching hospitals. The authors did not consider that hospital type was clearly associated with improved management but rather that individual hospitals had higher standards of care and that the reasons for this had not been determined.(Patel et al. 2007)

The data presented in this chapter show that management of non-ST elevation ACS varies for different patient groups and is worse for female patients and those with co-morbidities. Adherence to guidelines varies at a range of hospitals but the reasons for this have not been elucidated. It is possible that hospital characteristics such as type, size and volume of admissions contribute to management of ACS admissions, but data from the EQUIP-ACS programme do not support this and the literature implies that these characteristics only provide a partial explanation for differences observed. There have been attempts to explain these differences using qualitative methods and questionnaires and these provide some evidence that factors such as involvement of senior managers and good teamwork may be important. (Brennan et al. 2013;Schouten et al. 2008a;Weiner et al. 2006) The effect of these and other contextual factors will be explored in a later chapter using qualitative methodology.

4.4.3 Limitations

The results reported in this chapter are based on retrospective, exploratory analyses of the data collected during the EQUIP-ACS programme. The trial was not powered to assess the influence of individual factors on the outcome of the QI intervention and particularly in the case of number of centres, it is likely that the number of hospitals is too low to detect an effect of hospital characteristics on the outcome of the QI intervention.

The main trial excluded patients over 80 years of age so it is not possible to assess management of this patient group, nor whether the QI intervention could have improved this. The effect of age observed in univariate analyses was no longer statistically significant in the multivariate models but the effect of age cannot be excluded since patients over 80 years were not considered.
4.5 Conclusion

The QI intervention implemented during the QI programme improved the care of non-ST elevation ACS patients irrespective of hospital type, baseline performance and GRACE risk category. Management of female patients, patients with CKD, stroke or with a history of heart failure remained sub-optimal when all factors were accounted for, implying that further work is needed to ensure that healthcare professionals implement QI interventions consistently for all patients they manage. There is evidence that use of formal risk stratification can lead to improved use of ACS treatments.
CHAPTER 5. Long term follow-up of EQUIP-ACS project
5.1 Introduction

Despite considerable resources invested in QI programmes, there is limited information available about the long-term results of these. It has been noted in literature that further research of QI programmes is needed to understand the results and to assess whether improvement is sustained (Grol et al. 2008; Ovretveit & Gustafson 2002) Evidence that results are maintained after an intervention is delivered is needed, in order to plan future QI work.

The QI programme implemented during EQUIP-ACS led to improved management of ACS during the in-hospital phase, but it was not known whether this improvement would be maintained after the end of the study, nor whether further improvement could be observed. In order to evaluate this all centres were asked to collect data for an additional year after the end of the main study.

5.2 Aim

The aim of this exploratory analysis was to evaluate whether the results of the EQUIP-ACS QI programme were maintained a year after the end of the study.

5.3 Methods

No further QI training was delivered during the 12-month follow-up period but centres retained access to the online database and the feedback and reporting tool. Centres were asked to continue entering data for all eligible patients onto the database.

5.3.1 Statistical considerations

The same statistical methods as for the main study were used throughout this exploratory analysis. In this case, time-period was the covariate and allocation to QI was ignored, since both centres in the follow-up phase were in the QI arm of the trial.

5.4 Results

Two centres continued to collect data for the additional follow-up period, Basildon Hospital in the UK and Terrassa Hospital in Spain. Data for 218 eligible patients were entered onto the study database.

5.4.1 Baseline characteristics

Baseline characteristics for patients admitted to the 2 hospitals during the year following the end of the trial are summarised in Table 38 below. Data are presented for the whole group and follow-up centres separately, for each time-period.
Baseline characteristics for the follow-up centres were similar to those for the whole group in each phase.

<table>
<thead>
<tr>
<th>Description</th>
<th>All centres</th>
<th>Follow-up centres only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline phase N = 1395</td>
<td>Post-QI phase N = 1189</td>
</tr>
<tr>
<td><strong>Demographics N(%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (mean [SD])</td>
<td>65.4 [10.7]</td>
<td>65.8 [10.5]</td>
</tr>
<tr>
<td>Male</td>
<td>973 (69.8)</td>
<td>823 (69.2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>355 (25.6)</td>
<td>330 (27.8)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>923 (66.7)</td>
<td>787 (66.6)</td>
</tr>
<tr>
<td>Smoker</td>
<td>357 (26.9)</td>
<td>287 (25.7)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>392 (28.6)</td>
<td>339 (28.7)</td>
</tr>
<tr>
<td>History of heart failure</td>
<td>172 (12.5)</td>
<td>116 (9.8)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>255 (18.4)</td>
<td>211 (17.9)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>111 (8.0)</td>
<td>105 (8.9)</td>
</tr>
<tr>
<td>Prior Stroke</td>
<td>86 (6.2)</td>
<td>69 (5.8)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>133 (9.7)</td>
<td>92 (7.8)</td>
</tr>
<tr>
<td>Symptom onset to admission hours (median [IQR])</td>
<td>7 (3, 18.6)</td>
<td>6.8 (3, 17)</td>
</tr>
<tr>
<td>ST-depression on admission ECG</td>
<td>616 (44.4)</td>
<td>530 (44.6)</td>
</tr>
<tr>
<td>Cardiac marker positive (according to local cut-off)</td>
<td>1,158 (83.3)</td>
<td>1,015 (85.4)</td>
</tr>
<tr>
<td><strong>Medications at admission</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>456 (37.6)</td>
<td>384 (36.5)</td>
</tr>
<tr>
<td>A2 receptor blockers</td>
<td>144 (11.9)</td>
<td>130 (12.4)</td>
</tr>
<tr>
<td>Warfarin</td>
<td>28 (2.3)</td>
<td>24 (2.3)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>542 (44.4)</td>
<td>456 (43.3)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>161 (13.1)</td>
<td>120 (11.3)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>461 (38.2)</td>
<td>377 (35.8)</td>
</tr>
<tr>
<td>Calcium antagonists</td>
<td>233 (19.3)</td>
<td>201 (19.1)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>304 (25.1)</td>
<td>234 (22.2)</td>
</tr>
<tr>
<td>Statins</td>
<td>513 (42.2)</td>
<td>458 (43.5)</td>
</tr>
<tr>
<td><strong>Length of stay</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death in-hospital</td>
<td>24 (1.7)</td>
<td>20 (1.7)</td>
</tr>
<tr>
<td><strong>Discharge diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>857 (61.4)</td>
<td>770 (64.8)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>468 (33.6)</td>
<td>342 (28.8)</td>
</tr>
</tbody>
</table>

Table 38. Baseline characteristics
5.4.2 Composite and individual outcomes

The composite outcome measure of all treatments and use of individual treatments were evaluated for the two follow-up centres during the baseline, post-intervention and follow-up phase of the study. The results are summarised in Table 39 and Figure 23 to Figure 31.

5.4.2.1 Composite outcome measure

The proportion of patients receiving all recommended treatments during the year following the study was 77.3% at the two follow-up centres, a result which was statistically significantly higher than the proportion during the baseline phase. The proportion of patients receiving all treatments in the follow-up phase is lower than that observed in the post-intervention phase but this result is not statistically significant.

5.4.2.2 Individual treatments

The rate of prescription for five out of eight treatments remained higher than at baseline during the follow-up phase, with two of these showing statistical significance; risk assessment and clopidogrel loading dose. Rate of prescription of individual treatments during the follow-up phase was lower than the post-QI implementation phase for each of the treatments but the results are not statistically significant.

Use of coronary angiography at the follow-up centres was low throughout the study and was 5% lower during the follow-up phase than at baseline. Rate of angiography was 28% during the baseline phase, 25% following implementation of the QI intervention and 22.5% during the follow-up phase. Use of anticoagulation and statins was maintained above 95% throughout.

The proportion of patients receiving the individual treatments are shown by time period in Figure 23 to Figure 31 for the two centres and for the group overall.
<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Baseline phase N = 80</th>
<th>Post-QI phase N = 61</th>
<th>Post-study N=218</th>
<th>OR (95%CI) p-value (Baseline vs Post-QI)</th>
<th>OR (95%CI) p-value (Baseline vs Post Study)</th>
<th>OR (95%CI) p-value (Post-QI vs Post Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite endpoint</td>
<td>375/531 (70.6)</td>
<td>333/416 (80.1)</td>
<td>1,121/1,450 (77.3)</td>
<td>1.67 (1.23-2.26) p=0.001</td>
<td>1.41 (1.12-1.76) p=0.003</td>
<td>0.85 (0.65-1.11) p=0.236</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>36/80 (45.0)</td>
<td>47/61 (77.1)</td>
<td>148/218 (67.9)</td>
<td>4.44 (2.06-9.59) p&lt;0.001</td>
<td>2.59 (1.50-4.45) p=0.001</td>
<td>0.61 (0.31-1.19) p=0.147</td>
</tr>
<tr>
<td>Coronary Angiography</td>
<td>22/79 (27.9)</td>
<td>15/61 (24.6)</td>
<td>49/218 (22.5)</td>
<td>0.85 (0.39-1.83) P=0.670</td>
<td>0.77 (0.42-1.38) p=0.379</td>
<td>0.92 (0.47-1.80) p=0.800</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>80/80 (100)</td>
<td>59/61 (96.7)</td>
<td>210/218 (96.3)</td>
<td>N/A</td>
<td>N/A</td>
<td>0.89 (0.18-4.30) p=0.885</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>11/18 (61.1)</td>
<td>20/20 (100)</td>
<td>29/38 (76.3)</td>
<td>N/A</td>
<td>2.05 (0.61-6.86) p= 0.244</td>
<td>N/A</td>
</tr>
<tr>
<td>Statins</td>
<td>72/75 (96.0)</td>
<td>60/61 (98.4)</td>
<td>201/210 (95.7)</td>
<td>2.50 (0.25-24.66) p= 0.433</td>
<td>0.93 (0.25-3.53) p=0.916</td>
<td>0.37 (0.05-3.00) p=0.353</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>37/53 (69.8)</td>
<td>34/40 (85.0)</td>
<td>110/134 (82.1)</td>
<td>2.54 (0.88-7.31) p= 0.084</td>
<td>1.93 (0.92-4.04) p=0.083</td>
<td>0.81 (0.31-2.14) p=0.669</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>60/79 (76.0)</td>
<td>54/59 (91.5)</td>
<td>194/215 (90.2)</td>
<td>3.42 (1.19-9.81) p= 0.022</td>
<td>2.91 (1.46-5.78) p=0.002</td>
<td>0.86 (0.31-2.37) p=0.764</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>57/67 (85.1)</td>
<td>44/53 (83.0)</td>
<td>180/199 (90.5)</td>
<td>0.86 (0.32-2.31) p= 0.765</td>
<td>1.64 (0.72-3.74) p=0.242</td>
<td>1.88 (0.79-4.48) p=0.152</td>
</tr>
</tbody>
</table>

Table 39. Composite outcome and individual outcomes at follow-up centres
**Figure 23.** Percentage of patients receiving all treatments (composite outcome)

*Key*
- Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
- ● = Basildon hospital
- ○ = Terrassa hospital
- + = Mean percentage

**Figure 24.** Percentage of patients risk stratified

*Key*
- Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
- ● = Basildon hospital
- ○ = Terrassa hospital
- + = Mean percentage
Figure 25. Percentage of patients receiving coronary angiography

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage

Figure 26. Percentage of patients receiving anticoagulation

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage
Figure 27. Percentage of patients receiving beta-blockers

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage

Figure 28. Percentage of patients receiving statins

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage
Figure 29. Percentage of patients receiving ACE-inhibitors

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage

Figure 30. Percentage of patients receiving clopidogrel loading dose

Key
Time period: 1 = Baseline phase; 2=Post-intervention phase; 3=Post-study phase
● = Basildon hospital
○ = Terrassa hospital
+ = Mean percentage
5.4.2.3 Results assessed by age

The composite outcome measure and individual treatments were also analysed by age, using median age of 65 years as the cut-off. The results are summarised in Table 40 and it can be seen that there is a trend for patients above 65 years to be under-treated. This is consistent across all three time-periods but, as the numbers analysed are small, the numerical differences observed were not statistically significant.
<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Baseline phase N = 80</th>
<th>Post-QI phase N= 61</th>
<th>Post-study N=218</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Age&lt;65</td>
<td>Age&gt;65</td>
<td>Age&lt;65</td>
</tr>
<tr>
<td>Composite endpoint</td>
<td>75.0</td>
<td>66.4</td>
<td>81.3</td>
</tr>
<tr>
<td>Risk stratification</td>
<td>48.7</td>
<td>41.5</td>
<td>86.7</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>28.2</td>
<td>27.5</td>
<td>20.0</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>83.3</td>
<td>50.0</td>
<td>100</td>
</tr>
<tr>
<td>Statins</td>
<td>100</td>
<td>91.7</td>
<td>100</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>79.2</td>
<td>62.1</td>
<td>81.3</td>
</tr>
<tr>
<td>Clopidogrel loading dose</td>
<td>81.6</td>
<td>70.7</td>
<td>96.6</td>
</tr>
<tr>
<td>Clopidogrel maintenance dose</td>
<td>88.9</td>
<td>80.7</td>
<td>80</td>
</tr>
</tbody>
</table>

Table 40. Results by age

5.5 Discussion

5.5.1 Overview of results

The improvement achieved by the EQUIP-ACS QI intervention was maintained one year after the intervention in the 2 follow-up hospitals. The proportion of patients receiving all 8 recommended treatments during the year following delivery of the QI intervention was approximately 7% higher than at baseline. Comparison of rate of treatments during the baseline phase with those recorded a year later indicate that improvements were maintained. There was a trend for the individual treatments to be maintained at a higher level than at baseline with two of these, risk stratification and clopidogrel loading dose, achieving statistically significantly higher results during the follow-up phase. Comparing the post-QI implementation phase with the post-study phase however shows a slight decrease, although the results are not statistically significant.

In earlier chapters, it was noted that the duration of the measurement period following implementation of a QI initiative is important and that this could be particularly relevant for more complex treatments such as coronary angiography. The fact that the two centres evaluated maintained the improvement achieved by the QI initiative is encouraging, but further improvement was not observed. Rate of coronary angiography at the two follow-up centres was very low at approximately 25%, compared to 60% which was the rate observed for the overall study. It is surprising that more time did not enable these centres to improve their angiography service and that a year after the end of the study, rates were even lower.
than at the start, with only 22% of patients receiving angiography in accordance with the ESC guideline recommendations. (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology, Bassand, Ardissino, Boersma, Budaj, Fernandez-Avila, Fox, Hasdai, Ohman, Wallentin, & Wijns 2007) Access to angiography facilities could be an important factor; Hospital de Terrassa did not have PCI facilities on-site and although Basildon hospital did, the same facility served three District General Hospitals and Basildon patients were not prioritised over the other hospitals despite their proximity to the service. Discussions during the QI programme meetings and the semi-structured interviews which will be discussed in the next chapter highlighted that delivering angiography within 3 days of admission was challenging at many of the sites. Taking this into account, the data were re-analysed to evaluate the number of days from admission to angiography.

Figure 32 summarises the data for the follow-up centres, showing that the majority of patients received angiography within 6 days of admission. Comparing this to Figure 33 which summarises the data for all centres during the study phase, it can be seen that patients in the whole group received angiography in a shorter time-period than at the two follow-up centres. It can perhaps be assumed that patients admitted to these two centres were being referred for angiography but the centres were not able to deliver the service within 3 days, as recommended by the ESC guidelines.
5.5.2 Long term results of other QI programmes

The Get-With-The-Guidelines Coronary Artery Disease (GWTG-CAD) programme reported results from three 12-month time-periods for GWTG-CAD hospitals compared to hospitals not participating in the programme. The results confirmed that higher performance at the GWTG-CAD hospitals was sustained over time when compared with non GWTG-CAD hospitals. The hospitals participating in the programme maintained higher levels in six pre-specified performance measures over the three 12-month periods but the difference between the groups decreased over time. Differences were also modest, ranging from 1 to 3% for the six performance measures. GWTG is an ongoing QI programme involving public reporting of results and a performance recognition programme. (Xian et al. 2010)
The QUICC programme included a range of hospitals signed up to the Swedish RIKS-HIA myocardial infarction registry which enabled long-term results of the QI intervention to be assessed. (Carlhed et al. for the QUICC study group 2006) The authors reported results obtained during a 6-month measurement period which took place 6 months after the end of the initial programme. (Carlhed et al. Further improvement or sustained results were observed in four out of five quality indicators but this was accompanied by an improvement in the control group. The difference between performance at QUICC and control hospitals was smaller during the follow-up phase and only use of clopidogrel achieved statistically higher improvement. The authors explain the improvement observed at control centres by the fact that RIKS-HIA data was made public for all hospitals between the two measurement periods (May 2003 – Apr 2004 vs Aug 2004 to Jan 2005). One of the long term aims of the QUICC programme had been to assess whether the QI initiative led to improvement in measures that were not directly targeted by the programme, e.g. echocardiography or stress testing, but no effect on other indicators was observed. The authors hypothesised that all measures requiring improvement should be included in a QI programme from the start in order to have an impact on these. Continued data collection via a national registry also enabled the QUICC group to assess the effect of the QI intervention on clinical outcomes at one year. Numerical improvement was noted but this was not statistically significant. (Carlhed et al. 2009; Carlhed et al. 2012)

The GAP investigators also reported results at GAP hospitals one year after the project. Rates of in-hospital medications remained high but were numerically lower than at baseline, with the exception of early beta-blockers which had increased. Use of discharge treatments however, had reverted to levels recorded before the GAP intervention was delivered. The authors suggest that continued data collection and real-time feedback to all participating hospitals would enable sustainability of increased guideline-adherence. (Olomu et al. 2014)

Benzer et al reported evidence of long term sustainability following removal of a pay-for-performance incentive across Veteran Health Administration hospitals. This was assessed by a range of measures including three for ACS. Data were observed over a seven-year period and it was noted that improvement achieved during the pay-for-performance period was sustained for up to three years following removal of the incentive. (Benzer et al. 2014)
5.5.3 Factors influencing sustainability

A review of evaluation reports from five Health Foundation QI initiatives and associated literature identified 10 key challenges in delivering improvement work. (Dixon-Woods et al. 2012) Two of these challenges focused on what happens after the end of an initiative and whether results are sustained. The first challenge affecting sustainability of a QI initiative is that QI work is perceived as a standalone project and there is no incentive to continue improvement work after the project has finished. Clinicians focus on other priorities which are considered more important once the project is complete. The authors also cite resource as an important factor i.e. if the intervention is not cost neutral or low cost, it is unlikely to continue or indeed spread to other work processes. (Ling et al. 2010) It is important to think about how change can spread to other work processes and departments and to put systems in place to enable this from the outset. (The Health Foundation. 2011a; Walmsley and Miller 2008) The authors also noted that changes to policies and infrastructure at the organisational level would be required for results to spread beyond the initial project target group. (Bate et al. 2008) The second challenge relating to sustainability is that there could be unexpected side effects of a QI intervention; if the intervention is unsuccessful or requires clinicians to invest their own resource for it to succeed, their opinion of QI work in general could be tainted. (The Health Foundation. 2011b; Wachter 2006)

Bowman and Sobo have also remarked that plans for long-term results of a QI initiative need to be implemented from the start to prevent performance reverting to baseline levels after delivery of a programme. They also noted that there are three models of sustainability: a) results drop but remain above baseline, b) results revert to baseline or drop to levels below those observed at baseline c) improvement is sustained due to continued low level QI activity at regular intervals. They consider that the first two could occur if resource or tools introduced during delivery of the QI intervention are withdrawn immediately following the end of a project. (Bowman et al. 2008)

These observations from the literature support the results reported in this chapter as performance at the two EQUIP-ACS follow-up centres remained above that observed at baseline after the end of the study. Implementation of QI work did not require significant resource from the local teams, except for commitment of staff time, but there were no further meetings or publications of results planned during the follow-up phase.
5.5.4 Implications of results

Further research is needed to understand how improvement can be sustained over time. Analyses reported in this chapter show that performance remains above baseline levels after the end of a QI programme but management of ACS remains sub-optimal as approximately 20% of patients are not receiving guideline-recommended treatments. Further improvement is not observed and there is concern that over time, performance will revert back to baseline levels. Research using qualitative methodology could provide valuable insight into factors that enable or inhibit sustainability. (Bowman, Sobo, Asch, & Gifford 2008). In particular, this is because the influence of clinicians’ perceptions of QI work could explain a reluctance to continue improvement work and a resulting lack of sustainability. If clinicians are not convinced that improvement achieved by a QI intervention is clinically significant, they are unlikely to continue using the intervention, an effect that has also been observed for medicinal interventions. (Carlhed, Bellman, Bojestig, Bojö, Peterson, & Lindahl 2012)

A qualitative study performed by Hovlid et al, revealed the importance of analysing work processes and reflecting on ‘defects’ or errors in systems in order to gain a deeper understanding of existing clinical pathways and how these can be improved. The authors refer to the concept of ‘double-loop learning’ which occurs when individuals correct or change inadequate practice and simultaneously, the underlying system responsible for the sub-optimal process is also corrected. This implies that local individual practice and organisational systems are aligned and leads to an improved care process which is sustained. (Hovlid et al. 2012)

Researchers in whole system transformation, which is the practice of implementing improvement work across whole services or even health systems, have commented that sustainability can only be achieved when results achieved by QI work become standard practice. This happens when processes and standards of care have changed and importantly, the organisations and underlying systems supporting these processes have altered. (Greenhalgh et al. 2012; NHS Modernisation Agency 2002; Ovretveit 2011; Scheirer and Dearing 2011)

In addition to sustaining improved standards of care, the goal of QI work should be for improvement to extend to other measures over time. An improved process should ultimately mean that all indicators of patient care are affected, irrespective of whether these were targeted by the QI intervention. It is likely that the EQUIP-ACS QI intervention was perceived as a standalone project by the clinical teams taking part. Following the end of the study, new
priorities would have emerged for the team, taking the focus away from QI work. It is also important to acknowledge that this improvement work was perceived as a finite project by the QI researchers responsible for delivering the intervention, such that further work beyond the main publication of results was not adequately planned.

5.5.5 Limitations

The results presented in this chapter are based on data from only two out of the 38 EQUIP-ACS hospitals, both of which were randomised to receive the intervention. Lack of resources meant that centres were invited to participate in the follow-up phase on a voluntary basis, there was no fee for data collection and no meetings to discuss results were planned. Evidence of sustainability is therefore based on a small proportion of data and there was no control data available for comparison.

Data collection occurred after the end of study which meant that no data concerning local practice were collected, so it was not possible to establish whether QI work and associated meetings continued. The results were based on the same quality indicators as the main study and no further indicators were identified, so it was not possible to assess whether improvement may have spread to other important measures such as advice for smoking cessation, diet and exercise.

As for the main phase of the study, there is a lack of evidence to prove that all eligible ACS admissions were entered onto the database which means that the possibility of sites selecting cases for enrolment cannot be excluded. Finally, clinical endpoints were not reported for any patients entered into the study as data are only available for the in-hospital phase.

5.6 Conclusion

There is evidence that improved standards of care achieved by a simple QI programme for management of acute coronary syndromes are maintained a year after the intervention is delivered. Further intervention would be needed to effect additional improvement and ensure that performance does not decline over time. Long-term assessment of QI interventions is essential and should be built-in to future programmes from the outset.
CHAPTER 6. Qualitative evaluation of EQUIP-ACS
6.1 Introduction

The results of the QI programme implemented during the EQUIP-ACS project were statistically significant but it was clear that some centres improved more than others and that some components of the composite primary outcome improved more than others. If this type of QI intervention could be repeated, or implemented on a larger scale, it is crucial to gain a better understanding of the environment in which it was delivered as well as to identify contextual factors that could have influenced the outcome of the programme. A qualitative study was designed to explore these issues by conducting semi-structured interviews with healthcare professionals at the sites that took part in the QI programme of the EQUIP-ACS project. Methodology for qualitative research and use of semi-structured interviews has been discussed in an earlier chapter.

6.2 Aim

The aim of this aspect of the research was to explore contextual factors that could have affected the outcome of the QI programme by conducting semi-structured interviews at a sample of hospitals that took part in the programme.

6.3 Methods

6.3.1 Study design

This qualitative evaluation was performed after the randomised trial was completed and analysed, in order to gain a better understanding of the quantitative results. The use of qualitative methodology to explain findings from a quantitative study after its completion is defined as a sequential explanatory design because the outcome of qualitative analyses provides an explanation for quantitative results and contributes to appropriate interpretation of these. Triangulation will be used to combine results obtained using both methods in the final chapter of this thesis. Triangulation is the term used for comparing and combining qualitative and quantitative results.(Glaser & Strauss 1967)

6.3.2 Selection of centres

A proportion of QI centres that took part in the EQUIP-ACS study were invited to participate in the qualitative evaluation. Emphasis was on UK centres so as to avoid any miscommunication due to language barriers but two Spanish Investigators were also approached in the latter phase in order to obtain more data from QI centres once all the UK QI centres had been approached. This gave a total of 5 sites consisting of 4 QI centres (3 UK, 1 Spain) and 1 additional UK centre that was the central coordinating team managing the QI programme.

Daphne Babalis PhD Thesis
6.3.3 Selection of participants within centres

The QI teams set up within each QI centre were approached in order to obtain a range of perspectives on how the QI intervention was delivered within a centre. Local QI teams consisted of key members of staff responsible for overseeing the implementation of the QI intervention at a local level during the EQUIP-ACS programme.

15 interviews were conducted and participants approached included consultant cardiologists, cardiology registrars, research nurses, ward nurses and individuals involved in managing and delivering the QI programmes, defined as ‘QI researchers’.

6.3.4 Semi-structured interviews

The method selected for this aspect of the research was the semi-structured interview as this allows for some themes and questions to be pre-specified, based on assumptions about the delivery of the QI programme but also for individual views to be sought. In a semi-structured interview, the interviewer prepares an interview guide in order to direct the interview and additional areas for discussion may arise during the course of the interview. The interview questions do not necessarily have to be asked in the order they appear in the guide, and this allows the discussion to flow naturally and means there is opportunity for new discussion topics to arise. The interview guide can be amended to include new relevant themes throughout the research process.

Interviews lasted between 45 and 60 minutes and were conducted in a quiet room chosen by the participant, usually at the participant’s hospital. At the end of the interview the participants were shown results obtained at their individual centres throughout the QI programme as well as the main study results, and the final section of the interview was a discussion about these.

6.3.5 Interview guide

A pilot interview was conducted with one of the QI researchers in order to test the timing, the first version of the interview guide and the flow of the discussion. The interview guide was amended after 6 interviews to include some of the new recurrent themes that were considered relevant. The final version of the interview guide is provided in Table 41 below.
1. Quality Improvement experience
   - Tell me about your experience in QI to date? Have you been involved in previous studies, audits, own projects?
   - What sort of QI work are you/your hospital/other department planning?

2. EQUIP experience
   - Let’s talk about the EQUIP study.
     i. Could you summarise what you remember about the way the QI training was delivered?
     ii. Which of the tools or methods that were reviewed made the most impression if any? Could you expand on that?
   - Tell me about your QI team
     i. How did you decide who the members would be?
     ii. How often did you meet and what was discussed?
     iii. What would you change about your local QI team/meetings if you had a second chance?
     iv. Publication/sharing of results and local projects – reactions from those not on the QI team
   - You may remember that each team developed their own change concepts i.e. ideas to improve work processes.
     i. Describe some that you remember working on?
     ii. Please expand on that- why do you think it succeeded? Why do you think it didn’t succeed? Were they readily adopted?
     iii. What were the main problems you and your colleagues faced in managing patients with Acute Coronary Syndromes?
     iv. What are they now? Why do you think that is the case?

3. Quality Indicators
   - Are these appropriate?
   - Talk about barriers to achieving optimal levels of each
   - Risk stratification

4. Let’s look at some results from the study
   - Your centre after the QI programme- what do you think?
   - If you were able to measure the results for these same goals today how do you think your hospital would perform?
   - Summary of overall study results presented. What does this mean to you? Do you think this is worthwhile?

Table 41. Interview guide
6.3.6 Sample size

The target sample size for this evaluation was 15-20 interviews with healthcare professionals or QI researchers based in 4-5 hospitals. As formal sample size calculations are not performed for qualitative research, the objective was to achieve saturation of the data, i.e. to continue performing interviews until no further new themes arise. It was anticipated that 15-20 interviews would enable saturation of themes to be reached.

Interview content and emerging themes were assessed throughout this research and saturation was clearly achieved after 15 interviews.

6.3.7 Ethical considerations

Ethical approval for this qualitative evaluation was obtained from the Royal Free Hospital and Medical School Research Ethics committee prior to commencing the research. Written informed consent was obtained from each participant prior to the interview, using an ethically approved participant information sheet and consent form.

Data were held in an anonymised format and audio files were held securely with access restricted to the researcher. Interviews were recorded with permission from participants and recordings were transcribed verbatim by an independent professional transcription agency.

6.3.8 Analysis

Interview transcripts were analysed using constant comparison of themes. (Glaser & Strauss 1967) Recurrent themes were identified by comparing text from the interview transcripts and coded using the NVivo software (versions 9 and 10). Codes were used to organise text into main themes and sub-themes.

When half of the interview transcripts had been explored, a sample of the interviews (3 out of 15) were reviewed by an independent researcher (Sharon Fleming, PhD). Agreement was reached over the main themes and additional sub-themes were identified. Early analyses were re-coded to account for new sub-themes identified and remaining transcripts were then analysed to compare themes and sub-themes throughout.

6.4 Results

6.4.1 Participant characteristics

The number of interviews conducted and characteristics of participants are summarised in Table 42 below.
<table>
<thead>
<tr>
<th>Item</th>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
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</tr>
<tr>
<td>Participants</td>
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</tr>
<tr>
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<td></td>
<td>50-59</td>
<td>8</td>
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<td></td>
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<tr>
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<td>4</td>
</tr>
<tr>
<td></td>
<td>Cardiology registrar</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Research nurse</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Ward nurse</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>QI researcher</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 42. Participant characteristics

The participants are listed by pseudonym in Table 43.

<table>
<thead>
<tr>
<th>Pseudonym</th>
<th>Role</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrian</td>
<td>Consultant cardiologist</td>
<td>4</td>
</tr>
<tr>
<td>Elsa</td>
<td>Ward nurse</td>
<td>4</td>
</tr>
<tr>
<td>Fatima</td>
<td>QI researcher</td>
<td>1</td>
</tr>
<tr>
<td>Fred</td>
<td>Consultant cardiologist</td>
<td>2</td>
</tr>
<tr>
<td>Gareth</td>
<td>Cardiology registrar</td>
<td>2</td>
</tr>
<tr>
<td>Jacob</td>
<td>Consultant cardiologist</td>
<td>5</td>
</tr>
<tr>
<td>Janet</td>
<td>Research nurse</td>
<td>2</td>
</tr>
<tr>
<td>Jim</td>
<td>Consultant cardiologist</td>
<td>3</td>
</tr>
<tr>
<td>Lisa</td>
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</tr>
<tr>
<td>Louise</td>
<td>Ward nurse</td>
<td>3</td>
</tr>
<tr>
<td>Marina</td>
<td>Research nurse</td>
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</tr>
<tr>
<td>Mike</td>
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</tr>
<tr>
<td>Rima</td>
<td>QI researcher</td>
<td>1</td>
</tr>
<tr>
<td>Sara</td>
<td>Ward nurse</td>
<td>3</td>
</tr>
<tr>
<td>Tom</td>
<td>QI researcher</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 43. Participants

6.4.2 Key themes identified

Analysis of interview content led to identification of 6 key themes. The key themes identified were: (i) barriers to delivering optimal patient care, (ii) Factors that facilitate outcome i.e. “success factors”, (iii) planning and implementation of QI work, (iv) Quality indicators or
Goals, (v) Reactions to the QI programme implemented and (vi) Interpretation and implication of results.

The themes and sub-themes coded within them, are summarised in Table 44 below.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Sub-themes</th>
<th>Number of interviews</th>
<th>Number of references</th>
</tr>
</thead>
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<td>100</td>
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<tr>
<td></td>
<td>Process</td>
<td>12</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>Staff attitudes</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>Disagreement with guidelines</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Organisational factors and policies</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>High baseline performance</td>
<td>2</td>
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</tr>
<tr>
<td>Success factors</td>
<td>Incentives</td>
<td>15</td>
<td>116</td>
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<tr>
<td></td>
<td>Factors influencing QI programme &amp; meetings</td>
<td>14</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Leadership</td>
<td>12</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>Process</td>
<td>14</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>Expertise and training/credibility</td>
<td>14</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Communication</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Room for improvement</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Organisational culture</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Planning and implementing QI work</td>
<td>QI team</td>
<td>15</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>Measurement</td>
<td>13</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>QI tools/ ideas for improvement</td>
<td>12</td>
<td>48</td>
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<td></td>
<td>QI meetings</td>
<td>7</td>
<td>26</td>
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<tr>
<td>Quality indicators</td>
<td>Goals of the QI programme</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Risk stratification</td>
<td>14</td>
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<tr>
<td></td>
<td>ACS medications</td>
<td>13</td>
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<td></td>
<td>Coronary angiography</td>
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<td>61</td>
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<tr>
<td>Reactions to QI</td>
<td>Positive reactions</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Negative reactions</td>
<td>9</td>
<td>50</td>
</tr>
<tr>
<td>Interpretation and implications for future work, sustainability</td>
<td>Sustainability</td>
<td>13</td>
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<td></td>
<td>Interpretation of results</td>
<td>9</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Ongoing improvement work</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 44. Themes and sub-themes
6.4.2.1 Barriers to delivering optimal patient care

Interviewees were asked to identify the main factors they believed prevented their centres from delivering optimal care to non-ST elevation ACS patients with reference to the guideline-recommended goals set for the QI programme. Results for each centre, based on the eight quality indicators chosen for the QI programme, were reviewed during the interviews to aid this process.

(i) Resources

Lack of resources was most frequently cited as the obstacle to achieving optimal patient care, this was discussed in 14 out of 15 interviews. Discussion around this topic revealed that lack of resource in terms of staff, time and funding were all important.

One of the ward nurses who was a member of the local QI team, commented on the lack of time to carry out her work:

“So I could start doing it and then I’d be bleeped and as I said, my colleague’s on maternity leave, so I’m doing the work of two, it’s a bit, clinical work has been severely compromised.”

A consultant in the QI team at a different centre emphasised the problem of constant bed pressure affecting the level of care delivered:

“One of the things that we all find a bit frustrating is the perpetual bed crisis that tends to exist in this hospital, and I suspect a lot of district general hospitals where there are often bed pressures, there are targets that A&E have to deliver, they’ve got, no guest is allowed to wait more than four hours, and those pressures are transmitted to the bed managers who are trying just to offload patients into whichever bed is available, rather than the most appropriate bed.”

The same interviewee talked about the problems caused by frequent staff changes, particularly junior doctors and this was a theme that came up in 5 out of 15 interviews.

“Well, it’s very difficult you know, because one of the problems is that every few months you have another change, another intake comes in, and again it’s a constant battle trying to keep that awareness. They’re also, in fairness, stretched...”

It was also noted, during at least half the interviews, that staff levels were reduced over weekends, holidays and out of hours. The exchange below demonstrates how, at one of the district general hospitals, patients would not usually be seen by a cardiologist if admitted over the weekend.

“Interviewer: So when would they actually be seen by a cardiologist?
So, within 24 hours.

*Interviewer: Even if it's a weekend?*

That’s a good point. Not on weekends. But during the week from Monday to Friday, 24 hours, within 24 hours unless it’s a weekend.

*Interviewer: Was there never a cardiologist on a weekend on-call?*

Not really, no. They had a nominal cardiologist that you could phone I remember, but they wouldn’t necessarily do a ward round.

A similar issue was described by staff at other centres and this was particularly relevant for patients that may need to be referred for angiography or PCI, if they were admitted just before or during a holiday period such as Christmas, they could be waiting up to a week for a referral. Sara described how patients admitted to her centre on a Friday afternoon would have to wait until Monday to be reviewed for angiography and over bank holiday periods this would be even longer:

“Well if you come in on Christmas Eve this year, people are not back till Wednesday, because Monday, Tuesday are bank holidays, so nobody is in properly until Wednesday. So you’ve got four or five days before you’re even actually seen and reviewed and, plus until all the lists then get up and running again because there’ll be smaller lists in between Christmas and New Year, so.”

(ii) **Process**

Factors relating to the way a work process is delivered or managed were also discussed frequently during the interviews. The more complex a process was and the more members of staff it involved, the less likely it was to be successful. Staff mentioned that additional administrative or screening steps could delay processes and lengthy paperwork could add further delays or result in important steps being missed if they are too cumbersome. One of the consultants cited an example of a clinical pathway that needs to be completed prior to a surgical procedure:

“And the fundamental problem with it is that the key things like the checklist before the patient goes down to theatre, making sure this side is marked, all that, that is tucked away on page 20 of page 87, and when I spoke to some of the nursing staff, they didn’t even know it existed.”

Processes involving steps that depend on a decision being made were clearly more difficult to control and staff accepted that it would be more challenging to achieve high standards in these cases. The requirement for a ‘decision’ could be any of the following: the need to confer with a consultant prior to a referral or prescription, the need to check contraindications in the case of ACS medications or choosing a treatment where there is more than one equivalent option available.
Similarly, if a process involves multiple members of staff, it is more difficult to have an impact on it and ensure that it is carried out correctly each time. Rima gave an example of this:

“And I think the risk stratification and the drugs it’s because they’re easy to impact on because it’s just one person who’s got to prescribe and if it’s a nurse looking at it and then she goes to the doctor’s and says, well, you didn’t prescribe beta blockers in this patient, why didn’t you, blah, blah, blah. And then the next time the doctor might remember that he’s supposed to do that whereas the whole angiography I think that is a whole different ballgame because it’s not just one doctor or one nurse it’s a lot of people involved.”

(iii) Staff attitudes

A range of factors that derive from staff attitudes and behaviour also appeared to be important. The majority of interviewees, nine out of fifteen, talked about members of staff being complacent and completing paperwork in the medical records absent-mindedly. New alert systems or pathways may have been introduced but once these have been in place for extended periods of time, they may no longer serve their purpose.

Sara had observed that ACS prescriptions are sometimes missed even though the care pathway prompts this:

“The more familiar people become with things they just tick boxes rather than actually look at what they’re ticking because there are still times when you find patients that although throughout their ICP they will have had, clopidogrel has been started and you find out that it hasn’t at the end of the day when they go home, so you know, things do get missed with the best will in the world.”

Jim also felt that staff don’t always pay attention to the pathway documents and simply complete them without carrying out the required actions:

“And the danger with pathways which are that long is you see people mindlessly go through, just tick all the boxes, because they know. All they have to do is tick, tick, tick, tick, tick, tick, sign, but actually all that people have done is tick the boxes, it doesn’t mean they’ve actually done the stuff, that’s the problem”.

A poor knowledge of local standards of care meant that some staff did not query how a process was delivered. Interviewees commented that they had been unaware of their own standards of care and also talked about other members of staff that assumed treatments were appropriately prescribed and were not aware that paperwork was completed incorrectly, as per the examples cited above. This poor knowledge of how treatments are delivered led to incorrect decisions in some cases and to treatments being missed.
Individual as well as team attitudes are important in determining how a process is delivered and this means that if a change is required to overcome a barrier, it may be necessary to change the way an individual or team behaves, which is challenging. Interestingly, the action of simply missing or forgetting to prescribe a guideline-recommended medication is dismissed as a human error during the interviews, and accepted rather than questioned.

(iv) **Disagreement with guidelines**

The indicators used to evaluate management of patients with non-ST elevation ACS were based on the latest ESC guideline recommendations and whilst the majority of clinicians taking part in the QI programme agreed that these were appropriate, interviewees talked about colleagues that didn’t always agree with the recommended ACS treatments. If consultants were not convinced by the evidence for some of the treatments, they may not have prescribed these and it would have been difficult to alter their opinion. Rima recalled an example of this from the meetings:

“And then there were other things to do with some of the doctors, not some of the doctors, when the evidence is out there some people take it on board and some people disagree with the evidence. Because I can remember clopidogrel but say somebody might have a preference not for clopidogrel but one of the other antiplatelet agents so maybe if they'd been trained by another consultant or something that wasn't quite in agreement then they may decide not to prescribe something.”

(v) **Organisational factors and policies**

As well as individual attitudes and views on management of patients, there may be departmental or organisational policies which define how patients are treated in any given hospital. A consultant cardiologist at one of the centres described the fact that a local policy did not support the use of clopidogrel, which meant that prescriptions for this were challenged. This was discussed during the interview and the doctor commented that whilst this opinion was held by only a few members of staff, they were influential in the development of local policies and practice.

“…by having the idea that dual antiplatelet therapy may be had not enough scientific evidence to be recommended to all acute coronary patients before angiography. So I commented to you that we have an internal protocol, management protocol that *clearly* stated was much more restrictive for me, use of clopidogrel and the guidelines.”

(vi) **High baseline performance**

The idea that complexity of a process could lead to sub-optimal care was discussed earlier and this could apply to a number of the quality indicators chosen for the EQUIP-ACS QI intervention. Complexity of a process may influence its ability to improve but another
important factor is the level of a treatment at baseline. If a treatment is already given at a very high level before the QI intervention is delivered, the scope for improvement is less than for a treatment that is barely given at the outset.

Rima, commented on this and how it may be challenging to impact on a treatment that is already given at a high level:

“And so there was quite a few changes going on, so it was a little bit challenging to work out when you’re, because if you’re already performing at quite a high level to make a change can take quite a lot more effort and involvement and motivation, buy in from everybody. So if you’re already working at 80 or 90% prescription to move it up those extra percent can be much harder than maybe if you’re working in an institution that really are not performing at all”

6.4.2.2 Success factors

During the interviews, a range of factors that facilitated the outcome of the QI programme and led to improved standards of care were discussed. Analysis of the interview transcripts has led to the following themes being identified:

(i) Incentives

The theme that appeared to have the most influence on outcome was incentives and these could be personal or financial but also related to audits and publication of hospital performance. This theme was discussed in 12 out of 15 interviews.

The idea of being in competition with the other hospitals in the EQUIP-ACS study was raised during half the interviews. Competition arose because results of all hospitals were presented at the QI meetings and also because individual hospital results accessed from the database were shown in relation to the top three hospitals. Marina recalled how this generated discussion in her QI team:

“That can be a good thing, yeah, and that, and then, well, so it did lead to discussion as to why, oh, maybe if it was showing us not in such a good light, why, maybe, would it not be, you know, what’s going on? So yeah, they were, they were a good tool for initiating discussion.”

Sara also thought that competition was an important factor in maintaining momentum to improve standards of care:

“It's probably worked in, it's again, how do you sustain that impetus in things? Everybody if they know they're being audited, it's human nature, isn't it? I mean some people are very competitive, some people have that drive to, yes we want to improve, yes we want, but trying to keep that momentum going when you no longer are being looked at and audited is very difficult"
The idea that performance will be published in the form of an audit or report was mentioned in all of the interviews and this was sometimes considered important due to the competitive nature of teams as noted in the examples above, and on other occasions this was described as knowing you’re being observed. Sara noted that staff are more likely to pay attention to giving ACS treatments if they know their data is going to be reviewed:

“So you know somebody is going to be looking at whether or not you have achieved those things, so therefore it makes you more aware of what you’re doing and you make sure it’s done. As things, as time goes past and people are no longer looking then other things take priority in your day to day working life and you don’t necessarily check every single patient has had its 300mg of clopidogrel”

Fred talked about the same concept with respect to data being collected on the MINAP database (Herrett, Smeeth, Walker, Weston, & on behalf of the MINAP Academic Group 2010) and it is clear from his quote below that publication of the results, including sharing them with management, has an impact on patient care:

“Yeah, the MINAP returns are every annual, every year. Not only go into the public domain but they also go to the chief executive and so forth so we would have be pulled up if those returns are not up to scratch.”

Gareth had worked on a separate improvement project after EQUIP-ACS which did not gain support from senior colleagues initially and he described how a presentation at a prestigious conference helped to gain their interest.

“So luckily the initial study results that I had, we presented at TCT in America as a Late Breaking trial. So their perception of what I was doing suddenly changed and they became more open to getting involved in research and ensuring that the quality that we produce has to be the best, or the best it can be. We can try to be the best, so that certainly did change their minds.”

Financial incentives were only discussed in 4 of the interviews, suggesting that they were not considered as significant as other types of incentives. Mike talked about the influence of financial reimbursement for procedures in the US health system and how this increased levels of angiography:

“So in healthcare systems where, let’s say an angiogram gets reimbursed per procedure, people are more likely to do angiograms. But in healthcare systems where there is no fee per procedure, payment for a procedure, UK is a typical one, that’s even more difficult to make changes, so.”

It is interesting to note that financial incentives could also appear in the form of cost saving and Fatima noted that this was a significant driver for the QI work she was involved in:
“we have monthly meetings to review this information, how are we doing and also to try and translate, OK we can see that we've reduced some length of stay from this area here, how does that actually translate into a financial saving? Because the whole thing was done under, the need to do it came from financial imperative rather than just, oh this'd be nice to do”

Fred’s hospital had not had on-site PCI facilities while the EQUIP-ACS QI programme was ongoing but he described how his department were able to convince the hospital management and commissioners that this service was required, based on estimating financial savings:

“Interviewer: And how were you able to achieve actually setting up the local service then?

Financially? Yes it was just persuading commissioners that there was a lot of money to be saved and a lot of length of stay to be saved.”

Finally, some of the interviews revealed that personal incentives are required to motivate people to be involved in QI work. Elsa was a member of the QI team but her interview indicated that she did not consider the QI programme a priority and would have appreciated more explanation about the purpose of the QI programme.

“It wasn’t, not a priority in my job, but I felt quite pressured to produce something that maybe wasn’t as it should be and it wasn’t launched as I felt at the time, if you’re going to launch a new service or something new in A&E I’d want to educate everyone and make sure it’s utilised for every patient.”

Fatima also talked about personal incentives and that people are more motivated if they have chosen to be a part of the QI programme or have had to apply or overcome a barrier to participate:

“Whereas if you’ve had to invest something or you’ve had to try hard to get accepted onto some programme whether it's training and development for you or whatever, quality or whatever it is, if you really wanted to do it you had to get over some hurdle to get there, you’re much more

Interviewer: That's an interesting way of looking at it

Yeah, much more motivated.”

Similarly, if staff felt a sense of responsibility for local standards of care and took ownership of this, interviewees considered that the outcome would be improved. Rima described how the QI trainers encouraged the QI teams to think about the significance of a proportion of patients not receiving ACS treatments by imagining that those not receiving the treatments are relatives:
“So I think avoiding a blame culture but how to make that improvement and something else X said that always stuck in my head is if that’s your relative or your friend in there you don’t want them to be that two out of ten that doesn’t get the right treatment and when you put it like that it’s very understandable, concepts like that.”

Fatima described how including the QI teams in decision making helped to make them take responsibility for their own QI work:

“I think the important thing was to get them all together and to say, this is important, we want to hear what you want to change because this is your Quality Improvement programme, this is not us imposing something.”

Interviews indicated that another type of personal incentive to carry out improvement work was receiving recognition or being congratulated for results achieved. This led to staff feeling empowered and motivated them to continue working on improving care.

Rima talked about what can make staff feel motivated:

“Interviewer: But I suppose it is finding those triggers
I think it’s engagement, isn’t it?
Interviewer: Yeah.
And people feeling that they’re valued and that they are making a difference”

Fatima also thought it was important to share success stories and good news to encourage the teams:

“You start with the people that are open to it and then you demonstrate the early wins and you demonstrate the good news and all of that.”

Louise remembered her team receiving positive feedback following the central QI meetings and that this motivate them to continue working:

“Yes, I think she fed back and said what, how well we were doing compared to other areas I remember, so we were quite pleased and so was Dr X, because he does like to be top of the list.”

An example of how a lack of recognition can de-motivate staff can be seen from Elsa’s quote below. She recalls friction and pressure to work on an improvement idea, rather than positive feedback:

“No, I can’t, as I said, I’ve had very little information, Doctor X and Y were, went to the meetings and just said, oh we’re doing this, and at the time I felt a little bit of pressure to produce a document that might not have been

Interviewer: Did you produce that yourself then?
Yeah, yes, every, yes, all of them.

Interviewer: Entirely on your own?

Yes, yeah, there was a bit of, just sometimes a bit of friction about it so.”

(ii) Factors influencing QI programme & meetings

The QI programme meetings and implementation of QI work were discussed during the interviews and a number of factors that contributed to their success arose. The majority of staff interviewed talked about the importance stakeholder engagement in the development and delivery of improvement ideas so as to ensure they were relevant and applicable to local settings.

Rima’s impression from the QI training was that teams were encouraged to analyse their work processes and develop their own ideas for improvement rather than just employing tools developed by external parties:

“And the impression I got from X was that it was very much the local team need to work out what’s going to work for them so we can, it’s a bit like we can teach you to fish and then you can feed yourself so we’ll teach you some tools and then you need to work out what’s going to work best within your team and I think that’s perhaps a lot to do with people’s different personalities and challenges and just things how they are locally.”

Sara gave an example of an improvement idea implemented at her hospital without engaging the cardiology department. Her hospital implemented a new care pathway for acute admissions that did not include all the fields required for ACS admissions and as a result, this was not successful:

“I don’t think there were many specialities that had their own admission documentation, but they should have been aware that cardiology definitely did have its own documentation but they didn’t ask us at all. Did we want any input and was there anything that needed to go in there? They just brought out their new document.”

In addition to engaging staff involved directly in delivery of care, it is important to engage them early in the QI process and Fatima alluded to this in her interview. She felt that if clinicians are not engaged early, it could be more difficult to convince them of the value of QI work.

“You start with the people that are open to it and then you demonstrate the early wins and you demonstrate the good news and all of that

Interviewer: Exactly.

And then the later a doctor’s come on board, later on when they’ve seen, they need more evidence to prove to them that what’s the value of investing something in it to make a change.”
The working environment for QI meetings also appeared to be important as half of those interviewed talked about this during their interviews. This applies to the central training meetings but also the local team meetings. Jim recalled the pleasant, informal atmosphere of their team meetings and felt that this was productive:

“And I think it just shows that if you say, right, we’re going to commit to this, we’re going to do it, and then you get everyone’s timetables together, and if you just put those meetings in the diary, they will happen. I think what set those meetings apart, in a sense, from the kind of management meetings that we tend to get involved in, we never had a formal agenda, it was a more pleasant environment than we normally have. We didn’t minute things, we just had a chat about things, we knew what we wanted to talk about, the ground we wanted to cover, but everyone was just allowed to say what they thought, and I think ideas come out better that way.”

Rima also commented on the informal but productive environment of the central team meetings and it seems that this set the QI meetings apart from regular clinical training meetings:

“Well, they had, although there were some formal presentations or what I think of as semi-formal presentations because they used slides etc., their delivery style was very relaxed, encompassing and welcoming to everybody and so the mixture of what I think of as semi-formal presentations and then the workshop aspect where you get people to be engaged to tell them about their experience, to work in their small groups around the table I thought was fascinating.”

In addition to delivering the QI training in an informal, relaxed manner, the QI meetings provided the teams with protected time to reflect on their practice and think of ways to improve it. Mike talked about this and how rare it is to have this time in clinical practice:

“The meetings I think were interesting and exciting in many ways, we had people together, very rarely do we get frontline health professionals actually talking about their practice and how to improve their practice, I think that’s one thing that we really do not have, is that time, maybe the time, they need time to reflect also about what they’re doing in their clinical practice, and in a way clinicians are very much about service delivery orientated, and if there’s, if there’s a deficiency, their solution is simply to correct the deficiency.”

Fatima had similar feedback from the QI programme she was involved in where all participants had equal opportunity to participate, leading to productive discussion.

“I think we had a fair number turn up out of curiosity, what’s this going to be then? I think in general the feedback we had was really positive. Although I think that kind of, oh break out into groups and talk in a, everybody’s got the same, no holds barred about who says what, multidisciplinary groups, we want you to be all mixed up, nobody’s view
point is any more valuable than anyone else’s. This was not a way of working that many of the staff at all were used to, clinicians or otherwise.”

Finally, arranging QI training meetings requires a lot of administrative work to ensure that everything runs smoothly and it is important to ensure this work is adequately supported. Fatima commented that she would build in more of this support for future programmes if possible:

“Oh yeah, I'd have more low level admin support because actually in a lot of the, all this stakeholder engagement, these big event stuff, there’s lots of general work that needed to be done, it didn’t need to be done by high banded people but we needed pairs of hands at crucial times to get some of that done. So I would definitely have some more admin support”

(iii) Leadership

Staff talked about the importance of receiving support from senior staff and that they should be seen to be leading QI work. This theme was identified in 12 interviews.

When Janet was asked about her department’s response to the QI work, she explained that staff became more engaged when they realised the consultant cardiologist was supporting it:

“Yes, but normally I’ll get to, I’ll go to Dr X first and then they have seen me with Dr X talking and then next time when I go to them they’re more receptive to me, yeah.”

Similarly, Gareth felt that support for QI work and encouragement from consultants was essential:

“I think it has to be driven by the consultant. He has to actively encourage you and make time in the day for you to go.”

He also noted that senior staff did not consider QI work the main priority and this could have affected the implementation of improvement work on the wards:

“Whilst we were encouraged to get involved and go to the meetings in terms of going to Amsterdam and getting involved in that way, if there was anything to be done on the wards then it was made very clear that this was something extra to your day practice and this needs to be done first.”

Jacob’s quote below demonstrates a similar theme, the fact that a checklist tool developed by his QI team to ensure ACS treatments were prescribed, was completed more when the chief of the department mandated it.

“I think it was perhaps the perception that it was an accessory thing, that it was only a study, it was not compulsory and maybe an important point
regarding that had been that the, that filling the form had been declared compulsory by the chief of the department or something like that.”

Fatima considered that QI work should be led by senior members of staff to be successful:

“…ideally to help win your cynical consultants over you’d have either your chief exec or your chief operating officer there for a good proportion of the time, leading from the front, demonstrating how important this is by the time they’re prepared to put in.”

It was also noted that QI teams should include senior members of staff in order to succeed in improvement work. Lisa’s team engaged a Ward Manager for this reason:

“obviously X, I think X is obviously the Ward Manager, so anything we wanted to implement we felt obviously it only polite and right that we go through her and got her involved”

Finally, Tom explained that a key member of his QI team was selected for his leadership skills:

“I chose X because I think in our group he’s a leader because he has a very good relation[ship] with residents and he’s very well appreciated with the other medical staff. So the opinion of X is always very well appreciated. So I thought, well I need a leader to improve because in, what’s happening in general in cardiology we always think that we are the best and we are doing everything very well. And you need a leader to tell them, we are not the best, we, look at our results, so we have to change. So first to choose the leader.”

(iv) Process

Factors relating to process were considered earlier in terms of creating barriers to delivering optimal patient care. It is important therefore to consider those process factors which would facilitate improvement work.

Simplification

9 out of the 15 interviewees talked about the importance of processes being simple and this was also mentioned in the context of tools to improve care.

Jim commented on the implementation of a rubber stamp in his unit to prompt staff to prescribe ACS treatments. This had been effective in improving rates of prescription and he attributed this to its simplicity:

“I think it’s because it’s simple. Fundamentally, it’s a simple idea. Very easy to apply. And the one thing that I’ve noticed over the years, all the pathways we have now, patients get put on standard pathways, and they’re just mountains of paper.”

When asked what she thought would lead to a successful improvement idea, Rima also felt that it had to be simple and clear in order to be effective:
“But then there are, especially within clinical, there’s lots of doctors, there’s lots of nurses, there’s lots of other healthcare professionals. So I think it’s simplicity, clarity about what you’re trying to do and then what you’re going to get out of it, what’s the benefit for us all if we do this? So simple clear ideas that are easily implemented.”

During a discussion about use of risk stratification methods, Gareth mentioned that he preferred to use the TIMI score because it is the easiest:

“Interviewer: And is there any method that you would prefer to use or does it not make a difference?
Rather than TIMI or?
Interviewer: Of all the available
Yeah, I would just use TIMI because it’s just easy.”

Rima felt that some processes would be easier to change than others due to their simplicity and noted that angiography was more challenging to influence because there are more members of staff and steps involved in the process:

“I remember particularly one of the doctors because he thought that all his patients were being done but he took it on board and then they tried to look at the reasons of why and then it came down to logistics of scheduling and then once you start to increase the number of people that you’ve got to get involved in something it seemed that that would take longer to make those changes whereas the thing like the risk stratification that nurse and those doctors could immediately implement that in a very simple way”

Another factor that was considered to contribute to a successful process, was whether the process was centralised or automated. Adrian noted that this had improved the PCI service in his region as consultants were now on a regional rota and the on call system was managed centrally:

“Now it is different because it’s more organised, we have a system, alternate the on call 24 hours, our consultants are in ward in that rota, it’s a regional rota, including people from [names of referring hospitals removed] everyone. So every ward consultants just are rotating.”

A ward nurse from the same site, Elsa, also noted that centralising the PCI service had led to improvements:

“I think things have hugely tightened up, they’ve now got interventional cardiologists, we’ve got visiting interventionists as well that come, we’ve got a PCI coordinator that fills the lists on a daily basis so that she ensures that they’re actually full, each patient, each list, and there’s a, we’ve got an extra catheter lab now as well which outpatients come to for diagnostic angios. So I think that it’s changed dramatically from probably 2000 and,
even from last year, it's always very high in post. I think it's, everything's tightened up."

The issue of having control of a process also appeared to be important, Louise attributed the success of her ward to the fact that patients are treated there for their entire hospitalisation which enables staff to have control of each step of their care pathway:

"And I think that's one of the unique things about X ward is that we've, because we've got 23 beds we are able to keep our cardiology patients from admission to discharge, should we feel the need, yeah."

Conversely, Sara noted that her team had no control over angiography procedures and so, did not feel they could influence this treatment:

"There were certain issues that we found we had no control over, particularly with the meeting the target for angio, that was completely out of our control"

Finally, Janet recalled that she had more control over the use of ACS treatments during the EQUIP-ACS programme as part of her role, and this meant she could check when treatments weren't being given:

"But I have to say, during that time, because we were constantly in CCU or CDU looking through notes and stuff like that, so therefore there's better control. If things are not done or the card is not used I can go to the junior doctor and say, where's TIMI score?"

Another important process factor is ensuring that staff have clearly defined roles and responsibilities. This means that everyone knows which aspect of a process they are responsible for and avoids confusion.

Sara clearly remembers that it was her responsibility to check prescription of ACS medications during her ward round:

"Yes, if it was my cardiology ward round that day, then the patients that had come in overnight that were ACS patients and obviously that means that it was my responsibility to stick those into the notes and to check to see whether or not that things had been started, and if they hadn't to highlight them to the consultant on the ward round, that this patient had come in, no ACE had been started, is there any reason why you do or don't want to do that?"

(v) **Expertise and training/credibility**

The next most common success factor discussed in 14 of the interviews, was the importance of expertise and training. This related to staff in cardiology departments being appropriately trained but also to those delivering the QI training, in the latter case this gave the programme credibility.
Jim felt that the role of cardiac nurse practitioners in his department was crucial as they are very experienced:

“And that’s why I think the model we have of trying to get our cardiac nurse practitioners to do as much as possible, I think is generally pretty effective, because as I say it’s”

*Interviewer: Sounds very sensible.*

“They’re very, they’re well qualified, they’re a constant feature of the service, and they can also help to disseminate that knowledge.”

Jim also commented on the importance of involving consultant cardiologists in the delivery of ACS care. His view is that involving a cardiologist in ACS management leads to better care and he described a local study considering angioplasty during three different settings and how this was consistent due to presence of a consultant on each occasion:

“And there’s some work just being put together now, which hopefully we’ll try and get submitted for publication which, we’ve broken down the primary angioplasty admissions to working hours, weekends, bank holidays, or out of, not working hours, so it’s three different groups there basically, so during the week, out of hours, non-working week and then bank holidays. And what we’ve found is mortality is identical

*Interviewer: Really?*

“For all three, absolutely identical. But that’s because it’s a consultant delivered service. Every, there’s no case that happens without a consultant physically present. So I think it might add weight to the argument that you need senior presence all the time.”

He also stated that consultant input on a daily basis could significantly improve ACS management, something which was not yet provided at his centre:

“I guess if, what we don’t have still is every single patient being seen every day by a consultant cardiologist. We don’t have that. And I don’t know if we will get to that stage or not. That might make a big difference.”

Elsa was asked about how she thought non-ST elevation ACS care could be improved and her opinion was that specialist staff were required, once again highlighting the importance of training in delivering optimal care:

“A team of probably cardiac nurses, or a team of professionals specific for cardiology on call 24, not on call but covering the area 24/7 to ensure that this is addressed constantly and I think the in care would improve. But at the time there’s only, at the moment, so I think that’s all I could, yeah, say about it.”

Gareth was asked to summarise his view on the final outcome of the EQUIP-ACS study and he felt that education of staff can lead to improved care:
“I would probably say aggressive education from the bottom up can be translated into better outcomes for the patients really.”

The importance of involving experts in QI work was also mentioned in the context of the QI training. The interviewees felt that involving experts in the delivery of QI training, gave the programme credibility and encouraged staff attending the training to participate in and implement the programme. Rima felt that involving experts in the delivery of the QI training, helped to engage the clinicians:

“…working with very experienced people in this area who were accepted not only because of their expertise in quality improvement but because of their clinical expertise as well. So I personally think that Bertil Lindahl is one, who’s one of the leading physicians in acute coronary syndrome in Europe and has enormous respect, definitely when you’ve got people of that leadership level on your team I think it definitely can’t be anything but very positive and I think that helped with the clinical members of the researchers that were involved in the study.”

Fatima also felt that it was important to involve expert speakers in QI training and used a similar approach in another QI programme:

“We had external speakers both times, we felt that was really important, external clinical speakers, one anaesthetist and one surgeon, at different sites and we felt that was really important for giving it external credibility and so it wasn’t just managers, it wasn’t just our own clinicians standing up and saying, we think this’ll be good”

(vi) Communication

Communication came up in 8 of the interviews as an important factor in delivering ACS care. This could be communication within and between teams, communication across specialties or even across a network of hospitals working to a common goal.

Marina recalled that the opportunity to communicate with teams from other hospitals at the QI meetings was useful in order to exchange ideas and working practices:

“And then you find out, through something like EQUIP, with talking to other people that somebody’s found a better way obviously. You know, that’s where I think personally it, it was, it was a good thing to be able to, to exchange information like that.”

Mike made a similar comment about the value of getting teams from different hospitals together to share practice:

“But anyway, so I think it was that getting, people getting together and in fact that’s how it was planned, we were slightly sceptical that this would actually work, but that’s how it was planned, the most powerful bit was actually getting people together. Now we got people together from all the
different hospitals, different countries, but the idea was that as we rolled it out you could get people together within a hospital and that kind of group approach again would help to change the procedures in practice."

In terms of communication within a centre, the idea of having some members of staff acting as a central contact point was raised during Jim’s interview in the context of nurse practitioners:

“IInterviewer: And I suppose they can act as a central contact point for the department as well, so people know that they’re there and know where to go.

Very much so. Yeah, the system we have here of course is that the nurse practitioners are on bleep, they’ve got their own bleep, there is always one on duty, and they’re a point of contact. A&E know, the Medical Assessment Unit know that they contact them as the first port of call.”

Sara noted that there is a good relationship between nurses and consultants at her centre, which leads to effective communication:

“No, I mean we have a fantastic relationship with all of our consultants really, and that’s been positive through quite a few years, so all of us have done the job for quite a long while, so we’re quite able to approach them and they respect our role and our opinion on things, so.”

Effective teamwork was considered important by Rima who thought hospitals should focus on this more. More detail on working as a team and the individual roles required will be provided in the section on QI teams in this chapter.

“But I think it’s working within that team where you want to do, everybody wants to do the best they can but I think perhaps some teams get a little bit war weary and don’t realise that they’ve lost that je ne sais quoi maybe. And also giving people the tools. So I think there’s a lot of emphasis put on if I train you or there’s a published paper and you read it you will know and there’s less emphasis on training teams on how to work together as a team and leadership within a team.”

Fred talked about larger scale teamwork when he mentioned how his department work with the local network of hospitals to agree common goals for managing ACS patients:

“No, we’re certainly given our, because what, with the network level every two months we have a meeting for the network and we look at these sorts of QI procedures and the QI data for every, all of six hospitals in the network routinely. There are red, green, the traffic light models for QI for prescribing. In fact now there is even a committee set up for QIs for all measures in cardiac as a separate task force. Looking at trying to set up a QI markers for the pan London group, pan, so we’re actually trying to define for certain conditions what are the QIs.”
Room for improvement

It was noted above, in the section on barriers to delivering optimal care, that a high baseline performance means that there is limited scope for improvement. It is expected therefore, that a more marked improvement would be observed if performance at baseline is very low. Two of the centres with low performance at the start of the study commented on this as follows:

“Interviewer: I remember [your centre] did actually improve
Because we were very, very bad at the beginning.”

(Tom)

“We had a 0% of risk stratification.
Interviewer: I remember.
And a very low use of clopidogrel, so we had a big room between, to increase.”

(Jacob)

Organisational culture

The idea of long term improvement and sustaining results achieved was discussed in 13 of the interviews and will be considered again towards the end of this chapter but it is important to note in this section that interviewees indicated that a change on an organisational level may be required to effect longer lasting results. Fatima talked about the need for a ‘cultural change’ to take place within an organisation:

“And of course these problems are not click your fingers and solve them type issues
Interviewer: Exactly.
That we’re going to solve.
Interviewer: That’s why they are problems.
Yeah that’s why they are problems, that’s why we need quite a lot of stakeholder engagement to get working on them because they’re about cultural change and different ways of thinking about things, different ways of doing things.”

Planning and implementing QI work

The process of QI was considered during the interviews, with discussion focussing on how the teams planned their QI work, analysed their work processes and put systems in place to improve their practice.
(i) **QI team**

As noted previously, each centre randomised to the QI group was asked to set up a QI team to manage local implementation of the QI programme. Two representatives from the team were expected to attend each of the central meetings. Questions in interviews focused on the composition of the local QI team as well as the content and frequency of team meetings.

A range of roles are required to make a successful team (Institute for Healthcare Improvement 2003) and discussion during the interviews demonstrated that centres had considered this. Tom thought about this when setting up a team at his site, in particular with respect to identifying a team lead and including staff directly involved in care of ACS patients:

“So I thought, well I need a leader to improve because in, what’s happening in general in cardiology we always think that we are the best and we are doing everything very well. And you need a leader to tell them, we are not the best, we, look at our results, so we have to change…and the residents were very happy to participate, because at the end of the day the residents are the first that see the patient and the first that initiate the type, the treatment, so you need the residents to follow the guidelines.”

Jacob also commented on the importance of including residents in the team:

“I invited a resident to participate because I thought it was very important that the residents were involved because they were in charge of a substantial part of the management of the patients, particularly in the first moments of their admission.”

Marina described her own role in the team as a facilitator:

“Now, I was mostly facilitating the meetings and, and bit of a go between. So, although we were, I was there when they’re talking about things and what they were going to do, the actual implication and the putting into place of what was happening, really I wasn’t having anything to do with, apart from if they wanted a bit of help with the wordings”

Gareth, a registrar at one of the QI sites, reflected on the success of his team working in a cohesive manner to improve patient care:

“…support from the people on the shop floor like myself and everyone else ... the consultants and the people who can facilitate education sessions, training, changing protocols, working all together. This is phenomenal. Really good.”

The teams at each centre were encouraged to hold meetings on a regular basis to review their data and work on improving their local work processes. The majority of the teams interviewed noted that it was challenging to find a meeting time that was convenient for everyone.
Sara remembered that their meetings took place after the consultant’s ward round:

“Usually after Dr [X]’s ward round we would all meet up after that, because there would always be a nurse practitioner in and if it was Lisa’s research day and I was in on a practice development day then it’s kind of easy for us all to be around at the same time.”

As well as the importance of finding a suitable meeting time, the teams preferred to hold their meetings in an informal setting which meant that everyone felt at ease and led to productive meetings. Lisa recalls:

“I always thought about how positive it was that myself and X and Y and Dr Z were able to, it wasn’t always as easy as we’d have liked, but we were able to get together. It was very informal it was over at [location] over a coffee and we would look at our practice and what we could do to improve it, obviously trying to meet the goals of EQUIP which you’ll probably have to remind me of some of them”

It was recommended that teams should meet on a weekly basis to review their data but whilst this may have been the case initially, eventually the frequency was reduced to fit in with clinical workloads. Janet describes this in her quote below:

“But towards the end, towards the end we did try to meet every week but then it drifted to once every four weeks but we still managed to get, keep the team together and that’s how we came up with this TIMI risk score little postcard.”

Overall, the interviews indicated that most teams were able to meet regularly, even for brief meetings, and data extracted from the database in the form of reports was used to stimulate discussion and develop ideas to improve local practice. Jim reflected on the value of these meetings and the opportunity they provided to develop ideas for improvement:

“And those were actually quite short meetings, they were only 20 or 30 minutes maximum, but actually we’d have them down in the coffee bar, nice comfy seats, good coffee, bit of a chat, and actually you cared, that was actually where the rubber stamp came out, it was in that sort of environment. And I think it’s a real shame actually that we don’t take a bit more time out to do things like that, because that would not, it just wouldn’t be regarded as time that you can put down on your job plan, for example, because that’s what we’re all expected to fulfil now, is this job plan, which is, Monday morning, this is what I’m doing, and so it goes for the rest of the week. Where do you put one hour or two hours a week to be down in the coffee bar with your colleagues having a chat about things?”

(ii) Measurement

The theme of measuring performance came up in 13 out of the 15 interviews. Interviewees considered it important to collect and evaluate clinical data on patient management so as to assess the standard of care and identify areas requiring improvement.
One of the QI researchers Mike noted that data collection is valuable in that it provides evidence that there are deficiencies in compliance with guidelines:

“we realised that actually, well [we were] not the first to realise this, but that it is a powerful tool for determining gaps between either what people think they’re doing, what they should be doing, what guidelines are telling [them] to do and indeed often what national guidance we’re stating, so there’s a big gap between reality and either belief or what should be doing”

He added that clinicians would not know how their patients were being treated if this was not measured somehow.

“The second thing is the reliability of information about how people are practising and in general hospitals, even in sophisticated healthcare systems, are not really gathering information in a reliable way. So people actually didn’t really know what they were doing and that’s another problem. So if you don’t know what you’re doing, how can you improve or how can you even comply with what is considered to be a reasonable Quality standard?”

The database used for the EQUIP-ACS programme incorporated a feedback system that could provide real-time reports on the number of patients treated. This enabled the QI teams to evaluate their centre’s performance and Jim noted that this revealed performance at his centre was worse than they thought, triggering discussion within the team about what could be causing poor performance and how to address this.

“And very early on it struck me from that we were not as good as we thought we were, and I think that’s where we realised, well look, we’ve got all these things in our pathway, these five therapies that are evidence based that we’re measuring for this study that we think we’re prescribing 100% of the time, but we’re not, and it’s already in the pathway. So clearly there’s an issue, what should we do about it? Let’s have another check towards the end to make sure that people don’t get away. So those figures were coming out, X would bring them along, we would have a look and work out what we could do differently.”

A senior nurse Louise at another site also highlighted that her centre’s performance was worse than they had thought:

“And I think, I thought we were quite good at most of those things and sometimes these show you that you’re not as good as you think you are.”

Interviewees also commented on the challenges of collecting accurate data. In Elsa’s case she had to find a way to fit this in, in addition to her clinical workload, but also to get access to the medical records:

“No, well I work very early because I’m, I come in early then finish early, so I can get all my audit done when it’s quiet, take the notes from the ward when the doctors and the pharmacists don’t need them. And it’s far more effective that way, so I get rid of the audit like that.”
Mike highlighted the importance of having access to high quality data to continue improvement work, particularly in reference to any work that may be ongoing at the centres after the end of the EQUIP-ACS programme.

“And it is highly unlikely that they are collecting that high quality data as they go on. And, but I know you’re working with some centres to continue collecting that data, but unless you can look at high quality data, you can’t improve your quality.”

If a treatment hadn’t been prescribed, it was challenging to work out the reasons for this from the medical notes, since contraindications were not clearly recorded. Lisa noted:

“Because that’s half the battle sometimes, if you, if you’re looking back on things, it’s why haven’t they gone home on that, then you have to try and find out why they didn’t go, was it just simply missed or was there a reason?”

Rima also raised the issue of recording contraindications in relation to another study and noted that, even if these are recorded, often there is no clear rationale and it is difficult to know if it’s a true contraindication:

“actually we did capture if somebody was contraindicated to it that I remember there was a bit of confusion with the nurses at the time because it’s also who’s collecting the data, about what that really meant and so sometimes we weren’t quite sure whether the patient was a contraindication in the sense that it was on the drug, reasons why you don’t give this patient because they’ve got chronic kidney failure or something like that or it was more like a physician decision without any rationale behind it. They didn’t know. They hadn’t investigated at the time. There was no way for them to go back.”

Janet also commented on the challenge of recording contra-indications and how her centre is trying to address this in their medical records:

“And the other day, after the audit that we did, apparently some patients are still not being discharged on the full requirement, required drugs. So therefore I think one of the doctors has suggested to use the same sort of stickers to say it’s a must, take, if there’s any contraindication you must explain why.”

In addition to the issue of contraindications, quality of data collection in general was discussed. Fatima, a QI researcher that works on separate projects, had experienced problems with data collection in the past and noted that this needs to be planned in advance to ensure that a database is well-designed and that data collected are of high quality.

“Multifactor, because to solve those issues is multifactorial and with the bleeding there was quite a lot of, within the programmes that were just getting underway to address those issues, they had quite a lot of data collection issues where they thought it was all in the audit database, when they actually looked at the data it was, the quality of it was rubbish so they had to start doing prospective auditing.”
The teams were encouraged to review their data during their local meetings in order to analyse their work processes and identify any pitfalls. Lisa described reviewing reports of their data during a team meeting:

“Yeah, I printed them off, everybody had a folder and I’d print it all off for them and we’d sit there and we’d look at it and we’d try and decide, look at, OK well why are we only getting this for, and I’d actually audit the patient’s notes as such and say to Dr X, OK this patient didn’t go home on an ACE but they should have gone home on an ACE and we’d look why, whether he actually ever fed that back to the doctors involved, OK we’ve missed an ACE for this patient, don’t know whether he actually did or not”

It can be seen therefore that accurate measurement of patient care can provide a valuable tool to analyse work processes and identify areas for improvement.

(iii) QI tools and ideas for improvement

The QI teams were encouraged to analyse their work processes using the data collected and a range of established QI tools that can help to identify areas for improvement. Process maps were used to identify bottlenecks and barriers in patient care and teams then developed ideas for improving care during their meetings. These ideas were tested out initially using Plan-Do-Study-Act cycles (Deming 1986, Shewhart 1931), and were then implemented if initial tests proved successful. This section summarises some of the improvement ideas that were discussed during the interviews. Some of the teams developed tools to help with performing risk stratification such as the one Elsa describes here:

“So I’d enter all the data into MINAP and she was, had study sheets and she was linking onto that, and we developed a tool for the treatment of patients with a differential diagnosis of acute coronary syndrome. It was tailored to the consultants in post at the time in A&E with risk stratification, people had different ideas whether they wanted GRACE or TIMI so we ended up just calling it risk stratification.”

Jim’s team focussed on the prescription of ACS medications for one of their tools and developed a rubber stamp to be used in the medical records that prompted staff to check the five treatments prior to discharge:

“And I think it was because of that that we thought, right, these are the five things that everybody should be leading on, why don’t just have the final checklist of these five evidence based therapies, and to separate it out from just the standard pathway where people are just ticking boxes, there’s this rubber stamp which people put on just as the patient is about to leave.”

Louise, a member of the same team, agreed that the rubber stamp tool was effective but also noted that it was improved and changed into a label when the team realised it was too impractical to carry a stamp around the various departments. Her quote below demonstrates the ongoing assessment of improvement ideas and that they were adapted and changed as
required during the implementation of the QI programme.

“Yeah, which was quite cumbersome and what we said was that, that’s all very well and good but if we’re off on the medical assessment unit and we’re seeing patients there we don’t want to be carrying the stamp around with us. So we went to sticky labels, that’s how it worked I think, yeah, it was a stamp to start with but the labels are definitely better.”

Adrian described a tool in the form of a document that could be printed off the local intranet to document requirement for referral:

“That was a referring tool, it is there on the intranet, they can print it out and you print it out, you put in the notes and you tick different things what has been done and what’s next.”

Jacob’s team used a similar checklist which was monitored after use to assess its value and make changes to it where necessary:

“Yeah, when the patient was discharged we collected the form and some of them were very complete and some of them were in the same status that we had left them. And ways to improve, for example, discussion, changes that we had seen in the performance ... for that.”

The interviewees described various checklists and tools such as the rubber stamp described earlier and the purpose of these was to remind staff completing the medical records about the key ACS treatments in a systematic way. Janet worked on a team that developed a pocket risk stratification card and she observed an improvement in the level of risk stratification as a result:

“But towards the end, towards the end, after we have introduced the card it’s much better. I think it’s just jogged people’s memory to say, right OK, I’ve TIMI risked them and blah, blah, blah. And then subsequently they prescribe the relevant medication.”

Lisa thought that the simple tools they used to remind staff about prescribing ACS medications were effective because they were acting as a simple memory jog:

“Just prompting I think, it’s just a memory jog for people to remember to make sure they’ve considered everything and looked at the patient as a whole really, whether they’re on the right treatment, that they go home on the right treatment. I think that was all it was, it was just, oh there’s a sticker there I need to, and it made them think about it”

All of the improvement ideas described during interviews were simple and inexpensive but teams were able to design and implement them in a short timeframe and also to observe the effect they had on ACS treatments using the study database.
(iv) QI Meetings

The QI programme consisted of 3 meetings held in a central location. Representatives from each QI centre were invited to attend and encouraged to hold their own local meetings prior to the start of the programme and throughout its implementation. Interviewees were asked about the meetings including the format and delivery of these. Feedback about the meetings was positive and participants considered that they were well organised and productive. Janet remembered that meetings were efficiently organised:

“Everything was very well organised, very good communication with you especially whether, which hotel we’re staying, transport, everything, was no stress. So therefore I don’t mind, I didn’t mind going abroad.”

Adrian summarised his thoughts on the organisation of the meetings as follows:

“Well organised, well located for all these people. Some was in central position, in Amsterdam, things like that, which was obviously for different people to come to a common place, some in London in nice place and everything. So it was well organised and well thought, and the people who were doing it, obviously you were involved in the organisation, but other people who were coming and discussing things, was good in their fields.”

In addition to organisation, interviewees were positive about the content of the meetings for example, Jim found the meetings enjoyable:

“But they were, they were very, they were enjoyable, they were interesting, they were informative, and I thought it was all really worthwhile actually.”

The attendees involved in the organisation and delivery also considered the meetings enjoyable and commented on the positive atmosphere. An example of this can be seen below in a comment made by Rima:

“And I think at the training I got the impression just from seeing people’s body language and the chatter that was going on that actually people quite liked meeting the other teams from the other hospitals etc. and so it wasn’t just them being looked at in terms of my performance but they were all in it together and I actually thought it felt like a really good environment to be in. I enjoyed it.”

So it is clearly important to consider the logistics of arranging a meeting as well as the content and format to ensure a positive outcome. Fatima talked about logistical considerations for arranging meetings for a different QI programme;

“And difficult to schedule, we did it on an audit day but even that was not straightforward because staff have other commitments on audit days that …”

In addition to scheduling considerations, she had to think about providing refreshments and making sure attendees were comfortable during meetings;
“we had breakfast and we started at 7:45 and did quite a lot of things about timing and feeding people and trying to make it a nice.”

6.4.2.4 Quality indicators

(i) Goals of QI programme

The goals of the QI programme were based on the recommendations from the latest European Guidelines for management of non-ST elevation ACS (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology, Bassand, Ardissino, Boersma, Budaj, Fernandez-Avila, Fox, Hasdai, Ohman, Wallentin, & Wijns 2007) which were applicable to all participating countries and centres. Real-time reports summarising the proportion of patients receiving these treatments were available to each hospital via the web-based database. The eight guideline-recommended quality indicators were: risk stratification, anticoagulants, beta-blockers, ACE-inhibitors, statins, coronary angiography and clopidogrel as a loading dose and a maintenance dose. These were discussed during the interviews to ascertain whether they were considered appropriate goals and gain more information about how they are prescribed and why they might be under-used despite guideline recommendations.

The staff interviewed agreed that the goals selected were suitable and that these guideline-recommended treatments should be given to all non-ST elevation ACS patients. The evidence base for these treatments was widely accepted and the clinicians indicated that if patients did not receive these, it would be due to error rather than disagreement with the evidence and guidelines.

(ii) Risk stratification

The use of a formal risk stratification model was recorded during the EQUIP-ACS study. This quality indicator improved the most out of the 8 assessed and its use varied widely across the participating sites. Interviews revealed a range of views on the use of risk scores and these are outlined in this section.

Risk stratification of patients using established models, i.e. GRACE (Goodman, Huang, Yan, Budaj, Kennelly, Gore, Fox, Goldberg, Anderson, & for the Expanded Global Registry of Acute Coronary Events (GRACE) 2009) and TIMI (Antman E.M., Cohen, Bernink, McCabe, Horacek, Papuchis, Mautner, Corbalan, Radley, & Braunwald 2000), was considered an easy thing to do and many felt that assigning a risk score to each patient was an important step in their management. One of the QI researchers commented as follows:
“I think it makes it systematic, so if you’re doing it and you’re doing your score then everybody sees the score as well whereas if a doctor is doing it in his head, it’s just in his head. Whereas if we can all see like the nurses or the other allied professionals what you’ve identified as being the possible risk for this patient then I think that can definitely be of value and I think the evidence was out there to show that risk stratification helps because it’s just providing a systematic way of evaluating somebody”

The interviewees described the use of risk scores to support decisions for further treatment including angiography, particularly in cases that are not straightforward clinically. Risk scores are often calculated in the A&E departments and used as a trigger for patients to be referred to the Cardiology Ward. A registrar who was responsible for training A&E staff to use risk scores as part of his role on the QI team, described how he uses risk stratification to support patient care.

“Yeah, I do find it useful, yeah. Especially as it makes you objectively think whether or not you need to pick up the phone and alert the cath lab. So even if you’re in the tertiary centre I still do it. So I think it’s got two roles. One admission and discharge and the other one is to escalate or go to the cath lab.”

Discussion around the use of risk stratification revealed that it was not always considered valuable however and that the resulting score is not necessarily used to determine further treatment or prioritise one patient over another. Decisions are based on clinical judgement rather than a formal score in many cases. A senior ward nurse noted:

“No, I don’t think the TIMI scoring itself has a bearing on whether they have the treatment started or not. I think the clinical picture tends to suggest that the treatment is started.”

And a similar comment was made during another interview with a ward nurse regarding patients’ referral for angiography:

“And I do think that although you do TIMI score patients, the TIMI score isn’t used to prioritise patients as far as procedures are concerned. So I can understand from people’s point of view, why bother doing it if it doesn’t influence what happens to the patient? You could have a TIMI score of six but if you come in three days later than the one that’s got a TIMI score of one that goes date wise to have an angio, it doesn’t get prioritised on TIMI, so what is the benefit of doing TIMI?”

She also noted that risk scores are never discussed during ward rounds and that it was difficult to find purpose in meticulously carrying out scores if they were not going to lead to prioritisation of higher risk patients or in fact be used for anything at all.

It is clear that there is a lack of consistency regarding use of risk stratification methods as some centres consider it a valuable tool whilst others do not use a formal scoring method.
and instead prioritise patients on the basis of clinical symptoms or waiting time.

“So they are in a way risk stratified in the minds of the consultants who see them, but probably not formally written down.”

Reflecting on the overall study results, one of the QI researchers commented on the improvement observed in use of risk stratification and noted that in his view, the main purpose of risk scoring patients is to reach a decision about angiography.

“Yeah, it’s interesting, but it is quite difficult to understand how we improve the risk stratification but not in coronary angiography. Because then the main reason for the risk stratification is for perform a coronary angiography”

The QI programme permitted use of any formal, documented risk stratification method but emphasis was on the GRACE method (Goodman, Huang, Yan, Budaj, Kennelly, Gore, Fox, Goldberg, Anderson, & for the Expanded Global Registry of Acute Coronary Events (GRACE) 2009) since this was recommended in the ESC guidelines. When asked about the different methods, teams indicated a preference for the TIMI score as this was simpler to calculate in an acute setting whereas the GRACE model requires creatinine to be measured and a computer to calculate the score according to an algorithm.

“And the stumbling block was, the cardiologist wanted GRACE assessment, but it’s not always practical in the acute environment, you’ve not got blood results or the calculators to calculate, TIMI fits nicely in, it’s quite easy to do and user friendly.”

(iii) Acute Coronary Syndrome medications

Medications indicated for non-ST elevation ACS made up 6 of the 8 quality indicators for the QI programme. These were: statins, beta blockers, anticoagulation, ACE inhibitors and clopidogrel as a loading and maintenance dose.

Rates of use of these medications were discussed during interviews using control charts showing each centre’s performance over time as a prompt. Use of statins and anticoagulants was generally high across all centres and review of this data did not lead to much discussion as these were considered straightforward and applicable to all ACS patients. Any medications that depend on a test result or consultant decision prior to prescription appeared to be less likely to be given consistently.

One of the ward nurses Sara noted that ACE inhibitors and beta blockers have more contraindications than the other medications and these need to be taken into account when prescribing for non-ST elevation ACS patients.
“Well those out of anything are probably the more contra-indicated type medication, along with your beta blockers, Us and Es go off, patients can’t tolerate it, they get the cough, you know, there are, I think they’re possibly more reluctant to start patients on ACE inhibitors because of renal impairments and things, so. And a lot of your patients are diabetic, a lot of them have got underlying renal problems anyway.”

Contra-indications were in fact raised as a factor in prescribing ACS medications in 8 of the interviews and another research nurse Lisa also commented on the difficulty of identifying whether patients have contraindications to certain treatments since this is not well documented in the medical records.

“Which would be a shame really, because they should perhaps, could have incorporated the type thing in with that, so that yes you are checking that they go home with everything they should be, but is it their five cardiac medicine that they were going home on and if not why not? Because that’s half the battle sometimes, if you, if you’re looking back on things, it’s why haven’t they gone home on that, then you have to try and find out why they didn’t go, was it just simply missed or was there a reason?”

The need to wait for a consultant to decide that a medication should be prescribed was described during 5 of the interviews. This is noteworthy as it could lead to delays in treatments being prescribed.

“Most of the time when patients are admitted, as I said, cardiologists do your ward round and checking the drug board, so they’re usually started there in the first place. But there will be a lot of people who may not have received, coming at night, not seen by cardiologist, and starting in on the ward or coronary care, you may, you’re transferring out to centre in 48 hours, so it depends really, yeah.”

A registrar from another centre also noted that ACE-inhibitors were usually prescribed by a cardiologist:

“Yeah, they’ll wait, yeah, they’ll wait for probably the medic and most likely the cardiologist to come and start that one.”

He also added that if a patient was not seen by a cardiologist for any reason, he or she may be discharged without an ACE-inhibitor ever being prescribed.

“So they may have been, if they’re stable and then for some reason not seen a cardiologist, which is pretty rare, but they would have been discharged without and we would have missed them, but it’s pretty rare.”

Some ACS medications may therefore be missed if the clinical team are waiting for a cardiologist to prescribe them and, in the case of beta blockers and ACE-inhibitors, two of the interviewees referred to staff on the wards feeling that it is not urgent to start these treatments or in the latter case that it is appropriate to wait. This can lead to prescriptions being missed completely. The first quote is from Gareth, a registrar on one of the QI teams;
“Because of the long term benefit they’re looking for they will feel it’s less urgent to start without speaking to a cardiologist I think. That’s my experience.”

The second quote is from Janet, a nurse on the same QI team:

“And a lot of times there was still, we were told, when I was doing my training we were told that beta blockers shouldn’t be prescribed on the first day, you should prescribe it on the second day. Maybe the doctors they had the same mentality as well, so maybe you don’t prescribe this until whenever. So things got delayed and subsequently got forgotten, I think. But now I think, because, I think we were drummed it in by the consultant as well, aspirin, clopidogrel, statin, beta blocker and ACE, it’s a must.”

The medication that seemed to trigger most discussion upon reviewing the control charts and local results was ACE-inhibitors, with 11 out of 15 interviews focussing on this treatment. The need for decision steps before a treatment can be prescribed was introduced above and this is relevant in the case of ACE-inhibitors as clinicians commented that they feel it is necessary to consider blood pressure and renal function especially when this is prescribed. One of the consultants, Jim, noted the following:

“Yeah, I mean people are a little more driven by things like blood pressure and renal function, and they get a little bit concerned about sometimes just mild renal dysfunction, they’re probably not prescribed as often because of that. But there again it’s one of the therapies that’s definitely on the pathway, it’s on our five rubber stamp as well, and you would expect the majority to have ACE inhibitors”

One of the ward nurses, Sara, noted that giving ACE inhibitors is not as straightforward as the other medications since they are indicated for a proportion of non-ST elevation ACS patients and not all.

“No, it’s not as straightforward and originally ACE inhibitors were only really given to patients with anterior infarcts, low ejection fractions, those that would really, they would feel benefit from them so if you’ve got somebody that’s come in with an inferior infarct who’s not got any failure issues, if their renal function was borderline, I think they would have problems actually seeing the benefit of giving an ACE to those patients.”

Another senior nurse, Louise, made a similar comment and noted that this treatment may not be started immediately:

“But I think for the ACEs we’re, you tend to hold off more particularly from the renal function point of view and then consider introducing it at a later date if applicable.”

Finally, a registrar (Gareth) considered all these points relevant in the prescription of ACE-inhibitors, noting that renal function and blood pressure, the need to wait for a cardiologist to support the decision, and the fact that there is more than one ACE-inhibitor to choose from may all contribute to this treatment being missed.
“Interviewer: Is there anything that’s different about the way ACE inhibitors are prescribed that would make it more complex or that might mean that some patients that seem to require it don’t get it?

Well, there’s more than [one] ACE inhibitor that people know about, so they’re a bit worried about which one to use in which situation. The other thing is renal function initially may be a bit of a blurred area for patients, for medics to work out whether or not the ACE is going to knock them over or not, relative hypotension as well and I suspect it’s not seen as one of the urgent ones that need to be started and would probably wait for a cardiologist to take a look and have a more considered approach to it. So that’s why I don’t think it’s started immediately necessarily.”

The final medication discussed was clopidogrel given as both a loading dose and a maintenance dose. This was generally considered straightforward and applicable to all non-ST elevation ACS patients. The loading dose is usually given in the A&E department and it is included in the local care pathways for managing ACS patients. The only exception was one of the Spanish sites that were unable to prescribe clopidogrel in accordance with the ESC guidelines due to a restrictive local protocol. This local protocol was no longer in place at the time of the interview but had been implemented throughout the EQUIP-ACS QI programme.

(iv) Coronary Angiography

The final goal or ‘quality indicator’ considered was the use of coronary angiography at centres. The database recorded whether patients received angiography within 72 hours of admission, as per the ESC guidelines. (Task Force for Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of European Society of Cardiology, Bassand, Ardissino, Boersma, Budaj, Fernandez-Avila, Fox, Hasdai, Ohman, Wallentin, & Wijns 2007) The rates of angiography did improve after the QI programme but still remained low and there could be a range of reasons for this. The main reasons that were considered by the interviewees are summarised below.

Staff felt that patients requiring angiography were being referred for the procedure but that meeting the 72 hour timeline proposed by the guidelines was challenging. Jim’s site did not have access to angiography facilities on-site at the time of the QI programme but this had been implemented at the time of the interview and he still felt that the 72 hour timeline would not be met.

“And I think, as you’ve seen, it’s not really altered dramatically, because in that tight timeframe, we’re still not achieving. I think if you extended the timeframe, probably to, say, five days, you’d probably see the overwhelming bulk are being captured.”
Jim elaborated on the difficulty of meeting the 72 hour timeline and felt that an educational programme may not be adequate to achieve this goal.

“Yeah. Because angiography rates for example are not that different. And I suspect what you find is that, as we’ve discussed, this is the three day constraint. Because that’s what the guidelines recommend, but we’re clearly not achieving that. So I don’t know that an education programme, for example, would change that. You can make people aware and we all understand that we should try and do it within two or three days, but there are practical limitations in that.”

One of the QI researchers Rima, also felt that the 72 hour timeline was too much of a challenge for the QI intervention and that more time would have been needed to overcome this barrier.

“So I wasn’t, so I think some things were definitely, I felt there were some things that were very big barriers that this type of programme you’d have to have it rolling out over a much longer length of time and it would be things like the cath lab, so one of the things was trying to schedule an angiogram within the 72 hours as indicated in the ESC guidelines and it’s like when the clock starts ticking and so some people were surprised that they weren’t getting patients done within 72 hours.”

3 of the 5 hospitals interviewed did not have on-site PCI facilities and the staff interviewed from these sites cited this as an important factor to explain the rate of coronary angiography. Marina believed that rate of angiography would have improved at her site since on-site facilities were now available:

“That most of the straightforward angios can now be done here. So, I would imagine the timelines for getting those done will hopefully now be shorter, because we can do them onsite.”

Similarly, Fred noted that time to angiography had reduced considerably at his site since facilities were available on-site:

“So I think the problem we were having was just meeting the 72 hour transfer time. Because at the time we didn’t have our cath lab on site but in fact now we have, ours is the lowest inter-hospital transfer time, it’s down to a day.”

In addition to availability of facilities on-site, it was considered important for the service to be provided 24 hours a day and every day of the week in order to meet the guideline recommendations. Jim noted that this service was available for STEMI patients but not non-ST elevation ACS:

“Well, no, well you see, I think if you did this, you still would find that, although transfer times have improved, three days, 72 hours from admission, is probably not achieved. And the reason for that is we don’t
have seven day working. And I think if we are going to walk down that route, we would have to have seven day working. We’ve got 24/7 primary angioplasty for ST elevation MI, and of course you can say well, and we know this, the non STEMIs probably get a slightly less good deal, because they do, they’ve had their medical therapy, they’ve cooled off, and they come into the next slot. We’ve sort of arbitrarily set a transfer time here of three to four days, but it’s working days."

Gareth felt that clinicians would ensure patients receive angiography within the required timelines, if the catheter laboratory was available 24/7:

“If they had the keys to the cath lab that would be 100% I’m pretty sure. And the stays would be very short. If they could open the cath lab seven days a week they would do it. So I think it’s just a, it’s a factor out of their control, which is unfortunate."

At one of the other sites, Sara also noted the importance of having 24/7 access to angiography facilities:

“Well I think the one thing, the one stumbling block we had about everything is trying to meet that 72 hour to angio, which unless you offer 24/7 you are never going to achieve in a million years.”

The importance of staffing and resources being available 24 hours a day and during weekends and holidays was also introduced in the section on Barriers and in the examples above, it can be seen that this is also relevant for achieving guideline-recommended timelines for angiography procedures.

The interviewees noted that clinicians wanted to meet the recommended timelines for angiography but factors outside their control prevented this. In some cases, as has been shown above this was due to lack of available facilities and in others, this could have been a range of administrative or other factors. Lisa described how their QI team tried to come up with ways to shorten time to angiography:

“...and the one with getting an angio within so many days was always a big issue for us, we’d sit there brainstorming, what can we do to try and improve that? But I think in the end we just said there wasn’t, it was out of our control as such, because it did all have to go over there and be done, so.”

Sara, on the same QI team had a similar view:

“There were certain issues that we found we had no control over, particularly with the meeting the target for angio, that was completely out of our control”

Mike, one of the QI researchers, remembered that clinicians tried to approach this problem in a simple way initially and realised that there were other factors outside their control:
“If you’re not performing enough angiography then the clinician’s initial solution was, well just tell people to do more angiography and then when they went back to their hospitals they realised actually maybe it wasn’t quite that simple. They don’t have control, they don’t, they don’t have the control over the, what, how angiography’s done, so I think that came through.”

6.4.2.5 Reactions to QI

In order to assess the uptake of the QI intervention and how motivated staff at the QI centres were, questions were asked to gain insight into individual opinions on QI, with emphasis on the intervention delivered during the EQUIP-ACS study. Reactions to the improvement programme can be broadly divided into ‘positive’ and ‘negative’. Clearly those that have a positive reaction are more likely to implement the principles of a QI intervention and work on methods to improve management of ACS at their hospital. One of the QI researchers commented on the varied responses to the QI intervention observed during the QI programme meetings:

“We can’t do it like this because the A&E team won’t work with us or a different consultant says we can’t do it this way and they just create barriers whereas others were very, were I felt more receptive and didn’t necessarily know how to do a change but wanted to hear suggestions and were more taking on board the ideas.”

(i) Positive reactions

The majority of staff interviewed had reacted positively to the intervention and were motivated to improve their practice. The range of positive responses included staff expressing feelings of motivation, understanding the importance of improving patient care, a sense of ownership and responsibility regarding patient care and considering improvement work valuable. Teams experienced a sense of achievement when they observed measurable improvements and this motivated them to achieve further improvement.

One of the ward nurses noted that having access to real data about how patients were treated as part of the QI programme was valuable:

“And I think that, one of the brilliant things about the EQUIP study was it actually made us realise that even though we had these pathways and we all thought we were brilliant, actually we weren’t brilliant, we weren’t prescribing things at 100%, these evidence based therapies, even though we thought we were very good, and it really made us realise that.”

A nurse from another site described her team’s reaction to the central QI training meetings. Results for all centres would have been presented at the meeting and teams were asked to look at their own results and evaluate their local work processes to identify areas for
improvement. This team took ownership of their results and felt motivated to find ways to improve the way they managed NSTE-ACS.

“But it was always very motivating, the meetings, we did come away and think, right OK, what can we do now?”

It was also apparent that experienced research staff found the QI programme to be valuable and enjoyed working on it because the outcomes were meaningful. The relevance of identifying goals or indicators that staff perceive to be a priority was considered in the section above, but it is worth noting that choosing the correct outcome measures will also motivate staff to improve their patients’ care.

“I was interested in it, there are some data collection studies that you do and it’s just, you just feel like you’re doing it for the sake of doing it, but this, I think the outcome was going to benefit patients at the end of the day and as a nurse in particular, that’s what you want”

A similar reaction was noted by a senior ward nurse who had been involved in clinical audit and improvement projects before.

“Yeah, it’s things that whenever we try and initiate an initiative within the ward it all is about delivery of care and quality and not doing something just for the sake of doing it, but about changing the outcomes and improving outcomes and streamlining our service.”

The training programme was delivered using an interactive approach, some traditional lectures were given but the majority of the sessions were based on workshops where teams were invited to work together to interpret results and recommend solutions to the problems presented. This approach was unexpected but meant that the teams quickly understood they were responsible for improving their own patients’ care and that the programme was not going to provide them with a magic bullet for delivering optimal patient care.

Two consultants remarked on this aspect of the QI programme:

“So, because when you go to these meetings you think, you always think, oh there will be a fast, a very magic rule to improve, there’s not, because you have to improve by yourself.”

“Well, it was a surprise because yes we, I personally was not prepared to receive two sets of training and you expect to find some people with, passing slides and doing some theoretical work and lessons. And it was quite, it was very open. I think that, so that the work was that there were no recipes to improve that. You had to try to manage by yourself.”
(ii) Negative reactions

Most of the reactions described by those interviewed were positive but there were also some negative sentiments captured, mostly by the QI researchers involved in implementing the QI intervention. Negative reactions included cynicism about the intervention, a lack of interest in the programme and poor attendance at meetings, not perceiving QI work as a priority and finally, scepticism about the data presented.

A QI researcher that had been involved in implementing other QI programmes noted that some people approached the programmes with cynicism:

“And I think with the consultants there’s a fair bit of cynicism about what is this programme, just another of these management buzz words, the dah dah dah, if we shut up and put our heads down it will go away again, in another year there’ll be another flavour of the month.”

Four of the interviewees cited scenarios that showed QI work was not always considered a priority. For some of the health professionals involved, it was just another research study to fit in around clinical work and others either didn’t turn up at meetings or left part-way through.

In some cases, clinicians made initial attempts to improve their work processes but if these did not succeed immediately, they soon lost interest:

“Having made an effort to improve, if they didn’t see an improvement they sort of gave up, so they would make an effort and then if things hadn’t improved immediately they would sort of, they would think, oh well made an effort, that’s the best I can do.”

There was also a category of investigators that did not accept the data presented during the QI meetings and insisted on re-analysing the data to ensure their hospital’s results were represented accurately. Rather than accepting that the database used was reliable, they spent their time scrutinising the data only to find it was correct. Conversely, some did believe the results but did not appear to be concerned when it became clear that treatment was sub-optimal. An example of this is seen in the quote below:

“Whereas, health professionals would consider 70% compliance as being quite good, so that was one issue.”

6.4.2.6 Interpretation, implications for future work and sustainability

In addition to capturing reactions to the QI intervention, the interviews aimed to assess how the results of the programme were interpreted by the health professionals that had been involved and to look for evidence of continued improvement work at the centres.
(i) **Sustainability**

Members of the QI teams realised that results of QI work were not necessarily permanent and that more work would be required to ensure that improvements could be sustained. Ideas for sustaining the results included regular or annual publication of hospital performance and repeated intensive QI training sessions.

“I personally think a change of 8% is good and it's when you go to certain meetings and people are talking about changes in a non-research orientated way then, that everybody, I think generally there seems to be a perception that 8% would be seen as a good improvement. And then I think what you'd want to see is what would happen. So if you were doing things quarterly or annually you'd like to see that trend of the increase keep going up and up and up.”

The QI researchers in particular felt that more time to deliver the QI intervention would have led to more improvement as you need time to consider the evidence, analyse current work processes and implement a successful change. One of the researchers commented on this and noted that some people may be resistant to change initially but over time could become more engaged:

“I think a longer period of time to actually make the changes because I think there is a time that you have to take on the evidence and the information and then it just takes time to get a change and if you're dealing with people who are a little bit resistant it's not to say they will always be resistant I think, it's just that maybe with longer engagement and maybe trying different ways of giving them the information and challenging them etc. that might have had a bigger change, so. And I don't think we had very long. We just had one methodology, three days, which isn't actually a long time.”

(ii) **Interpretation of results**

In general, the results of the QI programme were considered meaningful and all those interviewed felt that the programme had been successful. They reflected on the variation in results, in particular the fact that some of the indicators improved more than others and also the fact that some hospitals improved more than others. It was acknowledged that more information about the centres and QI teams within them would be required to better understand the results. Interviewees also commented that more than one strategy would be required to result in a greater improvement and that a combined approach would be essential to improve overall service.

(iii) **Ongoing improvement work**

Some of the tools developed during the QI programme were still in use and development of new tools was also planned but the nurses noted that it was difficult to maintain motivation amongst their teams.
“...but I think the hardest thing for these things is sustaining the, you see the peaks where we'll put in a big effort and then a few months down the line it's, everybody's enthusiasm wanes and it is difficult I think just to sustain.”

Similarly a nurse at a different site commented on the influence of ongoing audits to maintain motivation for improvement:

“...but trying to keep that momentum going when you no longer are being looked at and audited is very difficult, because something else will come in as a priority and you will then focus on that, and things will drop by the wayside...”

6.5 Discussion

Analysis of the semi-structured interviews conducted during this research identified a range of important themes that contributed to the outcome of the QI intervention. These can be organised into three broad categories which are: “process”, “people” and “environment”. Whether discussion was about barriers and success factors or the specific treatments recommended for management of non-ST elevation ACS, or even participants’ reactions to the programme, the themes that came up were similar.

Factors that would facilitate “process” were: simplicity; reduced number of steps; no need to wait for a decision or outcome of a test; automating or centralising a system; ability to control an entire process from start to finish; low performance at baseline; access to reliable data about the process, obtained through an accurate measurement method.

In the case of “people”, the predominant themes identified were: leadership; incentives; training and expertise; teamwork; communication and motivation. Motivation and incentives were linked in that motivated staff tended to feel a sense of ownership and responsibility about their work which gave them an incentive to improve more.

“Environment” represents the physical location in which improvement work is being carried out i.e. the organisation, but also the working atmosphere and culture in which the intervention is being delivered. Environmental factors therefore included resources (staffing and financial), facilities and infrastructure, accessibility, working environment or culture and engagement of users in improvement work.

Clearly “people”, “process” and “environment” will interact in such a way that it is not possible to consider their effect on improvement work entirely separately. All three types of factor would need to be taken into account in planning and implementing QI work in order to
ensure this succeeds. This concept is summarised in Figure 34, which depicts the three major factors and key sub-themes within these.

![Figure 34. Factors influencing outcome of improvement work](image)

The themes identified by this qualitative evaluation are consistent with findings cited in the literature. Davis et al conducted a qualitative study in a range of specialties and therapeutic areas using focus groups and in-depth interviews to evaluate patient care during the transition from hospital to home.(Davis et al. 2012) This is a different care setting to that of non-ST elevation ACS in-hospital management, but key themes identified were the importance of standardised systems, training of staff, multi-disciplinary communication and stakeholder engagement.
The investigators of the CPACS trial, cited earlier (Du, Gao, Turnbull, Wu, Rong, Lo, Billot, Hao, Ranasinghe, Iedema, Kong, Hu, Lin, Shen, Huang, Yang, Ge, Han, Lv, Ma, Gao, & Patel 2014) conducted a qualitative evaluation in a sub-set of 10 centres participating in the programme (Ranasinghe et al. 2014) to explore system-level barriers to delivering evidence based care for ACS. The authors carried out 40 in-depth interviews and analysis using the framework method identified five barriers to optimal care: leadership, resources, fear of dispute and litigation, healthcare funding constraints or patient “out-of-pocket” expenses and patient-related factors. The barriers relating to potential litigation and healthcare resource or patient expenses are not applicable in the UK healthcare setting assessed in this chapter, but the themes of leadership and resources are consistent with findings reported in this chapter.

A systematic review of determinants of success in QI collaboratives (Hulscher, Schouten, & Grol 2013) identified leadership, resources, baseline performance, teamwork and engagement of staff in delivery of QI work as key factors all of which are consistent with the findings of this research. The review also assessed factors influencing long term results and these were continuous measurement and involvement of experts to support improvement work, again consistent with findings reported here.

A study consisting of 45 interviews was conducted in eight U.S. hospitals to assess factors that increase rates of prescribing beta-blockers at discharge for AMI patients. The study identified four prevalent factors in the highest performing hospitals: shared goals for improvement throughout the organisation, administrative support, physician leadership advocating beta-blocker use and access to high quality data feedback. (Bradley et al. 2001) These findings are in line with the themes of measurement, leadership and resource which were identified as important in this chapter.

The Health Foundation commissioned an independent evaluation of five of their improvement programmes to identify key challenges to conducting QI work, also cited in the previous chapter. The authors of the evaluation analysed the reports from the programmes using qualitative methods in addition to reviewing the relevant literature. Ten challenges to conducting QI programmes were identified: convincing participants that the problem identified is applicable to them; convincing participants that the solution is appropriate; using reliable data collection and monitoring systems; unrealistic ambitions; organisational culture, capacity and context; ‘tribalism’ and lack of staff engagement; leadership; incentives; securing sustainability; risk of unintended consequences. (Dixon-Woods, McNicol, & Martin 2012) The importance of data collection and measurement was also identified in the
research reported in this chapter as were the themes of leadership, incentives, organisational culture and staff engagement. The issue of sustainability was also highlighted in the interviews and discussions indicated that improvements achieved following QI work were not sustained in the long term. There was some evidence of ongoing QI work but this was limited and the interviewees noted that they were not motivated to continue improvement work after the end of the study when they were no longer being audited.

Glickman and colleagues have discussed factors that impact on organisation culture and emphasise that not only is it important to consider all these factors, but also how they interact with each other. The key organisational factors their work has cited are executive management, culture, organisational design, incentives and information technology. (Glickman et al. 2007) The themes of management, culture, incentives and information are common with the findings reported in this chapter.

The majority of themes identified in this chapter are also consistent with the NHS Institute for Innovation and Improvement’s ‘Sustainability Model’. (Maher et al. 2015) The NHS Institute developed a model for predicting sustainability of a QI initiative based on a range of QI programmes and literature sources. The three main areas considered to influence sustainability are staff, process and organisation. These three areas are divided into 10 factors overall, each of which are weighted within the model in accordance with their relative importance. The staff factors are: training and involvement, clinical leaders, senior leaders, and attitudes. Training, leadership and attitudes were all found to influence outcome of improvement work during the qualitative evaluation. Process factors listed in the NHS Institute Sustainability model are: monitoring, adaptability, credibility of evidence, benefits beyond helping patients. Comparing these factors to the findings reported in this chapter overlap with the themes of measurement can be seen. Organisational factors of the Sustainability model are infrastructure and ‘fit with goals and culture’; in terms of infrastructure, the themes of resources and facilities were found to be important in this research and culture and suitability of goals were also discussed.

This evaluation has shown that a number of factors can contribute to the outcome of a multifactorial QI programme. These should be taken into account in designing future QI initiatives and can be considered on two levels; local and organisational. At a local level, teams participating in a programme should analyse their own processes and endeavour to remove unnecessary steps and deliver these in a standardised manner. Data collection should be conducted throughout QI work and ideally should form an established component of patient management rather than limiting this to research studies or national initiatives so a
measure of performance is always available. Factors to be considered at an organisational level, i.e. by the organisation responsible for designing the QI initiative, are those that relate to environment and people. It is important to develop a positive, productive atmosphere during QI meetings to encourage participants to develop their QI work. Thought must be given to the individuals training participants to ensure that they have appropriate expertise and give the programme credibility. Stakeholders must be engaged in both design and delivery of work and leaders to carry out training and improvement work are essential to ensure success.

These findings will be combined with quantitative results in the next chapter to develop overall recommendations for initiatives to improve management of Non ST-elevation ACS.

6.6 Limitations

There are a number of limitations which could have influenced the findings of the qualitative evaluation. The author of this thesis who conducted the interviews had been involved in the development and delivery of the QI intervention. There is a potential for this to introduce a bias in analysing the emerging themes since the author cannot be purely subjective. There is likely to be a tendency for the interviewer to look for themes that are anticipated and to place more emphasis on these.

In terms of the interviewees, it is important to note that they were known to the interviewer as they had worked together throughout the EQUIP-ACS project. This helped to make the interviewees feel at ease during the interviews but could mean that they were reluctant to share negative feedback about the QI intervention.

The quotations presented in this chapter show that some of the interviewees’ responses feature more regularly than others. This could be because those interviewees were prone to discussing the themes raised in more detail than others but the potential for selection bias by the author cannot be excluded.
CHAPTER 7. Discussion and recommendations
7.1 Purpose of the research

Management of non-ST elevation ACS is sub-optimal despite recommendations set out by national and international guidelines. Data from clinical registries indicate that there is a considerable gap between guideline-recommendations and clinical practice. QI initiatives have shown that this gap can be reduced and improvements in standards of care have been observed, but the results are variable and short-lived.

A range of QI methods have been tested comprising clinical audit approaches or QI methodology derived from management theory as well as combinations of these, but a successful standardised approach has not yet been developed. There is a poor understanding of the factors that can lead to successful QI work and new programmes are designed and delivered without adequate evaluation of previous work.

It is necessary to evaluate QI work in depth using a mixed methods approach, in order to inform decisions about future QI initiatives in the field of ACS management. This thesis has evaluated a multi-centre, multi-factorial QI programme called the EQUIP-ACS project to explore delivery of the QI intervention, evaluate management of non-ST elevation ACS and improve understanding of the quantitative and qualitative factors that influenced the outcome of a QI programme for health professionals.

7.2 Summary of results by chapter

Results of each chapter were discussed at the end of the individual chapters, including comparison with relevant literature. A summary of the findings of each chapter is provided below to set a context for the triangulation of all results and overall discussion of the thesis.

7.2.1 Chapter 2: The EQUIP-ACS trial

A multi-factorial randomised QI programme delivered to a range of hospitals in Europe resulted in a measurable improvement in management of non-ST elevation ACS patients. 19 hospitals were randomly allocated to receive a QI intervention and 19 were allocated to no QI intervention. Management was assessed by measuring the rate of use of eight guideline-recommended treatments and comparing the use of these treatments as a composite measure, before and after delivery of the QI intervention. A statistically significant absolute improvement of 8% overall was observed for the group of hospitals allocated to the QI programme, compared to 1% for the non-intervention group. In terms of the individual treatments that make up the composite outcome measure, seven out of eight showed greater improvement for the QI group compared to the non-QI group. A statistically
significant improvement was noted for two of the individual treatments, use of risk stratification and clopidogrel prescribed as a loading dose.

The greatest improvement was recorded for use of risk stratification which improved by more than 30% for the QI hospitals compared to the non-QI hospitals. This could be attributed to the low baseline use of risk stratification methods and also to the fact that this is a simple task to complete. A risk score is straightforward to calculate based on the patient’s medical history and admission investigations. Improvement in prescription of ACS medications ranged from 2 to 10% but the baseline rate for all treatments was more than 75%. Coronary angiography had a low baseline rate and increased by 5%. The modest improvement observed for coronary angiography could be attributed to the fact that this is the most complex of the eight treatments, requiring a number of steps and members of staff in order to take place.

7.2.2 Chapter 3: Use of risk stratification methods

Use of risk stratification was the quality indicator that improved the most after delivery of the QI intervention. Use of risk stratification was defined as documented use of any formal score, e.g. GRACE or TIMI, within 24 hours of admission. This indicator improved by more than 30% for the QI group compared to the non-QI group, driven by an increase in use of the GRACE score among QI centres. The GRACE score was calculated retrospectively for all patients included in the study and patients were categorised as low, intermediate and high risk according to the GRACE definitions. The results were compared to risk categories derived by the centres throughout all phases of the EQUIP-ACS trial and found to be similar, indicating that centres were calculating risk scores appropriately. Assessment of baseline characteristics for both risk scoring methods, i.e. (i) defined by the centres during the trial and (ii) determined retrospectively for this thesis, highlighted some minor differences as age and presence of ST depression on the admission ECG increased more across the retrospectively determined GRACE categories. This could be explained by a combination of overestimation of risk for some low risk patients and under-estimation for some high risk patients since the intermediate category was the largest.

Improved risk scoring was associated with improved management of non-ST elevation ACS overall, as rates of the quality indicators were higher for patients that had been risk stratified. Importantly, risk stratified patients had higher rates of angiography and this was 10% higher for intermediate to high risk patients. There was a trend for all treatments to be higher for risk stratified patients. Improvement in the composite outcome measure was observed for all risk categories, indicating that the QI intervention targeted all patients, irrespective of risk.
Guidelines for management of non-ST elevation ACS recommend risk stratification using a formal method within the first 24 hours of admission. The results obtained in this chapter provide evidence that appropriate risk scoring leads to improved management of patients during the in-hospital phase.

7.2.3 Chapter 4: Patient and centre characteristics

A series of analyses were performed to assess the influence of individual patient and hospital characteristics on the outcome of the QI programme. The univariate analyses highlighted that patients with individual risk factors were less likely to be optimally managed. The proportion of patients receiving all eight ACS treatments was lower in the following categories: age more than 65 years, diabetes, female gender, previous stroke, previous MI, history of heart failure and high GRACE risk. In terms of hospital factors, lower performance at baseline was associated with improved management after the QI programme and the result varied across the five countries.

The influence of patient and centre characteristics was assessed in two multi-level multivariate mixed effects models, adjusting for patient and centre effects. Factors significantly associated with poorer management in the multivariate model assessing the composite outcome of eight ACS treatments were: female gender, history of heart failure, chronic kidney disease, prior stroke and Spain, UK or Italy. Factors significantly associated with improved management of ACS were: prior MI, admission to a QI centre during the post-QI implementation phase and number of cardiologists.

A second multivariate model to assess a composite outcome of seven ACS treatments, excluding risk stratification was conducted. Factors significantly associated with poorer management in the second multivariate model were: female gender, chronic kidney disease, prior stroke and admission to a centre in Spain. Factors significantly associated with improved use of ACS treatments were: prior MI, risk stratification, admission to a QI centre during the post-QI implementation phase and access to on-site PCI facilities.

The results of the multivariate analyses provide evidence that the QI intervention improved non-ST elevation ACS management irrespective of hospital size and type. Management of female patients, those with a history of heart failure, stroke or chronic kidney disease remained sub-optimal when all factors were accounted for, implying that further work is needed to ensure that healthcare professionals implement QI interventions consistently for
all patients admitted to their hospitals. Use of risk stratification was independently associated with increased use of all other ACS treatments expressed as a composite measure.

7.2.4 Chapter 5: Long-term follow-up

In order to look for sustainability of the improvement achieved by the QI intervention, two of the 38 hospitals continued to collect data for a year following delivery of the QI intervention. Both hospitals were in the QI group and data for 218 patients were collected during the additional year. The data collected showed that the effect of the QI intervention was relatively well maintained and performance, assessed by use of the eight guideline-recommended treatments expressed as a composite, remained higher than at baseline. The composite outcome measure and two of the individual treatments continued to be statistically higher than at baseline but further improvement was not observed. Prescription of treatments during the follow-up phase was lower than during the post-QI phase, indicating a possible trend for decline over time, although this was not statistically significant.

The results presented in this chapter provide evidence that improvement achieved by the EQUIP-ACS QI intervention was sustained up to a year after the QI intervention was delivered, but further improvement was not observed for any of the eight guideline-recommended treatments and the data indicate a trend for performance to decline after the study observation period. Further intervention may be required to ensure longer-term sustainability of results achieved and a different approach is needed to effect further improvement or improvement in areas other than those targeted by the initial QI programme. Plans for long-term or continuous evaluation of QI work should be built into a programme from the outset.

7.2.5 Chapter 6: Qualitative evaluation

A qualitative evaluation was designed to assess the impact of contextual factors on delivery of the QI intervention. Semi-structured interviews were conducted with 15 healthcare professionals that took part in the QI programme and this included nurses, clinicians and QI researchers. The interviews focused on delivery of the QI intervention, the goals selected, results achieved after the intervention, and the implications of these.

Analysis of the interview content revealed a range of themes that may facilitate or inhibit the successful delivery of the QI intervention. The themes identified were categorised into three main areas; people, process and environment. The sub-themes within these areas that appeared to be important were: leadership, incentives, training, teamwork, communication, simplicity of a process, automating or centralising a process, low baseline performance,
measurement, ability to have full control of a process, resources, accessibility to process and staff, working environment and culture. The three over-arching areas interact with each other and many of the sub-themes could apply to two or more of the main themes, implying that all of these need to be taken into account when designing and implementing QI work, rather than considering some factors in isolation.

7.3 Triangulation and interpretation of results

7.3.1 Sub-optimal adherence to guidelines

The QI intervention implemented during EQUIP-ACS resulted in a modest improvement in adherence to guidelines for non-ST elevation ACS. The QI intervention targeted all non-ST elevation patients irrespective of risk score and characteristics but there is evidence that some patient groups, notably females, those with a history of heart failure, prior stroke or chronic kidney disease are less likely to receive all the treatments. Interviews with health professionals indicated a reluctance to prescribe ACS medications for patients with chronic kidney disease which was also reflected in the results presented in Chapter 4.

Even in the absence of comorbidities, treatments were not given to all patients admitted to participating hospitals. For seven out of the eight treatments, this ranged from 80 to 95% and coronary angiography reached only 60% after delivery of the QI programme. The health professionals interviewed during the qualitative evaluation were surprised by the results they were shown in some cases, as they had expected level of treatment to be higher.

7.3.2 Factors influencing delivery of QI work

This research shows that quantitative factors alone do not explain the ability of the QI intervention to improve management of non-ST elevation ACS. Although there was a trend for high risk patients and those with comorbidities to receive less treatment, improvement was observed for all risk categories after delivery of the QI programme. Some patient characteristics were found to inhibit delivery of the QI programme, such as female gender, history of heart failure, prior stroke and chronic kidney disease but the effects were small and do not provide much information that can direct future QI work in this field.

Analyses conducted during this research do not indicate that hospital characteristics such as teaching status, size or number of admissions affect delivery of QI, although there is evidence that country and access to on-site PCI facilities is important. The number of cardiologists at a site was associated with improved level of treatment which is consistent with findings from the qualitative evaluation, where interviewees commented on the importance of involving consultant cardiologists in management of non-ST elevation ACS.
Results obtained from the qualitative evaluation do not fully explain delivery of the QI intervention either, though they have provided valuable insight into contextual factors that may be important. Analysis of the semi-structured interviews identified three key areas which should all be considered when designing and delivering a QI intervention. ‘Process’ factors are relevant for assessing how a treatment is given within a hospital and all the steps involved. Complexity of a process was considered important and this helps to explain why rates of angiography were still low after the QI intervention, since it is the most complex of the eight treatments assessed. ‘People’ factors explain individual and organisational incentives, the role of leadership, teamwork and involvement of stakeholders from design all the way through to interpretation of findings. In order to ensure all process and people factors are adequately addressed, ‘environment’ must also be considered to take account of organisational culture, available resource and organisational goals.

Considering these findings in concert highlights that QI is itself a complex process. In this research, the QI intervention targeted eight clinical management goals that were based on accepted clinical guidelines. During the randomised clinical trial, measurement was conducted using quantitative techniques only. The response to the intervention was variable, with variability present at both the individual and organisational level. Walshe et al have previously commented on the heterogeneous nature of QI as an intervention. (Walshe & Freeman 2002) The intervention is delivered in a complex, heterogeneous environment and yet the approach used is the same across all organisations. There is a need for QI interventions to be tailored to the setting and individuals working within that setting.

QI for healthcare attempts to bring two different schools of thought together to achieve a common goal; better patient care. Improvement scientists have developed tools based on proven industry models that can streamline work processes and clinicians use audit and publication of performance metrics to strive for optimal patient care. Attempts have been made to merge these two approaches but this has not yet succeeded. The original QI models were developed for the manufacturing industry which is likely to respond well to a standardised approach and is also driven by profit. Healthcare is delivered by people rather than technology and a standardised approach is not sufficient as it does not take account of behavioural factors. Whilst profit may be a driver in the U.S. healthcare setting, this is not the case for U.K. and European healthcare which are publicly funded. (Boaden, Harvey, Moxham, & Proudlove 2008; Simmons 2002)
Clinicians follow guidance for adoption of a new licensed treatment based on publication of convincing quantitative data. If the data for a new treatment show clear benefit to patients, it will be implemented in practice in due course. A similar approach is needed for QI work. If improvement scientists can present convincing efficacy data for QI interventions that translate to measurable benefit for patients, the uptake of QI work will increase. At present, QI initiatives are delivered by teams that are not directly involved in clinical practice or as part of a research study, so clinicians may not have input into the design and implementation of these.

7.3.2.1 Risk stratification

Interestingly, the only factor relating to patient management that was shown to improve overall adherence to guidelines was use of a formal risk score such as the GRACE or TIMI score. Analyses showed that there was a trend for rates of all treatments to increase if a patient was risk stratified and the greatest effect was noted for coronary angiography in intermediate and high risk patients. This is an important finding as rates of angiography remained low, at about 60%, after delivery of the QI programme and this provides evidence that appropriate risk stratification could have informed decisions about referral for angiography.

Discussions with healthcare professionals during the semi-structured interviews highlighted that clinicians are not convinced that formal risk scoring is valuable and consider that a global clinical evaluation to assess patient risk is adequate. The data presented in Chapters 3 and 4 however, indicate that clinicians did not make decisions on management strategy on the basis of clinical risk factors. This implies that when formal risk scores were not used, appropriate treatment was not always given. Treatment was sub-optimal for all patients and was worse for high risk patients and those with comorbidities, irrespective of whether risk is defined by a formal risk score or individual clinical factors.

7.3.3 Sustainability

The results obtained from this research show that more work is needed to ensure that improvement achieved can be sustained over time. Performance at the two centres that continued to collect data for an additional year remained higher than at baseline, but no further improvement was noted. As management of non-ST elevation ACS remained sub-optimal after delivery of the QI intervention, it would be expected that improvement should continue until near-optimal performance is achieved.
Interviews with staff from the two follow-up and other centres indicated that QI work was not ongoing and in most cases this had stopped soon after the end of the QI programme. The interviewees acknowledged that further work was needed to achieve higher standards of care and they also indicated that focus shifted once the trial had completed and results were no longer assessed.

Long term effects of the QI intervention were not considered until the end of the EQUIP-ACS project and whilst recommendations were made to the teams, the QI researchers did not follow up on the advice given nor did they plan further publications. Thus, the QI activity ended for both the researchers and the participating teams once the main results were published.

### 7.4 Recommendations

#### 7.4.1 Future clinical research and evaluation of QI work

The research reported in this thesis has identified a need for further evaluation of QI work in management of Acute Coronary Syndrome. Carefully designed research to assess QI programmes will generate convincing data to show that implementation on a wider scale would be valuable. In the same way that robust evidence for medicinal treatments or clinical procedures feeds into clinical guidelines eventually leading to change in clinical practice, evidence that QI work improves guideline-adherence would encourage uptake of QI work.

Improvement scientists should take the following important factors into account in designing QI programmes.

**Stakeholder engagement**

It is important to engage key stakeholders in the design, delivery and interpretation of QI work. The most important stakeholders for the programme described in this thesis were the clinical teams responsible for management of non-ST elevation ACS. In order to deliver a QI programme that is relevant to clinicians, they must be involved in goal selection, design, implementation and evaluation of the intervention.

Improvement scientists designing QI initiatives for healthcare should not be remote to the clinical community. Staff designing and delivering these initiatives need to identify a common goal and common language to ensure a cohesive approach. To ensure that clinicians are motivated to participate in QI programmes, it is advisable to present evidence of previous
successful QI programmes during training or launch meetings, using metrics that are clinically meaningful.

**QI interventions**
This thesis has shown that response to QI is variable. Some treatment goals increase more than others and some individuals and organisations are more susceptible to change than others. The choice of QI intervention should take all factors into account; those relating to patients, healthcare professionals delivering care, work processes involved, involvement of leadership and managerial staff, existence of teams that can deliver QI work and factors that motivate and incentivise stakeholders.

There cannot be one single QI approach and on the contrary, the approach needs to be tailored to suit the situation and clinical need. Encouraging clinicians to develop their own QI strategies locally, as was the case for the EQUIP-ACS project, ensures that the local teams take ownership for the planned QI work which in turn increases the likelihood of this being delivered effectively.

It would be valuable to conduct qualitative research in the form of semi-structured or in depth interviews prior to implementing a QI intervention, in order to identify potential areas for improvement, potential barriers and the likely response to the planned QI intervention.

**Measurement**
Availability of high quality data on an ongoing basis would enhance research of QI methods. The programme analysed for this thesis made use of a web-based data collection tool for the purposes of the study, but consideration should be given to using existing databases and registries to minimise the workload for participating clinicians. This will ensure that reliable data on practice patterns prior to delivering the intervention are available, but also that performance can be assessed in the future to evaluate the long-term effects of QI work.

Linking QI to existing registries is already possible for QI programmes conducted in the US where the ACTION registries are ongoing(Peterson, Roe, Rumsfeld, Shaw, Brindis, Fonarow, & Cannon 2009), or in Sweden where SWEDEHEART has been in place and is accessed by all hospitals(Jernberg, Attebring, Hambraeus, Ivert, James, Jeppsson, Lagerqvist, Lindahl, Stenestrand, & Wallentin 2010). QI work in the UK could benefit from collaborations between existing registries such as MINAP(Herrett et al. on behalf of the MINAP Academic Group 2010) and researchers planning QI programmes.
Consideration should also be given to the format of data used for QI research. Summary data or totals are not sufficiently informative for QI. Data on performance should be presented over time and broken down by regions, hospitals or departments where possible. This allows variation in performance to be identified so that improvement work can be targeted at the areas of greatest need.

Teams at the sites taking part in QI programmes should have access to data about their own performance and should attend central meetings where they can report on their performance to their peers. Knowledge that performance will be reported at public meetings will contribute to creating a culture of transparency and accountability.

**Sustainability**

Plans for long-term evaluation of QI interventions should be incorporated from the start and these should include quantitative and qualitative methods. Participating centres should be informed about plans for long term follow-up from the outset and this should be integral to taking part in the programme, not an optional aspect.

Consideration should be given to incentives associated with taking part in a QI programme, especially in the longer term. Incentives may take the form of monitoring or feedback reports and do not necessarily need to be financial. The centres participating in the EQUIP-ACS programme did not receive notable financial incentives, the only fee provided was a reimbursement to their organisations for time taken to enter data onto the trial database. Staff interviewed for the qualitative evaluation reported that presenting their results at local and central project meetings motivated them to continue improvement work and that this motivation waned when they knew they would no longer be required to present their data.

**Cost-effectiveness**

Estimating cost effectiveness of the EQUIP-ACS QI programme was beyond the scope of this thesis. Future QI research should focus on estimating the cost and cost-effectiveness of delivering QI interventions. Availability of cost-effectiveness data would enhance the evidence base for QI work and support decisions to implement interventions on a wider scale.

7.4.2 **Management of non-ST elevation ACS**

The data presented in this thesis show that management of non-ST elevation ACS remains sub-optimal with respect to guideline-recommendations. The research conducted for this thesis also provides evidence that use of formal risk stratification is associated with improved
prescription of ACS treatments and referral for coronary angiography. These data show that formal risk scoring is crucial as it can lead to appropriate decisions about invasive strategy and prescription of treatments.

It has been noted that clinicians interviewed during the qualitative evaluation were not convinced of the usefulness of risk scoring and it is important to address this issue so that this valuable tool for management of ACS is performed as a matter of routine. If more research focused on the effectiveness of risk scores at guiding management decisions compared to non-formal scores, use of scores would be more widely accepted. There is a need for robust evaluation of risk stratification methods in order to obtain convincing efficacy data.

Female patients and those with comorbidities including previous stroke, chronic kidney disease and a history of heart failure should receive the same standards of care as all other patients with ACS. In the absence of contraindications, clinicians should ensure that guideline recommended treatments are prescribed for all patient groups. Reports summarising rates of treatment in these populations should be provided to centres to raise awareness and encourage improved management.

7.4.3 Education

It has already been noted that engagement of clinicians at all stages of QI work is crucial to ensuring its successful delivery. It is necessary to provide formal training in QI concepts and methods to encourage health professionals to be engaged in improvement work. If health professionals have a good understanding of the methods required to improve healthcare, they will be more motivated to evaluate their own work processes and to set up their own initiatives.

Currently in the UK training courses are available for health professionals as part of continual professional development. Modules on evidence-based medicine and clinical audit are included in undergraduate medical training but this does not extend to implementing tools for improving healthcare.

An evidence scan conducted by the Health Foundation in 2012 to evaluate QI training noted that QI is now a mandatory component of education for medical students in the U.S. (The Health Foundation 2012) Training in QI methods is included from the early stages of undergraduate medicine in U.S. universities and includes a range of lectures and practical exercises to develop skills in QI tools and methods. (Ogrinc et al. 2011)
Research to assess the effect of QI training on outcomes is limited but a systematic review conducted by Wong et al reported that there is some evidence that introducing training at this early stage is effective. (Wong et al. 2010) The systematic review evaluated 41 curricula that targeted either medical students, residents or both, to assess the effect of QI education on associated evaluations conducted in healthcare settings. 32% of the studies conducted implemented changes in delivery of care and 17% improved processes of care.

The integration of QI methods into undergraduate medical training in the UK would develop future health professionals that possess the skills to analyse their own work processes, to identify areas for improvement and ultimately to implement methods to improve quality of care. If the key QI concepts and tools are introduced early in their training, clinicians will be capable of assessing their own processes on an ongoing basis. It is important to equip clinicians with the skills to improve quality of care, not just to enhance their understanding of the importance of guideline adherence.

7.4.4 Healthcare policy

It is important to consider the implications that this research has for healthcare policy. This section focuses on the implications for the NHS since the integrated results from quantitative and qualitative findings were mainly focussed on the UK setting. Over the course of this research there has been a change of government from Labour to Coalition, leading to changes in healthcare policy and extensive re-structuring of the NHS. It is timely to consider the government’s position on quality improvement, as the elections for a new parliament approach.

Current government policy

The current government presented plans for healthcare reforms in the White Paper entitled “Equity and Excellence: Liberating the NHS”. (Department of Health 2010) In terms of QI measures, the paper emphasised the importance of reporting outcomes which led to establishing the NHS Outcomes Framework. Five domains for reporting key outcomes were identified through the Outcomes Framework and these are reviewed on an annual basis with suggestions for additional indicators made as required. (Department of Health 2015)

The Department of Health (DOH) published a report on cardiovascular outcomes in 2013, describing improvement in cardiovascular outcomes but identifying actions for NHS Commissioners so as to ensure further improvement. (Department of Health 2013) Outcome data reported for all cardiovascular disease, including Acute Coronary Syndrome, identified
a wide variation of outcomes according to region. Poorer treatment for patients admitted
during the weekend was also reported. ACS patients with chronic kidney disease were found
to receive substantially fewer treatments despite higher mortality rates, which is consistent
with the findings reported in this thesis. (Department of Health 2013; Fox, Muntner, Chen,
Alexander, Roe, Cannon, Saucedo, Kontos, & Wiviott 2010a) The issue of worse treatment
being delivered over the weekend emerged as a theme from the qualitative evaluation
conducted as part of this thesis. Patients admitted for ACS should receive the same level of
care irrespective of the time of day or day of the week, something which has not been
achieved yet.

The DOH report on cardiovascular outcomes also noted that, despite recommendations
made by NICE guidelines (National Institute for Health and Clinical Excellence (NICE) 2010),
not all ACS patients are seen by a cardiologist or member of the cardiology team. The latest
MINAP annual report reports an improvement of this as over 90% of non-ST elevation ACS
patients were seen by a cardiologist or member of the team. (Myocardial Ischaemia National
Audit Project 2014)

The recent move to make clinical outcome data publicly available via the “Everyone Counts”
initiative was cited in the introduction of this thesis and demonstrates implementation of
some of the goals set out in the 2010 White Paper. (Department of Health 2010; NHS
Commissioning Board 2014) The importance of accessing good quality data has been
acknowledged throughout this thesis, but access to data does not constitute a complete QI
strategy. Publication of outcome data can help to identify areas for improvement but NHS
staff need to receive guidance on how to achieve improvement.

The King’s Fund, an independent charity that focuses on improving healthcare in England,
has published reports on the government’s implementation of NHS reform. (Gregory et al.
2012) The mid-term report highlighted that treatment continued to be variable particularly
with respect to weekends compared to mid-week hospital admission, but also with respect to
geographical location. The latest report entitled “The NHS under the coalition government:
Part One” recommends less emphasis on regulation and more focus on supporting NHS
staff to improve patient care. Inspections conducted by the Care Quality Commission (CQC)
in response to the Francis report on the Mid-Staffordshire disaster are considered useful in
that they identify areas requiring improvement, but the King’s Fund do not feel that this is
sufficient to justify the huge cost of CQC inspections. (Francis 2013; Ham et al. 2015)
The Berwick report “A promise to learn – a commitment to act”, written in response to the Francis enquiry, also emphasised that reforming healthcare and implementing more complex regulations will not lead to improved patient care. (Berwick 2013) Endless healthcare reforms create an atmosphere of insecurity rather than a proactive workforce. Berwick stresses that NHS staff need to be trained in QI methods in order to achieve a culture of continuous improvement in the NHS. He believes that investing in professional development in this way will create health professionals that would identify and resolve problems such as those that led to the Mid-Staffordshire disaster.

**Emerging and future healthcare policy**

The NHS “Five Year Forward” publication developed by the organisations that deliver health services in England represents emerging and future goals for the NHS. (NHS England 2014) Planned policies for QI include focusing on performance measurement and reporting of outcomes. This approach will continue to reveal areas for improvement but neglects to identify who is responsible for addressing these areas. The onus is on local authorities and organisations to improve their care but tools for them to achieve this are not to be provided. Emerging policies do not seem to include a robust strategy for quality improvement despite continuing reports of sub-optimal standards of care.

The current government aimed to save £20 billion over four years on the NHS and the Five Year Forward report hints at future plans for further cost saving in order to reduce the current deficit. Appleby, chief economist at the King’s Fund, does not feel that further cuts to NHS funding are realistic. The cuts proposed would require almost 5% saving per year and at present, the NHS is struggling to achieve a saving of 1%. (Appleby 2012)

Future plans for healthcare QI appear to be inadequate and NHS staff will struggle to improve standards of care in a continuing climate of financial hardship. Healthcare policies need to include robust plans for evaluation of QI interventions in order to generate reliable evidence that these strategies are effective. Results of QI programmes should be publicised, including details of the resources required to run these. Funding bodies should be encouraged to support well-conducted QI research.

The need for further clinical research has been recognised but this does not include evaluation of existing QI strategies. Investment in QI-focussed education is needed so that NHS staff will have the skills to be able to detect areas of sub-optimal care, develop strategies to resolve these and achieve sustainable improvements.
“The NHS in England can become the safest health care system in the world. That will require unified will, optimism, investment, and change. Everyone can and should help. And, it will require a culture firmly rooted in continual improvement. Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.”

Don Berwick, in response to the Francis inquiry on Mid-Staffordshire NHS Trust (Berwick 2013)

7.5 Limitations

There are a number of limitations that could have affected the research described in this thesis. The trial did not include measurement of clinical endpoints so it was not possible to assess whether improvements in the eight quality indicators selected was associated with improved patient outcomes. The assessment of clinical endpoints is especially important for evaluating management of non-ST elevation ACS since mortality rates for this population increase in the long term and may be even higher than for STEMI patients approximately 4 years after the index event. The EQUIP-ACS QI intervention did not include a formal long-term follow-up or plans to assess sustainability, this was implemented at the end of the project and only two of the 38 hospitals agreed to take part.

The importance of QI work being a continuous process has been acknowledged but the EQUIP-ACS programme was delivered as a standalone study with focus being maintained by the researchers only up to the point of publication of results. This means that both the researchers and the healthcare professionals at participating sites were guilty of ceasing to implement QI work once the study was complete.

The EQUIP-ACS study and all exploratory analyses reported here used the same eight quality indicators as the basis for assessing effectiveness of the QI programme. It would have been useful to include measurement of lifestyle factors including smoking cessation, diet and nutrition to evaluate the ability of QI to improve these.

It is also important to note that the programme did not include all non-ST elevation ACS admissions; patients over the age of 80 years were excluded. Patients over 80 years had been excluded because it was considered that applying a standard management approach to them would not be appropriate. The ESC 2007 guideline recommendations apply to patients over the age of 75 although they suggest a careful approach if there are multiple
comorbidities, but there is also evidence that improved guideline adherence for nonagenarians leads to decreased mortality rates. (Skolnick et al. 2007)

The EQUIP-ACS eligibility criteria also excluded true ‘low risk’ patients since patients needed to have either a troponin rise or ECG changes indicative of ischaemia to be entered onto the database. It would have been valuable to include data for all low risk admissions as well so that management of all non-ST elevation ACS patients could be appropriately assessed.

The exploratory analyses to assess influence of individual factors on the QI programme and effect of patient risk were conducted retrospectively and the main trial was not powered for these. Similarly, the long term follow-up involving two centres was an exploratory substudy and was not powered.

The qualitative evaluation was conducted and analysed by the author of this thesis who was also a member of the research team that delivered the QI programme. This could have introduced bias to the interpretation of results as it would be difficult to be purely subjective in the approach to coding content from the semi-structured interviews.

7.6 Conclusion

The hypothesis of this research was that a QI programme for healthcare professionals treating patients with non-ST elevation ACS can lead to measurable, meaningful and persistent improvement in standards of care. The multi-faceted QI intervention delivered during the EQUIP-ACS project was independently associated with improved management of non-ST elevation ACS, where management was assessed by use of eight guideline recommended treatments as a composite measure and as individual treatments. The absolute improvement observed for the composite measure was 8% which was considered clinically meaningful. A substudy to assess sustainability showed that standards of care remained higher than at baseline one year after delivery of the QI programme but that there may be a trend for performance to decline over time if further improvement initiatives are not implemented.

Management of non-ST elevation ACS remains sub-optimal even after implementation of a QI programme and the presence of comorbidities inhibits guideline-adherence. The use of formal risk scores was independently associated with improved use of all other ACS treatments including coronary angiography for intermediate and high risk patients.
Qualitative interviews conducted with healthcare professionals that took part in the EQUIP-ACS project however, indicated that the value of risk stratification methods is not recognised.

A range of process, staff and organisational factors must be considered prior to designing and implementing a QI intervention and notably, clinicians must be central to the entire process of QI. Investment in robust QI research must continue in order to obtain convincing evidence that patient care can be improved. Evidence that QI is successful coupled with in-depth training in QI methodology will lead to routine implementation of improvement work.
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APPENDIX 1. PUBLICATIONS AND PRESENTATIONS

Manuscripts


Abstracts


Submitted abstract
Babalis, D; Banya, W.; Cowie, M; Flather, MD., on behalf of the EQUIP-ACS Investigators: The effect of patient and centre characteristics on the outcome of a multi-faceted Quality Improvement programme. Submitted to the ESC 2015
## Appendix 2. Equip-Acs Case Report Form

### Admission – Personal Information

<table>
<thead>
<tr>
<th>Initials</th>
<th>Gender</th>
<th>Date of birth</th>
</tr>
</thead>
</table>

### Admission – Arrival Information

<table>
<thead>
<tr>
<th>Onset of symptoms</th>
<th>Date:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admitted to hospital</td>
<td>Date:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

### Admission - Risk factors

<table>
<thead>
<tr>
<th>Disease</th>
<th>0 No</th>
<th>1 Yes</th>
<th>9 Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Admission - Previous diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>0 No</th>
<th>1 Yes</th>
<th>9 Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous MI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous PCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous heart surgery</td>
<td>1 CABG</td>
<td>2 Other heart surgery</td>
<td>9 Unknown</td>
</tr>
<tr>
<td>Previous stroke</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic renal disease</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Medications taken prior to admission

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>0 No</th>
<th>1 Yes</th>
<th>9 Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE-inhibitors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A2-receptor blockers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anticoagulants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other platelet inhibitors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-blockers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium antagonists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes treatment-Insulin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes treatment-oral med.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac glycosides</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other lipid-lowering agents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-acting Nitrate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Admission - ECG and status at arrival

<table>
<thead>
<tr>
<th>ECG rhythm at arrival</th>
<th>1 Sinus</th>
<th>2 Atrial Fibrillation</th>
<th>3 Other</th>
<th>9 Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG QRS</td>
<td>1 Normal</td>
<td>2 Pacemaker</td>
<td>3 LBBB</td>
<td>4 Pathological Q-wave</td>
</tr>
<tr>
<td>ECG STT</td>
<td>1 Normal</td>
<td>2 ST-elevation</td>
<td>3 ST-depression</td>
<td>4 Pathol. T-wave</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart rate: Bloodpress:</th>
<th>/</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung rales</td>
<td>0 No</td>
</tr>
<tr>
<td>Cardiog. shock at arrival</td>
<td>0 No</td>
</tr>
</tbody>
</table>

### Actions performed within 24h

<table>
<thead>
<tr>
<th>Risk stratification (performed)</th>
<th>0 No</th>
<th>1 Yes with Grace score</th>
<th>2 Yes with TIMI score</th>
<th>3 Yes with other method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result risk stratification</td>
<td>1 Low risk</td>
<td>2 Intermediate risk</td>
<td>3 High risk</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel loading dose (&gt;300 mg)*</td>
<td>0 No</td>
<td>1 Yes</td>
<td></td>
<td></td>
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</table>

### Hospitalisation - Medications

<table>
<thead>
<tr>
<th>Reperfusion treatment</th>
<th>0 No</th>
<th>1 Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iv/sc Anticoagulants</td>
<td>0 No</td>
<td>1 Iv Heparin</td>
</tr>
<tr>
<td>Statins within 4 days</td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>Iv Platelet inhibitors</td>
<td>0 No</td>
<td>1 Abciximab</td>
</tr>
<tr>
<td>Iv/oral Beta-blockers</td>
<td>0 No</td>
<td>1 Iv Beta-blockers</td>
</tr>
<tr>
<td></td>
<td>0 No</td>
<td>1 Yes</td>
</tr>
<tr>
<td>------------------------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>Iv Diuretics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iv Inotropic drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iv Nitrate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospitalisation - Investigations and Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of stress test</strong></td>
</tr>
<tr>
<td><strong>Result of stress test</strong></td>
</tr>
<tr>
<td><strong>LVEF evaluated by</strong></td>
</tr>
<tr>
<td><strong>LVEF</strong></td>
</tr>
<tr>
<td><strong>Coronary angiography</strong></td>
</tr>
<tr>
<td><strong>PCI</strong></td>
</tr>
<tr>
<td><strong>CABG</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Hospitalisation - Laboratory results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiac marker</strong></td>
</tr>
<tr>
<td><strong>Maximum value of marker</strong></td>
</tr>
<tr>
<td><strong>Total Cholesterol</strong></td>
</tr>
<tr>
<td><strong>Triglycerides</strong></td>
</tr>
<tr>
<td><strong>HDL</strong></td>
</tr>
<tr>
<td><strong>Creatinine</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospitalisation - Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New infarction during hospitalisation</strong></td>
</tr>
<tr>
<td><strong>Bleeding during hospitalisation</strong></td>
</tr>
<tr>
<td><strong>CPR or cardioversion in assoc. with circulatory arrest</strong></td>
</tr>
<tr>
<td><strong>Cardiogenic shock</strong></td>
</tr>
<tr>
<td><strong>AV-block</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Discharge - Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACE-inhibitors</strong></td>
</tr>
<tr>
<td><strong>A2-receptor antagonists</strong></td>
</tr>
<tr>
<td><strong>Oral anticoagulants</strong></td>
</tr>
<tr>
<td><strong>Aspirin</strong></td>
</tr>
<tr>
<td><strong>Other platelet inhibitors</strong></td>
</tr>
<tr>
<td><strong>Beta-blockers</strong></td>
</tr>
<tr>
<td><strong>Calcium antagonist</strong></td>
</tr>
<tr>
<td><strong>Diabetes treatment - Insulin</strong></td>
</tr>
<tr>
<td><strong>Diabetes treatment - Oral medication</strong></td>
</tr>
<tr>
<td><strong>Cardiac glycosides</strong></td>
</tr>
<tr>
<td><strong>Diuretics</strong></td>
</tr>
<tr>
<td><strong>Statins</strong></td>
</tr>
<tr>
<td>Other lipid-lowering drugs</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Long-acting Nitrate</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Discharge – Diagnosis**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>1 Myocardial infarction</th>
<th>2 Unstable Angina</th>
<th>3 Other cardiac disease</th>
<th>4 Other specified non-cardiac disease</th>
<th>5 Unspecified chest pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0 No</td>
<td>1 Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date of Discharge or Death:**
APPENDIX 3. ETHICAL APPROVAL FOR EQUIP-ACS PROJECT

Essex 1 Research Ethics Committee
(Note: ESSEX 1 and ESSEX 2 REC’s are an amalgamation of South Essex, North & Mid Essex and West Essex REC’s)
Level 9 Terminus House The High
Harlow Essex CM20 1XA

Tel/Fax: 01279 604917
Email: liz.wrighton@eeo.nhs.uk

20 March 2007

Dr Marcus Flather
Director, Clinical Trials and Evaluation Unit
Clinical Trials and Evaluation Unit
Royal Brompton Hospital
Sydney Street
London SW3 6NP

Dear Dr Flather

Full title of study: European Quality Improvement Programme for Acute Coronary Syndrome
REC reference number: 07/Q/0301/11

Thank you for your letter of 28 February 2007, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chairman.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed they have no objection.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td></td>
<td>22 January 2007</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>17 August 2006</td>
</tr>
</tbody>
</table>
Protocol | 10 | 27 November 2006  
Protocol | 10.1 | 28 February 2007  
Covering Letter | | 19 January 2007  
Summary/Synopsis | 1.0 | 27 November 2006  
Letter from Sponsor | | 09 January 2007  
Response to Request for Further Information | | 28 February 2007  
List of proposed UK sites | |  
Summary of sample size calculations | 1 | 27 November 2006  

R&D approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final approval from the R&D office for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/Q0301/11

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely,

Hugh Bills
Chairman

Enclosures:

- Standard approval conditions
- Site approval form

Copy to:

Mrs Wendy Butcher
Royal Brompton & Harefield NHS Trust
Research and Development Department
Sydney Street
London
SW3 6NP

An advisory Committee to East of England Strategic Health Authority
APPENDIX 4. ETHICAL APPROVAL FOR INTER-EQUIP STUDY

National Research Ethics Service
Royal Free Hospital & Medical School Research Ethics Committee
Royal Free Hospital NHS Trust
Royal Free Hospital
South House, Block A
Pond Street
London
NW3 2QG

Telephone: 0207 794 0581
Facsimile: 0207 794 0714

24 March 2010

Miss Daphne Babalis
Clinical Trials and Evaluation Unit
Royal Brompton Hospital
Sydney Street, London
SW3 6NP

Dear Miss Babalis

Study Title: A semi-structured INTERview programme to explore the factors that determine outcome of a European Quality Improvement Programme for Acute Coronary Syndromes (EQUIP-ACS).

REC reference number: 10/H0720/20
Protocol number: 1.3

The Research Ethics Committee reviewed the above application at the meeting held on 17 March 2010. Thank you for attending to discuss the study.

Ethical opinion

“This study followed on from a previous study and the committee noted that the results of that study were not yet in the public domain. Miss Babalis reassured the committee that she had the final version of the results as a starting point for this study and that the study was ready for publication. The results indicated that the intervention produced improvement in the average institution but there were institutions whose performance deteriorated after the intervention. The reasons for this discrepancy warranted further investigation”.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of
the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www rdforum nhs uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering Letter</td>
<td></td>
<td>05 February 2010</td>
</tr>
<tr>
<td>REC application</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol</td>
<td>1.3</td>
<td>28 January 2010</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>1.0</td>
<td>28 January 2010</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>1.0</td>
<td>28 January 2010</td>
</tr>
<tr>
<td>Supervisor CV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
<td>1.0</td>
<td>28 January 2010</td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:
• Notifying substantial amendments
• Adding new sites and investigators
• Progress and safety reports
• Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.rpsa.nhs.uk.

10/H0720/20

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

Dr Michael Pegg
Chair

Email: rosemary.brown@royalfree.nhs.uk

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" [SL-AR1 for CTIMPs, SL-AR2 for other studies]

Copy to:

Miss Lucy Parker
[R&D office for NHS care organisation at lead site]