Assessing the Use of the

Medication Safety Thermometer

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Contents

List of Tables 5
List of Figures 6
List of Appendices 7
List of Abbreviations 8
Thesis Abstract 9
Declaration and Copyright Statement 10
Acknowledgements 11
Rationale for Submitting in the Alternative Thesis Format 12
Dissemination of Research 13
    Publications 13
    Presentations 13
    Other Forms of Dissemination 14

SECTION ONE: INTRODUCTION AND BACKGROUND 15
Introduction to the Research Studies and Thesis Structure 16
Brief Overview of Thesis Sections 17
    Section One 17
    Section Two 17
    Section Three 17
    Section Four 18
    Section Five 18
Contributors 19

Chapter One: 22
Introduction 22
    1.1 Introduction 22

Chapter Two: 25
Background on Medication Safety 25
    2.1 Patient safety 25
    2.2Medication Safety 26
        2.2.1 Definitions and Classification Systems Used for Medication Errors 29
        2.2.2 Prescribing Errors 35
        2.2.3 Dispensing Errors 37
        2.2.4 Administration Errors 38
        2.2.5 Definitions Used in this Programme of Work 39
    2.3 Types of Harm from Medication 40
    2.4 Measuring Medication Safety and Associated Harm 41
    2.5 Summary of Chapter 42

Chapter Three: 44
Background on Improvement Science and the Safety Thermometers 44
    3.1 Improvement Science 44
    3.2 Using Improvement Science to Improve Patient Safety 45
        3.2.1 Plan-Do-Study-Act Cycle Methodology 46
    3.3 The Importance of Evaluating Improvement Initiatives 47

3.4 The NHS Safety Thermometers 48
3.4.1 The Original Safety Thermometer 48
3.4.2 Evaluation of the Original Safety Thermometer 51
3.4.3 The Next Generation Safety Thermometers 53
3.5 The Medication Safety Thermometer 53
3.5.1 Development of the Medication Safety Thermometer 54
3.5.2 The Current Medication Safety Thermometer Tool: Version 16 55
3.5.3 MedsST Guidance 57
3.5.4 CQUIN Targets 58
3.5.6 Medication Safety Thermometer Data 58
3.5.7 Evaluation of the Medication Safety Thermometer and Use of its Data 59
3.6 Summary of Chapter 60

Chapter Four – Thesis Aim 62

SECTION TWO: METHODOLOGY 63

Chapter Five: 65
Methods 65
5.1 Paradigms 65
5.1.1 Postpositivism 65
5.1.2 Constructivism 66
5.1.3 Transformatism 66
5.1.4 Pragmatism 67
5.2 Use of the Pragmatist Paradigm to Guide this Programme of Work 67
5.2.1 Reflexivity 68
5.3 Mixed-Methods Methodology 69
5.4 Rationale for Using a Mixed-Methods Approach 69
5.5 Types of Mixed-Methods Research Designs 70
5.6 Rationale for Using Sequential Mixed-Methods Approach 71
5.7 Qualitative Strategies Used in this Research 72
5.7.1 Qualitative Documentary Analysis 73
5.7.2 Underpinning Theories for the Qualitative Strand of Research 73
5.7.3 Use of Grounded Theory 74
5.7.4 Use of Normalisation Process Theory 74
5.8 Quantitative Strategies Used in this Research 75
5.9 Key Issues in this Programme of Research 76
5.9.1 Reliability and Trustworthiness of the Research 76
5.9.2 Ethical Issues 77
5.9.3 Ethical Approvals 78

SECTION THREE: INVESTIGATING HOW THE MEDICATION SAFETY THERMOMETER HAS BEEN DEISGNED, DEVELOPED AND IMPLEMENTED NATIONALLY AND LOCALLY WITHIN ORGANISATIONS 80

Chapter Six: 82

Chapter Seven: 112

SECTION FOUR: EXPLORING THE USE OF THE MEDICATION SAFETY THERMOMETER DATA 150

Chapter Eight: 152

Chapter Nine: 194

SECTION FIVE: GENERAL DISCUSSION 228

Chapter Ten: 230
Discussion 230
- **10.1 Summary of Findings** 230
- **10.2 Key Strengths and Limitations of the Studies** 233
- **10.3 Contribution of Thesis Studies to the Literature** 236
  - **10.3.1 Normalising Use of the Medication Safety Thermometer.** 238
  - **10.3.2 Use of Data Collected for Medication Safety Research Purposes** 239
  - **10.3.3 The System of Data Collection, Review and Use for Improvement** 240
- **10.4 Implications for Policy and Practice** 240
- **10.5 Future Research and Quality Improvement** 244
  - **10.5.1 Improving the Quality of Medication Safety Data Collected** 244
  - **10.5.2 Future Research for Primary Care Settings** 245
  - **10.5.3 Use of Implementation Theory for Implementing Initiatives.** 246
  - **10.5.4 Further Research using Medication Safety Thermometer Data** 246
  - **10.5.5 Further Research of Positive Deviance** 246
- **10.6 Final Conclusions** 247

Thesis References 249
Thesis Appendices 261

List of Tables

Thesis Sub-section Tables

Table 1.0 –The Four Domains of the World Health Organizations' Third Patient Safety Challenge: Medication Without Harm **28**
Table 2.0 – Definitions of Medication Errors and Severity in Studies Undertaken in NHS secondary care **31**
Table 3.0 – Run Chart Rules for Special Cause Variation **51**
Table 4.0 – Steps of the Medication Safety Thermometer **56**

Study Tables

Study One Tables

Table A.1 – Changes in Operational Definitions Over Time **101**
Table A.2 – Summary of PDSA Cycles Involved in Developing Step 1 ..... **104**
Table A.3 – Summary of PDSA Cycles Involved in Developing Step 2 ..... **107**

Study Two Tables

Table B.1 – Descriptive Themes and their Definition **142**
Table B.2 – Participant Details **143**

Study Three Tables

Table C.1 – Run Chart Rules for Special Cause Variation **176**
Table C.2 – Descriptive Themes and their Definitions **176**
Table C.3 – Case studies of how Medication Safety Thermometer data had been Used **177**

Study Four Tables

Table D.1 – Reasons for Overall Omissions and Within Each High-risk Drug Group **213**
Table D.2 – Reasons for Omissions of High-Risk Medicines on Medical and Surgical Wards **214**
Table D.3 – Univariable Logistic Regression Model: Prevalence of Patients with Omissions and Chi-Square tests **215**
Table D.4 – Multivariable Model: Prevalence of Patients with Omissions, Surveyed by the MedsST in January 2015 with Adjusted Odds Ratios from a Three-Level Logistic Regression Model with Random Effects at Hospital and Ward Levels **216**

List of Figures

Thesis Sub-Section Figures

Figure 1.0 – Reason's Model of Accident Causation **36**
Figure 2.0 – The Relationship Between Adverse Drug Events, Potential Adverse Drug Events, and Medication Errors **41**
Figure 3.0 – Framing the Science of Improvement **44**
Figure 4.0 – The Quality Improvement model **46**
Figure 5.0 – NHS Outcome Framework 2010/2011 ..... **50**
Figure 6.0 – The Safety Thermometer Family **53**
Figure 7.0 – Mixed-Methods Design Matrix **70**
Figure 8.0 – Summary of the Aims of the Studies Presented in this PhD Thesis..... **230**

Study Figures

Study One Figures

Figure A.1 – Project Plan Framework **99**
Figure A.2:
Figure A.2a - Proportion of Patients with a Medicines Reconciliation Started in the Last Twenty-Four Hours of Admission to Setting **100**
Figure A.2b - Proportion of Patients with Omissions of Critical Medicine(s) in the Last Twenty-Four Hours **100**
Figure A.2c - Proportion of Patients who have had an Omitted Dose in the Last Twenty-Four Hours **100**
Figure A.2d - Number of Critical Omissions by Medication Class ... **100**

Study Three Figures

Figure C.1 – Run Chart 1: Proportion of Patients with Medicines Reconciliation Started Within Twenty-Four hours on Ward A6 (General Surgery) of Hospital A **178**
Figure C.2 –Run Chart 2: Proportion of Patients with Omissions Excluding Valid Clinical Reasons on Wards C1 & C2 (Hepatology and Gastroenterology) at Hospital C **178**

Study Four Figures

Figure D.1 – Medication Safety Thermometer Question 1.6 (from Version 16) Regarding Medication Administration Omissions **199**

List of Appendices

Thesis Sub-Section Appendices

Appendix 1.0 – The Medication Safety Thermometer (Version 16a Acute) **261**
Appendix 2.0 – The Medication Safety Thermometer (Version 16b Community) **262**
Appendix 3.0 – The Medication Safety Thermometer Step 3 (Version 16 Acute and Community) **263**
Appendix 4.0 – The Original Safety Thermometer **264**
Appendix 5.0 – University Research Ethics Committee Approval **265**
Appendix 6.0 – Invitation Email **266**
Appendix 7.0 – Participant Information Sheet (Leads) **267**
Appendix 8.0 – Participant Information Sheet Form (Users) **270**
Appendix 9.0 – Consent Form **273**
Appendix 10.0 – Certification of Participation **274**

Study Appendices

Study One

Appendix A.1 – The Medication Safety Thermometer Version 1 (Step 1) .. **109**
Appendix A.2 – The Medication Safety Thermometer Version 8 (Step 1) .. **110**

Study Two

Appendix B.1 – Approximate Interview Schedule **144**
Appendix B.2 – COREQ Checklist **145**

Study Three

Appendix C.1 – Aggregated Hospital data **179**
Appendix C.2 – Hospital A Medication Safety Thermometer Data **180**
Appendix C.3 – Hospital B Medication Safety Thermometer Data **182**
Appendix C.4 – Hospital C Medication Safety Thermometer Data **185**
Appendix C.5 – SQUIRE Checklist **187**

Study Four

Appendix D.1 –RECORD Checklist **217**

List of Abbreviations

ACE Inhibitor	Angiotensin-Converting-Enzyme Inhibitor
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
App	Application (for mobile phone or electronic tablets)
BMJ	British Medical Journal
CCG	Clinical Commissioning Group
CEO	Chief Executive Officer
CI	Confidence Interval
CQUIN	Commissioning for Quality and Innovation
DoH	Department of Health
HSRPP	Health Services Research and Pharmacy Practice
IJQHC	International Journal for Quality in Health Care
IHI	Institute of Healthcare Innovation
INR	International Normalised Ratio
IoM	Institute of Medicine
ISQua	International Society for Quality in health-care
IQR	Interquartile range
MDT	Multi-Disciplinary Team
MedsST	Medication Safety Thermometer
ME	Medication Error
NHS	National Health Service
NPSA	National Patient Safety Agency
NPT	Normalisation Process Theory
NRLS	National Reporting and Learning System
OR	Odds Ratio
Original ST	Original Safety Thermometer
PDSA	Plan-Do-Study-Act
PLOS one	Public Library of Science one
PR	Patient Refusal omissions
QC	Queens Counsel
QIPP	Quality, Innovation, Productivity and Prevention
RPS	Royal Pharmaceutical Society
SCV	Special Cause Variation
SPC	Statistical Process Control
ST	Safety Thermometer
UK	United Kingdom
USA	United States of America
UTI	Urinary Tract Infection
UREC	University Research and Ethics Committee
VCR	Valid Clinical Reason omissions
VTE	Venous Thromboembolism
WHO	World Health Organization

Thesis Abstract

Despite the increased focus on medication safety in the last two decades, it is difficult to know if anticipated improvements are occurring as medication safety is not routinely measured in healthcare settings. To address this issue within the UK National Health Service (NHS), the Medication Safety Thermometer (MedsST) was developed in 2013 with the aim of enabling organisations to collect routine data to monitor medication safety and related improvement over time. Guidance about use of the MedsST was developed, but a knowledge gap existed about how it had been implemented into practice, used to monitor medication safety and to facilitate improvements. This programme of research aimed to examine these issues by conducting four related studies.

The initial part of the programme of research explored how the MedsST has been designed, developed and implemented nationally. Study One investigated the design, development and national implementation of the MedsST and found that measuring harm from medication errors is complex and requires several steps to measure individual errors, triggers of harm and actual harm. Improvement science methods, particularly Plan-Do-Study-Act cycles, were found to be useful for developing complex systems. Study Two was a qualitative study that explored how the MedsST had been implemented within individual organisations. This study found that all staff involved with the MedsST understood what the tool was and why measurement was vital for facilitating improvements in medication safety. However, less understanding existed about how MedsST data could be used for improvement. Several issues with the MedsST implementation were also highlighted such as it being unsuitable for use in primary care settings.

The second part of the programme of research investigated how MedsST data were used or could be used for learning about and improving medication safety. Study Three was a qualitative study that used quantitative MedsST data to find out how data had been used for improving medication safety in hospitals. The study found that only a small amount of data had been used for improvement, and that this was often at ward-level. Although some improvement had occurred, communication about improvements was poor and most data remained not viewed and unused. Study Four was quantitative and used nationally aggregated MedsST data to determine the prevalence, nature and predictors of patients experiencing medication administration omissions in hospitals, as an exemplar of how MedsST data could be used to learn about medication safety issues. It was found that 30% of patients experienced omissions (95% confidence interval [CI] 29-30) (excluding valid clinical reasons). The rates found were similar to that of previous research, reiterating that omissions are a substantial problem.

The research presented in this thesis demonstrated that there had been success in the implementation of the MedsST for data collection, but limited success in terms of using collected data for learning and improvement purposes. In order for more improvements in medication safety to occur, more work needs to be done within the NHS to successfully implement a system of data collection, review and use of MedsST data as a holistic system. This thesis has provided specific recommendations to increase engagement with this holistic system, and for healthcare organisations and researchers to benefit from collected MedsST data with the aim of improving medication safety.

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Rationale for Submitting in the Alternative Thesis Format

The alternative thesis format has been used as the structure for this thesis. The background, methods and discussion chapters of the alternative format is similar to that of standard format theses. However, in the alternative format, empirical work is organised as stand-alone papers in a format similar to a manuscript submitted for publication. This format was chosen based on the aim of this programme of research, which was to explore how the MedsST has been designed, developed and used and to inform and help improvements in medication safety practice. Findings from each study dictated the design of the subsequent studies. The construction of this programme of research, therefore, allowed individual papers to be written and submitted to suitable journals. The alternative format thesis was chosen as a method to disseminate findings to the wide range of healthcare staff using the MedsST to ensure best use. The alternative format also assisted the author in acquiring the skills and experience required for publishing journal articles.

Dissemination of Research

Publications

All four studies from this thesis have been written as journal articles. To date, two studies have been published by journals and two studies have been submitted to journals. The published studies are:

- Study One (Chapter Six): *Learning from the design, development and implementation of the Medication Safety Thermometer* – published in the International Journal of quality in Health Care (IJQHC) in 2017(1).
- Study Two (Chapter Seven): *A formative evaluation of the implementation of a Medication Safety data collection tool in English healthcare settings: a qualitative interview study using normalisation process theory* – published in PLOS One in 2018 (2).

The studies with manuscripts that have been submitted to journals are:

- Study Three (Chapter Eight): *A qualitative study exploring how routinely collected Medication Safety Thermometer data have been used for Quality Improvement purposes, using case studies from three UK hospitals* – submitted to BMJ Open in July 2018.
- Study Four (Chapter Nine): *Prevalence, nature and risk factors for medication administration omissions in hospital inpatients: a retrospective multi-centre study* – submitted to BMJ Open in November 2018.

Presentations

Studies One - Three have been presented in the form of posters and oral presentations at various conferences to various audiences including pharmacists, nurses, doctors and improvement scientists. An abstract based on Study Four has also been submitted to a conference. Details of presentations and conferences are as follows:

- Study One (Chapter Six): has been presented by poster at the Innovation Showcase of the Royal Pharmaceutical Society (RPS) Conference 2016 in Birmingham to an audience consisting mainly of pharmacy professionals and researchers, and by oral presentation at the Improvement Science Conference in Harrogate in 2016 to an audience

consisting of both improvement scientists and various healthcare professionals.

- Study Two (Chapter Seven): has been disseminated by poster presentation at the Health Services Research and Pharmacy Practice Conference 2017 in Nottingham (3) and by oral presentation at the International Society for Quality in Healthcare Conference 2017 in London to an audience consisting of healthcare professionals and researchers interested in improving healthcare settings (4).
- Study Three (Chapter Eight): has been presented at the RPS Winter Summit in London in 2017 (5) and the Improvement Science Research Symposium of the BMJ Quality and Safety Forum 2018 in Amsterdam.
- Study Four (Chapter Nine): has been submitted for presentation at the RPS Science and Research Summit 2019.

Other Forms of Dissemination

Findings from all studies have also been presented at meetings and used for teaching purposes:

- Study One (Chapter Six) has been used to facilitate a quality-in-practice publications workshop for the Health Foundation's "Innovate for Improvement mid-point event" in September 2017.
- Study Two (Chapter Seven) has been presented in an MedsST monthly online meeting in May 2015 to the steering committee facilitating the development of staff involved with the development of the MedsST.
- Study Three (Chapter Seven) has been presented at the Manchester Academic Health Sciences Centre (MAHSC) Population Health and Implementation domain meeting in March 2017.
- Findings from Study Four have been used to develop a module for secondary school pupils in Chesterfield titled "Missing Medications: Safe or Sorry" which is being taught between October 2018 – January 2019.

SECTION ONE: INTRODUCTION AND BACKGROUND

Introduction to the Research Studies and Thesis Structure

This thesis comprises a series of research studies related to a programme of research evaluating the NHS Medication Safety Thermometer (MedsST), a tool that was developed to assist healthcare organisations to measure medication safety, by providing a 'temperature check' on harm and to monitor related improvement over time. To date, the MedsST has been used by over 100 organisations to collect data about patients but evaluating the use of the MedsST is not just about reviewing collected data. It is about understanding what the MedsST is and how its data can be used for patient-centred improvement of healthcare. This requires focus on the social and cultural factors affecting the implementation and use of the tool.

Each of the studies included in this thesis aims to add to the current understanding of patient safety measurement tools in the context of medication safety and to suggest ways of improving engagement with the MedsST.

As the thesis is presented in the alternative format, the chapters presenting the empirical studies of this programme of research have been written and presented as journal articles (Chapters Six – Nine). As these studies have already been published or submitted to journals, formatting and layout of each of the study chapters are consistent with the published paper or target journal guidelines. Furthermore, references and appendices that were published or submitted with the article are placed at the end of each of these chapters rather than at the end of the thesis. This has been clearly indicated at the start of each chapter with the most up-to-date submission status.

Brief Overview of Thesis Sections

Section One

Section One comprises three chapters that provide an introduction and background to this programme of research. Chapter One provides a brief introduction to and description of this programme of research. Chapter Two provides the necessary background information about medication safety. Chapter Three provides the necessary background about Improvement Science, the Safety Thermometers, and a detailed description of the MedsST. The summary of Section One outlines the current gaps in knowledge that this programme seeks to address.

Section Two

Section Two comprises two chapters about the aims and objectives of this programme of research and the methodology that has been used to achieve them. Chapter Four states the aim and objectives that this programme of work seeks to address. Chapter Five provides a rationale for the overall approach taken for this programme of research and a description of the methods employed in each study. The underpinning theoretical framework, methodological issues and ethical considerations in this programme of research are also presented and discussed.

Section Three

Section Three comprises two empirical studies presented in journal article formats. These studies investigated how the MedsST has been designed, developed and implemented nationally, and locally within organisations. Chapter Six presents Study One, which involved a narrative literature review of the design, development and implementation of the MedsST. Chapter Seven presents Study Two, which was a qualitative interview study exploring how the MedsST has been implemented across English healthcare settings using implementation theory.

Section Four

Section Four comprises two further empirical studies presented in journal article formats. These studies investigated how the data collected by the MedsST can be used to improve medication safety. This included how data can be used at local levels within individual hospitals (Chapter Eight) and how nationally aggregated data can be used to investigate medication omissions (Chapter Nine).

Chapter Eight presents Study Three, which used a mixed-methods approach to explore how the MedsST has been used locally to aid improvement within Greater Manchester, where it was originally designed and has been used for the longest period of time.

Chapter Nine presents Study Four, which was a retrospective multi-centre study exploring the prevalence, nature and risk factors for medication administration omissions in hospital inpatients by using MedsST. This study demonstrated how MedsST data can be aggregated and used at national levels and used omissions data as an exemplar MedsST measure.

Section Five

Section Five, consists of Chapter Ten, which draws the programme of research to a conclusion. It summarises the key findings from each study in this programme of research, outlines the key strengths and limitations, and discusses the contribution of findings to the existing literature. This chapter also outlines the implication of the findings for policy and practice and suggests areas for further research.

Contributors

The candidate, Paryaneh Rostami, took the main role in the production of all papers included in this thesis and wrote the other chapters within this thesis. The Supervisors of this PhD (MPT and DMA) provided feedback on all chapters.

This programme of work included four separate studies. Ms Rostami conceptualised and designed all of these studies, collected or extracted data, conducted analyses, drafted and revised manuscripts, submitted the manuscripts, responded to peer reviews and wrote the thesis.

The MedsST was developed by a large multi-disciplinary collaborative and development was initiated in 2011, before this programme of work commenced. It was important to involve these individuals as authors in some of the studies (Studies One, Three and Four) to ensure a balanced and accurate description of the development, design and implementation of the MedsST, using their varying knowledge and documentation from the early stages of development.

Co-contributors and co-authors are presented in this section, along with the studies they contributed to and their qualifications.

Mary P. Tully, ***Reader in Pharmacy Practice, The University of Manchester***
PhD, FFRPS, FRPharmS
Studies One, Two, Three and Four
Dr Tully is PR's main supervisor. She conceptualised all of these studies with PR, contributed to analyses and critically reviewed all manuscripts.

Darren Ashcroft, ***Professor of Pharmacoepidemiology, The University of Manchester***
BPharm, MSc, PhD, FRPharmS
Studies One, Two, Three and Four

Professor Ashcroft is PR's second supervisor. He also conceptualised the studies, contributed to analyses and critically reviewed PR's manuscripts

Abigail Harrison, *Director of Innovation, Haelo*

MA

Studies One, Three and Four

Ms Harrison oversaw the early stages of the development of the MedsST and therefore assisted with Study One regarding the development of the tool. She also assisted with access to data in Studies One, Two and Four, and contributed to the interpretation of quantitative data in these studies. Ms Harrison also contributed to and critically reviewed the resulting papers for these three studies.

Gareth Parry, *Senior Improvement Scientist, The Institute of Health Care Improvement (IHI)*

PhD, MSc

Studies Three and Four

Dr Parry acted as adviser with expertise in Improvement Science, in the final 2 years of this PhD programme. He contributed to the design of Studies Two and Four and critically reviewed associated manuscripts and abstracts.

Maxine Power, *Former Chief Executive Officer (CEO), Haelo.*

PhD, MPH

Study One

Professor Power was the former CEO of Haelo (an independent innovation and improvement centre, hosted by Salford Royal Foundation Trust) who facilitated the development of the MedsST. Professor Power was also one of the leaders of the development of the original Safety Thermometer (ST), on which the MedsST is based, and contributed to the design of Study 1 and critically reviewed the associated manuscript.

Kurt Bramfitt, Senior Improvement Advisor, Haelo

BA (hons)

Study One

Mr Bramfitt acted as an adviser with expertise in ST data analysis. He assisted with access and interpretation of data in Study One and critically reviewed the associated manuscript.

Steve Williams, ***Former Consultant Medication Safety Pharmacist, University Hospitals of Southern Manchester***

MPhil, MRPharmS

Study One

Mr Williams acted as an adviser who had been involved with the development and national rollout of the MedsST and assisted with interpretation of data for Study One and reviewed the associated manuscript.

Yogini Jani, ***Consultant Medication Safety Pharmacist, University College London***

PhD, ClinDip, MRPharmS

Study One

Ms Jani had been involved with the development and national rollout of the MedsST and contributed to writing the manuscript for Study One and critical review of the paper.

Calvin Heal, ***Medical Statistician, The University of Manchester***

MSc

Study Four

Mr Heal provided statistical advice and critically reviewed the statistical methodology of Study Four.

Chapter One:
Introduction

1.1 Introduction

The UK NHS was launched on July 5th, 1948. It aims to provide a comprehensive healthcare service to all citizens in the UK and is funded by public taxes. Its main principles include ensuring the highest standards of excellence and putting patients at the heart of everything it does, and therefore it is held accountable to the public that it serves (6).

In the last two decades, there has been an increased focus on patient safety within the NHS, since the publication of reports both in the UK and globally highlighting that approximately one in ten patients are harmed by healthcare(7, 8). These reports, such as 'To Err is Human'(9) by the US Institute of Medicine (IoM) and 'An Organisation with a Memory'(10) by the UK Department of Health (DoH), led to an increased focus on patient safety both within the UK NHS and internationally. Both reports highlighted that adverse events had occurred frequently in healthcare (9, 11) and that many events were preventable (12, 13).

Much publicised clinical care failures in NHS healthcare settings have further increased focus on patient safety. In particular, the failures at Mid-Staffordshire NHS Foundation Trust between 2005 and 2008 (14) led to the Government commissioning a subsequent public inquiry, the results of which were published in "The Francis Report". The inquiry was led by Robert Francis QC, cost £13 million and resulted in 290 recommendations to improve patient safety across the health service (15).

One of the problematic areas highlighted by Francis was medication safety. For example the omissions of medication at scheduled times of administration was found to be an issue at Mid-Staffordshire NHS Foundation Trust (15). It is thought that 15% of harms to patients are associated with medication-related incidents (8) and that they are the single largest source of repetitive healthcare error (16).

In order to reduce harm from medication, the World Health Organization (WHO) has made the improvement of medication safety its current "Global Patient Safety Challenge" (17). Within this challenge, WHO have invited health ministers to initiate national plans addressing four domains of medication safety (explained in more detail below):

1) Engaging patients and the public.
2) Medication as products.
3) Education, training and monitoring of health-Care professionals.
4) Systems and practices of medication management.

Globally, a number of initiatives have been developed to improve the four domains highlighted above, examples of which have been provided in Chapter 2 (see Section 2.2, Table 1.0). However, even prior to the Global Patient Safety Challenge the need for initiatives to improve medication safety was highlighted in the aforementioned patient safety reports by the DoH and IOM (9, 10). The DoH report, which was specifically about the NHS, identified two main areas where the NHS could draw valuable lessons from the experience of other sectors to reduce the rate of preventable harm from medication. The first area was safety culture, where open reporting and balanced analysis are encouraged, which can have a positive and quantifiable impact on the recognition and management of preventable harms (10). The second area was reporting systems, which were considered vital in providing sound, representative information on which to base analysis and recommendations(10).

Within the NHS, initiatives to better address the problem of patient safety have been introduced prior to the Global Patient Safety Challenge. For example, the National Reporting and Learning System (NRLS), was established in 2003 by the National Patient Safety Agency (NPSA) to help monitor patient safety incidents, including medication-related incidents, within NHS organisations in England and Wales (18). The NRLS is the world's largest and most comprehensive patient safety incident reporting system and receives over two million reports each year (19, 20). The NRLS is a system that helps

organisations to link their internal reporting systems to a wider national system by monitoring safety incidents.

Voluntary reporting systems, such as the NRLS, that assist with monitoring and learning from medication safety events are vital for improving medication safety and use of them is in line with the fourth domain of the WHO Global Patient Safety Challenge, listed above: Systems and Practices of medication management. Such systems, have allowed research and healthcare organisations to learn a great deal about medication harm. However, voluntary reports do not allow us to measure medication safety and monitor associated improvement. It has been difficult to ascertain if medication safety initiatives have led to improvements, as medication safety has not traditionally been routinely measured (21, 22).

In addition to voluntary reporting, to help monitor systems related to medication safety, measurement tools are vital to help organisations to know whether medication safety improvement is occurring (22). Measurement of medication safety will allow those introducing initiatives, related to all four domains, know whether improvements have occurred.

Following the introduction of the NRLS, a further improvement initiative was introduced within the NHS in 2012 by a large multi-disciplinary collaborative. Based on the original Safety Thermometer (ST) (see Section 3.4.1) they developed a tool called the Medication Safety Thermometer (MedsST) as part of a wider group of STs (23). The STs are a group of quality improvement tools developed using improvement science to measure different areas of patient safety (see Section 3.4.3).

The focus of the programme of work presented in this PhD thesis is to evaluate the MedsST. As with any quality improvement initiative that is introduced to healthcare, it is vital to evaluate the use of this tool. Evaluation helps to assess whether healthcare staff are engaging with the MedsST, to learn how it may be improved to ensure the most effective use and to help other settings translate how improvements can occur.

Chapter Two:
Background on Medication Safety

2.1 Patient safety

WHO has defined patient safety as "freedom for a patient from unnecessary harm or potential harm associated with healthcare" (24). Despite efforts to ensure this, approximately 10% of patients are harmed whilst in healthcare (7, 25, 26).

As mentioned in Chapter One, a number of patient safety reports have led to increased focus on patient safety both in the UK and internationally (11, 27, 28). These reports highlighted that many adverse events that occur in hospitals are preventable (12, 13). A recent systematic review of preventable patient harm across healthcare settings found that 6% of patients experience preventable harm and 13% of this preventable harm leads to permanent disability or patient death (29).

Furthermore, many healthcare system failures are often repeated, and more emphasis is required on learning from these events to prevent reoccurrence. Following the large-scale failures at the Mid Staffordshire NHS Foundation Trust mentioned in Chapter One (14), Professor Donald Berwick (a renowned international expert in patient safety) was commissioned to write a report to aid learning within the NHS. His report was titled 'A Promise to Learn – a Commitment to Act' (30) and placed great emphasis on organisational culture and reflective, learning environments, recommending that the NHS should make patient safety a 'number one priority' (30). This recommendation is appropriate, considering the morbidity and mortality that could be prevented and the resources that could be saved (31).

In his report, Berwick highlighted that improvement requires a system of support, and that the capability to measure and continually improve the quality of patient care needs to be taught and learned or improvement of safety will not occur (30). Specifically, tools are required within healthcare systems to allow measurement of baselines and related improvement in different areas of

safety. The measurement of patient safety allows concerns to be identified and *"alarms to ring"* before potential problems occur and lead to large-scale failures, as they did in Mid-Staffordshire. At the time of the report, Berwick stated that *"Most health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information. This gap is costly, and should be closed"* (30).

Since then, a number of initiatives to improve healthcare have been developed and introduced within healthcare settings to encourage *"quality improvement"*. Quality improvement describes the combined efforts of healthcare professionals, patients and their families, researchers, payers, planners and educators to make the changes that will lead to better patient outcomes, better system performance and better professional development (32). Many quality improvement initiatives have used *'improvement science'* (33) an emerging concept that focuses on exploring how to undertake quality improvement well. A number of terms have been used to refer to improvement science concepts, including the science of improvement, implementation science, translational research, quality improvement science, science of quality improvement, measurement for improvement and quality improvement methods (33). Marshall et al. (34), have previously proposed that the lack of a single definition for improvement science may be because it has been in a state previously described as the *'pre-paradigm phase of the emergence of a new discipline'*(35). Nonetheless, "Improvement Science" has been most widely used and is used by the UK Health Foundation (33) and therefore will be used in this programme of work.

2.2 Medication Safety

Improving medication safety is an important aspect of patient safety. Medication errors (MEs) have been found to be the largest cause of preventable patient harm (8, 9) and are defined as 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.' (36). In the UK, around 5% of hospital admissions have been related to preventable drug-related morbidity and preventable harm from medicines (37).

A recent report by Elliot *et al.* estimated that approximately 237 million MEs occur in the NHS every year and that almost one in four is likely to result in harm to patients (38). Elliott *et al.* found that 'definitely' avoidable adverse drug reactions (ADRs) are estimated to cause 712 deaths per year, contribute to 1,708 deaths and cost a minimum of £98.5 million every year to the NHS (38).

The aforementioned statistics concerned both primary and secondary care NHS settings. However, the MedsST tool that this programme of work is assessing has predominantly been used in secondary care settings. In secondary care specifically, ADRs are estimated to cost approximately £14.8 million, cause 85 deaths and contribute to 1,081 deaths annually (38).

The remainder of this chapter will specifically focus on secondary care settings. However, the report by Elliott *et al.* highlighted that there is a lack of data from hospitals to monitor MEs. In the report, data from the various UK studies were extrapolated against NHS England Statistics about bed availability and occupancy (38) to generate information about ME rates in the NHS hospitals, which may have led to underestimation (38).

Monitoring medication safety is an important aspect of improving medication safety overall. As mentioned in Chapter One, WHO have identified four domains of medication safety in which using medications can cause avoidable harm(17, 39). Any initiatives introduced to tackle these four domains need some aspect of monitoring, to assist organisations to evaluate whether improvement is occurring.

Table 1.0 presents the four domains of the WHO global patient safety challenge. The table also provides a description of each domain and examples of initiatives introduced within the UK NHS to tackle the four domains.

Table 1.0: The Four domains of the World Health Organizations' Third Patient Safety Challenge: Medication Without Harm (39)

Domain	Description	Example initiatives
1) Patients and the Public.	Engaging patients and the public with the medicines use process and empowering them to play their part in making the process safer. This contrasts with the passive role patients have traditionally taken when decisions are made about their medicines. (17, 39).	The 'Shared Involvement in Medication Management Education project' was a training intervention developed to promote shared decision-making in medication management(40).
2) Medicines	Perceiving medicines as medicinal products. Medicines can often be complex and puzzling in their names, or packaging and sometimes lack sufficient or clear information. Confusing 'look-alike, soundalike' medicine names and/or labelling and packaging are frequent sources of error and medication-related harm (17, 39).	Initiatives aimed to reduce errors due to unclear medicine labels, for example, using Tall Man lettering to help reduce look-alike medication errors (41).
3) Healthcare Professionals	Educating, training and monitoring of health-care professionals, as they sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients (17, 39).	The recently developed WHO Pharmacovigilance Core Curriculum that has been designed and developed for University Teaching of multi-disciplinary healthcare students (42).
4) Systems and Practices of Medication Management	Systems and practices of medication management are complex and often dysfunctional. If these systems and practices are well designed, they can be made more resilient to risk and harm (17, 39).	The Medication Safety Thermometer developed to be used as part of routine practice in organisations to monitor measures related to medication safety over time (1).

The domains are not mutually exclusive, and initiatives may target more than one domain. For example, the Shared Involvement in Medication Management Education project (mentioned in Table 1.0) increased the engagement of patients and carers with medication management (Domains One and Four) by educating them about shared-decision making. This included educating them about specific drugs and side effects (Domain Two), the project also involved

training healthcare professionals about shared decision-making (Domain Three) (40). All of the domains are interlinked and initiatives under any domain have the common goal of improving medication safety. However, in order to know if any of these initiatives are having an impact on medication safety, initiatives to assist measurement and monitoring of medication safety are required as part of routine practice (Domain Four).

In order to measure medication safety, standardised definitions and classification system for MEs are required. As mentioned previously, the rate of MEs is greatly underestimated and this is partly due to varying definitions and classification systems (38, 43). Some commonly used definitions and classification systems are described and discussed in the following section.

2.2.1 Definitions and Classification Systems Used for Medication Errors

Estimating the prevalence of MEs is difficult due to the varying definitions and classification systems employed. Rates can vary depending on the denominator used (e.g. patient, prescription or a specific medication)(38).

The aforementioned report by Elliott *et al.* identified definitions of ME and classification systems that have been used in UK studies. Some definitions may not be relevant to this programme of work. However, it is important to acknowledge their existence, level of heterogeneity, and then determine which might be the most appropriate to adopt for each given context. This research is more concerned with errors that occur with medicines under the direct control of healthcare professionals, particularly in hospital settings as mentioned previously. Therefore, definitions used for ME and severity ratings from studies conducted in secondary care have been focussed on. Table 2.0 summarises some key definitions of MEs as summarised by Elliot et al. (38). In Elliot et al.'s report, intervention studies were excluded, however some additional commonly used definitions from intervention studies have been added to Table 2.0 as they were relevant to this programme of work. The definitions in Table 2.0 cover all stages in the medication use process. MEs can occur at various stages of the medication use process, resulting in many types

of ME (44). The most common MEs are prescribing errors, dispensing errors and administration errors (45).

Table 2.0: Definitions of Medication Errors and Severity in Studies Undertaken in NHS Secondary Care. Adapted from Elliot *et al.* (38)

Medication Error Group	Study	Definition of Error	Error Severity Definition
General Medication Errors	Covvey *et al.* (46)	Prescribing, administration and monitoring errors associated with antimicrobials.	Incident severity: Negligible, Minor, Moderate, Major, Severe.
Administration Errors	Cottney and Innes (47)	A dose administered differently than as prescribed on the patient's medication chart. An opportunity for error was defined as a dose that was either observed being given or omitted (48).	Severity of error was categorized according to a previously reported system (49). Minor clinical severity, negligible clinical severity, potentially serious clinical consequences, potentially life threatening.
	Ghaleb *et al.* (50)	*Administration error:* The administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policy and procedures. This includes errors in the preparation and administration of intravenous medicines on the ward.	Study authors report that the severity of these medication errors remains to be explored.
	Haw *et al.* (49)	A deviation from a prescriber's valid prescription or the hospital's policy in relation to drug administration, including failure to correctly record the administration of a medication (48, 51).	Medication administration errors categorised as follows(52): Grade 1: errors or omissions of doubtful or negligible importance. Grade 2: errors or omissions likely to result in minor adverse effects or worsening condition. Grade 3: errors or omissions likely to result in serious effects or relapse. Grade 4: errors or omissions likely to result in fatality. Grade X: unrateable.

	Kelly *et al.* (53)	Using the British National Formulary (54), British Association of Parenteral Nutrition guidelines (55) and White and Bradnam's (2006) guidelines appropriateness of administration was evaluated. The results were then categorised using Dean's (56) adapted American Society of Hospital Pharmacists (ASHP) classification (57). Time errors, and 'others' were added to Dean's classification to give an 11-point classification system. Severity not assessed. Morton and Errera (58). Eight categories of serious clinical incidents were identified in advance by an expert panel including drug error (not defined).	Severity not assessed.
Dispensing Errors	James *et al.* (59)	UK Dispensing Error Analysis Scheme - an established system for reporting standardised dispensing error data, classified in accordance with the UK National Patient Safety Agency guidance to ensure consistency with the UK National Reporting and Learning System (60-62).	Severity not assessed.
	James et al. 55(63)	Deviations from a written prescription occurring during the dispensing process of selecting and assembling medication (drug/content errors), generating and affixing of dispensing labels (labelling errors) and issue of the dispensed products to patients (issue errors).	Severity not assessed.
Prescribing Errors	Ashcroft *et al.* (64)	This study was part of a wider study; the EQUIP project (65). Error was one which occurs when, as a result of a prescribing decision or prescription writing process, there is an unintended, significant reduction in the probability of treatment being timely and effective, or increase in the risk of harm when compared with generally accepted practice (66).	Severity categories included minor, significant, serious, or potentially lethal errors and were based on rating scales used in previous medication error research (67, 68).
	Baqir *et al.* (69)	Any intervention the clinical pharmacist had to make to ensure that the prescribing was clinically correct and legal. Errors were classified according to the EQUIP study by mentioned above (65).	Severity not assessed.
	Bolt *et al.* (70)	Difference between prescribed and calculated doses.	Severity not assessed.
	Denison Davies *et al.* (71)	The study authors created a pool of potential prescribing errors based on a series of quality statements based on local (72, 73), national (74), and international guidelines (75, 76).	Potentially Lethal (Category A) Serious (Category B) Significant (Category C) Minor (Category D) Severity categories not defined
	Franklin *et al.* (77)	A prescribing error was defined as a prescribing decision or prescription-writing process that results in an unintentional, significant: (i) reduction in the probability	Study authors chose not to assess severity or type of errors.

		of treatment being timely and effective or (ii) increase in the risk of harm, when compared to generally accepted practice (66, 78).	
	Franklin *et al.* (77)	A prescribing error was defined as a prescribing decision or prescription-writing process that results in an unintentional, significant: (i) reduction in the probability of treatment being timely and effective or (ii) increase in the risk of harm, when compared to generally accepted practice (66, 78).	Study authors chose not to assess severity or type of errors.
	Franklin, *et al.* (79)	A practitioner-led definition of a prescribing error (66).	Severity not assessed
	Ghaleb *et al.* (50)	*Prescribing error:* A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant: (1) Reduction in the probability of treatment being timely and effective or (2) Increase in the risk of harm when compared with generally accepted practice (80).	Study authors report that the severity of these medication errors remains to be explored.
	Huynh *et al.* (81)	A discrepancy was defined as a difference between the patient's pre-admission medication (PAM) compared with the initial admission medication orders (AMO) written by the hospital doctor. The discrepancies were classified into intentional and unintentional discrepancies. The unintentional discrepancies were assessed for potential clinical harm.	Unintentional discrepancies were classifiable into the 'harm' classification (82).
	Jones and Bhandari (83)	Potentially inappropriate medications were defined by using the modified Beers' criteria (84) as any medication deemed inappropriate by the authors if it was contraindicated or prescribed at an inappropriate dose for the level of renal function.	Severity not assessed.
	Keers *et al.* (85)	A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective, or an increase in the risk of harm when compared with generally accepted practice.(66) Scope extended to include prescribing a drug without first registering a patient with the appropriate monitoring service and prescribing a drug to treat mental health illness without authorisation from a Mental Health Act form.	Prescribing error classification: (65) Not clinically relevant: Minor. Clinically relevant prescribing errors: Significant, Serious, life threatening.
	Ryan *et al.* (86)	One which occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of	Severity not assessed.

		treatment being timely and effective or an increase in the risk of harm when compared with generally accepted practice (66).	
	Seden *et al.* (87)	A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant: (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice (66).	A modified EQUIP study criteria (65) was used for error categorisation and severity (minor, serious or potentially life-threatening).
	Tully et al. (88)	Pharmacists judged whether a prescribing error had occurred and categorised it, using the definition and typology of Dean *et al.* (66).	Severity was defined using the categorization of Lesar *et al.*(67) (problem orders, potentially significant, potentially serious and potentially severe or fatal)

One of the main types of MEs that this programme of work will focus on is administration errors, which are a common ME (89) (see section 2.2.4). However, other measures of the MedsST are related to all three types of error and all of them will be discussed in the following sub-sections. Furthermore, the MedsST was designed to measure harm from medication, regardless of whether the harm is due to error. Therefore, section 2.3 will discuss harm from medication.

The following sub-sections will also discuss reported rates of each MEs at each stage of the medication use process. As reports are voluntary, they greatly underestimate the actual rate of errors. The presence of an error does not necessarily lead to patient harm but increases the probability of harm, including serious patient harm and occasionally death, which is why they are still particularly important to study with the aim of future prevention.

2.2.2 Prescribing Errors

What constitutes a prescribing error can be subjective, and many studies develop their own definitions, whilst many do not provide any definitions (43). One of the most commonly used definitions in UK studies for prescribing errors, developed by Dean and Barber, has been defined below. Table 2.0 highlights that this definition has been used by seven papers, reporting six UK studies (64, 77, 79, 85-87, 90).

"Errors which occur when, as a result of a prescribing decision or prescription writing process, there is an unintended, significant reduction in the probability of treatment being timely and effective, or increase in the risk of harm when compared with generally accepted practice" (66).

Reasons for prescribing errors were explored in a systematic review conducted by Tully *et al.* (91). In the review, causes of prescribing errors were grouped according to Reason's accident causation model, into "active failures", "error-provoking conditions" and "latent conditions" (see Figure 1.0) (91). Reason's accident causation model is a human error model based on the assumption that

"active failures", by front line healthcare staff, are mainly the result of the conditions in which they work, often termed "error-provoking conditions". These in turn are the result of "latent conditions", error-prone decisions made at organisational levels. Initiatives may or may not be able to prevent this chain of events from resulting in harm. There is therefore less focus on the individual who makes the error and more on pre-existing organisational factors (92).

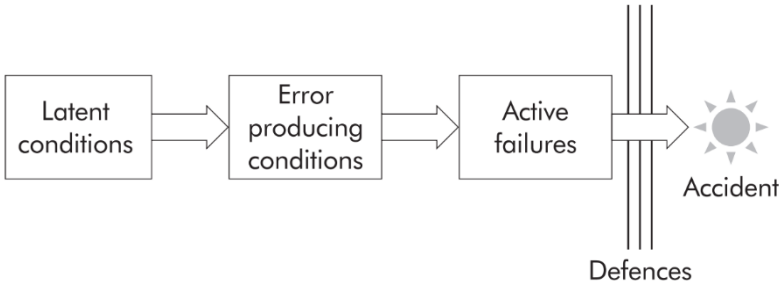

Figure 1.0 - Reason's Model of Accident Causation (92, 93)

Causes of prescribing errors are often multifactorial, with several active failures and error-provoking conditions acting together to cause them. Tully *et al.* found that the active failure most frequently cited was a mistake due to inadequate knowledge of the drug or the patient (91). Skills-based slips and memory lapses were also common (91). Where error-provoking conditions were reported, there was at least one per error. These included lack of training or experience, fatigue, stress, high workload for the prescriber and inadequate communication between healthcare professionals (91). Latent conditions included reluctance to question senior colleagues and inadequate provision of training (91).

Previous research has found prescribing errors to be a common type of ME (94) and in the UK, 16% of medication safety incidents reported to the NPSA between January and December 2007 involved prescribing errors (62). A systematic review of studies focussed on prescribing errors found a median of 7% of all medication orders are affected by prescribing errors and approximately 50% of all hospital admissions (90). The systematic review, by Lewis *et al.*, found that error rates also varied greatly between studies (90). They

concluded that this may partly be explained by different definitions of a prescribing error and different methods used for collection of data and settings. This systematic review further highlighted that many variations exist between definitions used in studies, and that this can lead to difficulties in operational use (90).

2.2.3 Dispensing Errors

Dispensing errors are another type of ME, which may occur at any stage of the dispensing process, ranging from receiving the prescription in the dispensary to supplying the patient or administrator with the medication. Dispensing errors may involve the wrong drug, wrong patient or selection of the wrong strength or product (45). One definition that covers all stages the dispensing process is:

"*Deviations from a written prescription occurring during the dispensing process of selecting and assembling medication (drug/content errors), generating and affixing of dispensing labels (labelling errors) and issue of the dispensed products to patients (issue errors)"* (63).

The review looked at external and internal errors, which were referred to as unprevented and prevented dispensing errors respectively. Dispensing errors can be divided into the following categories:

- External errors: dispensing errors detected and reported after medications have left the pharmacy.
- Internal errors (also known as near-misses): dispensing errors detected during dispensing before medications have been issued to the patient, ward, or clinical area.

In the UK, 18% of medication safety incidents reported to the NPSA between January and December 2007 involved preparation and dispensing errors (62). A systematic review of studies looking at incidence, type and cause of dispensing errors was performed by James et al. (2009). In UK hospitals, it was found that external dispensing errors ranged from 0.008 to 0.02% and prevented dispensing errors occurred more frequently at a rate of 0.11–2.7%. James *et al.* proposed that the wide range of error rates reported for dispensing errors may be attributed to differences in research methods, dispensing

systems and operational definitions (95). James *et al.* also found that there is great variation in terms and definitions used to describe dispensing errors and that terminology was being used interchangeably (95). Factors most commonly cited as contributing to dispensing errors, in the papers reviewed by James et al., were workload, similar drug names, similar drug packaging, staffing levels, interruptions and poor handwriting (95).

2.2.4 Administration Errors

Administration errors occur in situations where a discrepancy occurs between the drug treatment that the prescriber intended the patient to receive, whether any medication was received and what medication was actually received. A frequently used definition is:

"The administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policy and procedures. This includes errors in the preparation and administration of intravenous medicines on the ward."(50)

There are various types of administration errors including:

- Incorrect administration techniques
- Administration of incorrect or expired preparations
- Some omissions of medications (45)

A recent systematic review of administration errors found that they are common in hospital settings (89). The review reported an estimated median of 19.1 % of 'total opportunities for error' in hospitals being medication administration errors (89). The way that medication administration error rates are calculated also varied greatly as a product of differing ME definitions, data collection methods, and settings of included studies (89). In order to calculate omissions rates, a suitable numerator and denominator are required(96).

Some studies have used "patient-focused" numerators and denominators for calculating medication administration errors, where the numerator is the total number of patients with a medication administration error, and the denominator is the total number of patients prescribed medicines. However,

studies have mainly used various "dose-focused" numerators and denominators to calculate omissions rates. These include studies where the numerator was the number of doses with one or more MEs or the total number of MEs (96). For the denominator, the majority of studies use the sum of the total number of doses ordered plus any unordered doses, often described as "total opportunities for error" (89, 96). Another denominator used in studies include the number of doses observed (which therefore excludes omitted medicines) (96). However, medication administration omissions (henceforth referred to as omissions) are a large medication safety issue that can lead to serious harm and it is important to include them (97, 98).

Often medication safety research studies have investigated the rate of omissions as the number of doses that have not been administered (99-102), rather than the number of patients that have not received their medicines. Whilst it is useful to know about the former, it is also useful to know about the latter so that specific patient groups can be prioritised for improvement of omissions.

Focussing on patients experiencing errors, rather than the affected doses, is consistent with the NHS 'Harm Free Care' programme, which aims to promote a mind-set of providing all patients with 'excellent healthcare whilst avoiding harm' (see Section 3.4)(23). The MedsST is part of the harm free care programme and therefore uses focuses on the proportion of patients experiencing MEs, which will be used in Studies Three (Chapter Eight) and Four (Chapter Nine) of this thesis.

2.2.5 Definitions Used in this Programme of Work

Whilst there has been guidance for organisations about how to use the MedsST (23), it has not provided specific definitions for ME, or the for the three types of ME described in the above sections. Therefore, this programme of work will use the most common definitions used by the UK studies stated previously (36, 50, 63, 66). However, the operational definitions provided by the latest version of the main MedsST form (Version 16b for hospitals) will be adhered to (see Appendices 1.0, 2.0 and 3.0).

Establishing appropriate operational definitions for measuring medication safety is difficult, and improvement science (see Section 3.2) was used to test and develop the operational definitions used by the MedsST (see Study One, Chapter Six). In particular, developing standardised operational definitions to measure harm from medication can be very complex and often requires input from several from healthcare staff (22, 103).

2.3 Types of Harm from Medication

As mentioned above, MEs are failures in the process of medical management, and are the cause of some harms to patients (22). However, not all harms from medications are due to MEs. In some instances, patients experience medication-related harm despite no failures occurring in the process of medical management. Both medication-related harms due to error and those not due to error can be defined as Adverse Drug Events (ADE). As mentioned above, few MEs result in ADEs (38). It has been suggested that all preventable ADEs are MEs (104). Other MEs that occur do not lead to actual harm but have the potential to lead to ADEs and are classified as potentially harmful. Minor errors that have little or no potential for harm are not considered potential ADEs. These relationships have been represented by Marimoto *et al.* below (Figure 2.0) (104).

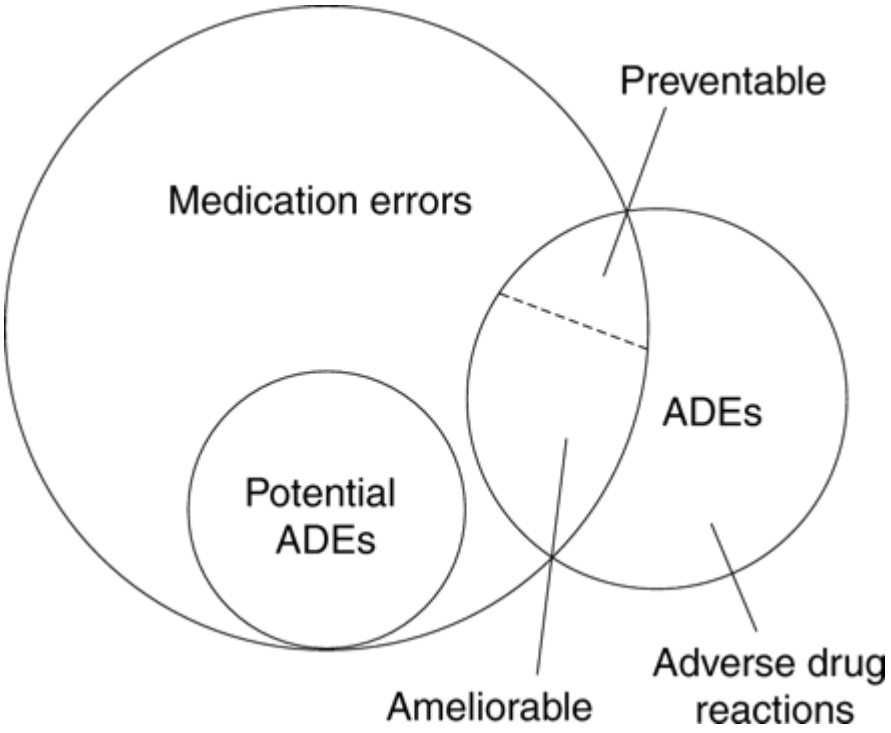

Figure 2.0 - The Relationship Between Adverse Drug Events, Potential Adverse Drug Events, and Medication Errors (104)

2.4 Measuring Medication Safety and Associated Harm

Attributing harm to MEs can be challenging as it is often difficult to ascertain whether a medication-related harm is preventable or not, and therefore an ME. For example, Angiotensin-Converting Enzyme (ACE) inhibitor drugs, a type of drug used to lower patients' blood pressure, can cause patients to develop coughing symptoms, and alternative medicines should be used for lowering their blood pressure (105). If coughing symptoms develop in a patient given an ACE inhibitor without a history of this problem previously, this would not be an ME (104). If a patient is given an ACE inhibitor drug, but has a history of an ACE inhibitor induced cough previously, this can be classified as an ME, unless it was prescribed as a re-challenge test to confirm whether the ACE inhibitor caused the cough. In addition to the difficulties in identifying MEs, another reason that MEs are greatly underestimated is that medication safety data has predominantly been collected in the form of voluntary reports. Voluntary reporting greatly underestimates the number of MEs and the quality of reports are variable (18, 106) and whilst they are useful for learning purposes (18), they cannot be used for measurement purposes (22). Many studies in this

area have outlined the great difficulty associated with getting clinicians to report either MEs or adverse drug events voluntarily (22). Furthermore, it has been highlighted that healthcare practitioners often struggle to assign severity ratings to incidents that they have encountered. In particular, inconsistencies in severity ratings have been noted when different healthcare professionals have reported the same ME, or when 'near miss' events have been detected (106).

Research studies investigating the prevalence of MEs have often used non-voluntary reporting methods, including retrospective chart or electronic record reviews (22, 107). Medication safety is a complex process and measurement of medication safety requires focus on different areas of MEs including actual and potential errors and related harms. Therefore, many of the innovations to improve medication safety have consisted of a variety of measures for both actual and potential harm. These use a combination of measures of actual harm and process measures, as it is thought if processes are correct the likelihood of errors decrease (21) . The MedsST is one of the tools that has used a combination of steps and process measures to measure both potential harm and actual harm.

Most measurement of medication safety that has occurred has been for research projects, and recent studies have shown that medication safety has not improved over time (38). This is true for other areas of healthcare and patient safety also – and still 1 in 10 patients are harmed by healthcare. This has called for us to start thinking about improvement of healthcare in a different way – for example, by using improvement science. Improvement science is healthcare is an emerging discipline that is becoming popular for helping healthcare organisations to develop new tools and innovations to improve different aspects of healthcare (see Section 3.1) (33, 108).

2.5 Summary of Chapter

Medication safety is a priority area within patient safety as highlighted by the current Global Patient Safety Challenge. Medication use processes are very complex and there are many types of errors at various stages of different processes. Definitions for errors at these different stages are often subjective

and difficult to make generalisable between contexts. Defining severity of errors and the harm they lead to is also difficult, as highlighted by the many variations of severity categories described in Table 2.0.

Most of the information we have about MEs are from research studies or voluntary reports. Voluntary reports greatly underestimate errors and research studies are time-consuming and expensive. Furthermore, aggregated data from reports and research studies can take several months to reach staff on the frontline. Routine data about medication safety is not available and the report by Elliott et al. where data from the various UK studies were extrapolated against NHS England Statistics about bed availability and occupancy (38) to generate information about ME rates in the NHS hospitals highlighted that initiatives for monitoring medication safety in hospitals are required. Such systems to enable measurement as part of routine practice are required to help avert risks as per domain 4 of the WHO Global Patient Safety Challenge. This programme of work focuses on the MedsST which is a routinely used medication safety data collection tool and an example of an initiative that has been designed to assist with monitoring of medication safety overall. Initiatives developed using Improvement Science, such as the MedsST, focus holistically on systems, rather than individuals, and could aid measuring medication safety. A Background of Improvement Science and a description of the MedsST and other STs will be provided in the following chapter.

Chapter Three:
Background on Improvement Science and the Safety Thermometers

3.1 Improvement Science

Improvement science is a concept which focuses on exploring how to improve the quality of healthcare efficiently. It inhabits the sphere between research and quality improvement by applying research methods to help understand what impacts on quality improvement (33). Improvement science stems from operations research, industrial engineering and management and the overarching goal of using it in healthcare is to ensure that quality improvement efforts are based as much on evidence as the best practices they seek to implement (33). Improvement science combines academic expertise to improve the decisions made about the organisation and delivery of care, with the pragmatic science of the health service, and knowledge and practical wisdom held by healthcare clinicians and managers (108). This overlap between the "Health Service World" and "Academic World" has been presented in Figure 3.0.

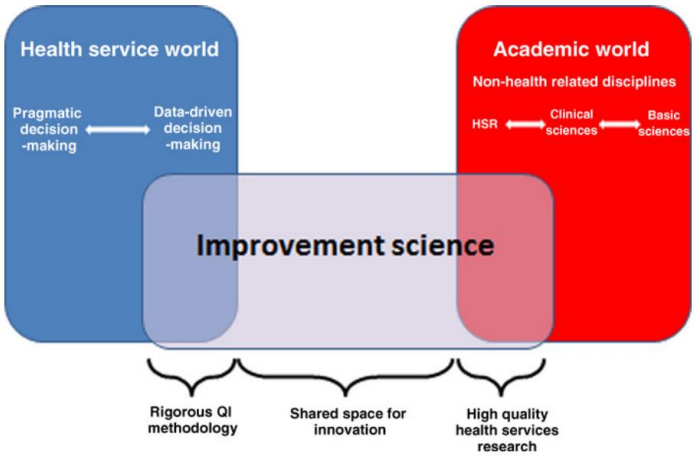

Figure 3.0 - Framing the Science of Improvement (108)

3.2 Using Improvement Science to Improve Patient Safety

The use of improvement science in healthcare has gradually increased and a number of patient safety improvement initiatives have been developed using improvement science (109, 110). For example, the '1000 Lives' campaign in Wales was a two-year improvement initiative adapted from the successful 'Save 100,000 Lives' campaign in the USA run by the Institute for Healthcare Improvement (IHI). These programmes aimed to improve patient safety and increase healthcare quality by targeting medicines management, healthcare associated infections and better medical and surgical care (109, 110). Both the American and Welsh programmes were reported to have aided improvements in healthcare; it was estimated that the American campaign had helped to save 122,300 lives (111) and that the Welsh campaign had helped to save 1,199 lives (112).

Another programme conducted within the NHS based on an American programme was the 'Matching Michigan' programme, which was based on an improvement programme conducted in the USA referred to as the 'Michigan Keystone project'; a large-scale project designed by a group of clinicians and health service researchers in Michigan (USA) that focussed on improving central venous catheters and bloodstream infections. The Michigan Keystone project was found to be successful in reducing rates of catheter-related bloodstream infections by 66% (113). Though Matching Michigan reproduced many of the components of the original Keystone project, it did not reproduce the same success (114). To see why certain components of an intervention succeed or fail, evaluations are required to see whether the changes could be related to the intervention (115, 116). The importance of the evaluation of the quality improvement initiatives has been discussed further in Section 3.3.

A number of improvement science methods have been used to develop and implement the interventions in healthcare, for example, organisationally-based initiatives such as using Plan-Do-Study-Act (PDSA) cycles (117). It was reported that PDSA cycles played a particularly instrumental role in the development of the STs and were chosen for development of the Thermometers as they enhanced the chances of application at scale as it

allowed testing of a planned change in a 'live' setting and consideration of its strengths and weaknesses before adaption of the STs for further testing (118). The following section focuses on PDSA methodology and examples of PDSA cycles used to develop the MedsST can be found in the tables of Study One (Chapter Six).

3.2.1 Plan-Do-Study-Act Cycle Methodology

The PDSA cycle is one of the most commonly used improvement science methods (119) and is part of the quality improvement model (Figure 4.0) (120). PDSA cycles provide a framework for developing, testing and implementing changes (121). It helps users of improvement science specify what they are trying to accomplish, how to tell whether a change is an improvement, and what changes can be made that will result in improvement. When PDSA cycles are used, usually changes are first implemented on a small scale and tested and refined before scaled-up and rolled out on a larger scale (115).

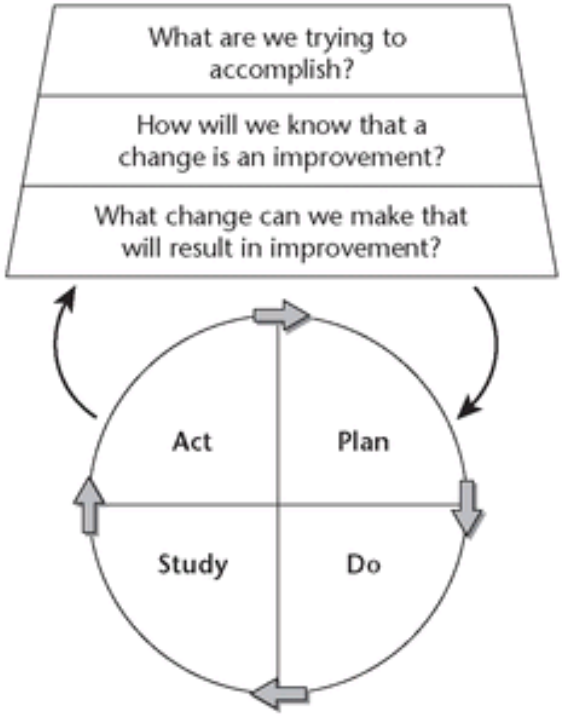

Figure 4.0 – The Quality Improvement Model (120)

The four steps of the cycle include the following:

- Plan - the change to be tested or implemented

- Do - carry out the test or change
- Study - data before and after the change and reflect on what was learned
- Act - plan the next change cycle or full implementation (121)

As mentioned above, use of the PDSA cycles for developing the STs enhanced the chances of application at scale as it tested changes in a 'live' setting, and considered strengths and weaknesses of the STs at each change before adapting it for further testing. At each stage of testing, evidence was gathered to find the best way to implement the programme and re-evaluate if it is not successful. This programme of work will explore specific examples of how PDSA cycles were used to develop the MedsST (Study One, Chapter Six).

3.3 The Importance of Evaluating Improvement Initiatives

Whilst many initiatives to improve patient safety have been introduced, there is often a lack of knowledge about how effective the initiatives have been. To fully learn about the impact of interventions and what works and what doesn't, both qualitative and quantitative approaches are required. Quantitative approaches allow us to measure associated changes, such as the number of lives potentially saved. Qualitative evaluation allows us to understand what aspect of the programme has worked and what has not. Furthermore, just because an initiative is successful in one context, it will not automatically be successful in another. As mentioned previously, the Michigan Keystone project was found to be successful in reducing rates of catheter-related bloodstream infections. However, an in-depth evaluation of the UK Matching Michigan programme found that there was no difference in the reduction of infections in intensive care units who were on the matching Michigan programme compared to those that weren't, suggesting that the UK programme did not work, and if it did work it is difficult to prove this (116, 122). The evaluation found that the UK programme was challenged both in showing that it was outperforming the secular trend and in defending against the decline effect for reasons relating to the design and execution of the program, the national context into which it was introduced, the impact of individual ICUs' histories, and local approaches to measurement and engagement (123).

The authors of the above-mentioned evaluation, Dixon-Woods et al., reported that the Matching Michigan interventions themselves (data collection, non-technical and technical) 'work' to reduce central venous catheter (central line) bloodstream infections, however, Matching Michigan did not fully work as a programme because of certain features of the programme's design, delivery and context of implementation. For example, staff engagement with the programme was an issue because staff did not like the introduction of Matching Michigan and felt it was a failure to respect what they had already achieved, and, given the other challenges facing hospitals, a misdirection of resources (124). When designing and delivering improvement initiatives, it is vital to have a good understanding of programme mechanisms and contexts of implementation and the evaluation of the programme enabled clinicians and researchers to understand why the programme didn't work and highlighted the importance of involving frontline staff in development and evaluation of future innovations in the NHS to ensure success. Innovations such as the NHS Safety Thermometers have therefore had more involvement of frontline clinicians in the development process.

3.4 The NHS Safety Thermometers

Another NHS improvement innovation that has recently been developed and evaluated is the Safety Thermometer (STs) which consist of simple audit tools to provide monthly data about different areas of harm (125). STs are part of a wider 'Harm Free Care' programme, which takes into account that in order to collect reliable data it is vital to ensure that there is a focus on 'Harm Free Care' and patient centred improvement through *the act of measurement*. The 'Harm Free Care' programme aims to promote a mind-set of providing all patients with 'excellent healthcare whilst avoiding harm' (23). 'Harm Free Care' is a term used for an innovative patient-level composite measure of the absence of harm (125).

3.4.1 The Original Safety Thermometer

The first ST, the original ST, resulted from the 'Safety Express' pilot scheme in 2011, in which approximately 1,000 healthcare professionals were asked to design and test innovative ways to achieve a reduction of patient harm (126,

127). The paper version of the original ST can be found in Appendix 4.0. The original ST was then developed to provide a quick and simple method for surveying patient harms and analysing results so that healthcare staff could collect data to enable the measurement and monitoring of local improvement and harm-free care over time, but that could also be aggregated to learn about harms at a national level (118, 128).

The original ST helped organisations to measure the prevalence of four common harms; pressure ulcers, harm from falls, urinary infection in patients with catheters, and venous thromboembolism (VTE) (125). These four harms were chosen as they account for a large proportion of avoidable injury in healthcare settings and incur high human and economic costs (129). Data were collected on one day per month and inputted into Statistical Process Control (SPC) charts to enable healthcare teams to track improvement progress (125). A composite measure that looked at the proportion of patients who lacked the four harms was also used, where patients who had not incurred any of these harms were deemed 'harm-free' (125).

Testing and refinement of the NHS ST involved the PDSA method. According to Power *et al.*, this method was chosen as it enhances the chances of application at scale, as it tests a planned change in a 'live' setting and considers its strengths and weaknesses before adapting it for further testing (118). Power *et al.* stated that there was a mixed reaction to this method (118). Some organisations and individuals appreciated that their feedback was being used to build and refine the tool and were more engaged as a result, whereas others preferred only to use the finished version and were uncomfortable with the concept of spending staff time and resources in order to improve versions (23, 118).

The ST was developed to provide a 'temperature check' on harm, hence the term 'thermometer'. In the context of an ST, a temperature check involves obtaining data to measure the level of harm occurring due to a particular type of patient safety incident. Therefore, a high 'temperature' suggests harm is

occurring and can indicate that something is wrong and needs further investigation and improvement.

The introduction of the ST was a result of a shift in government policy to focus on improving outcomes in health, leading the DoH to commission programmes such as the Quality, Innovation, Productivity and Prevention (QIPP) programme. The QIPP programme comprised of 12 national work streams, one of which was a 'safety work stream' which focuses on the four harms that the original ST has been developed to measure: falls, pressure ulcers, VTEs and catheter associated UTIs (127) . The first two of these harms were highlighted as improvement areas in Domain 5 (Safety) of the NHS outcomes framework 2010/2011 (Figure 5.0) (130), and were estimated to affect over 200,000 patients a year, costing £430 million in England alone (31). The NHS outcomes framework was developed by NHS England to provide a way of measuring the actual outcomes that are achieved, in terms of healthcare (131).

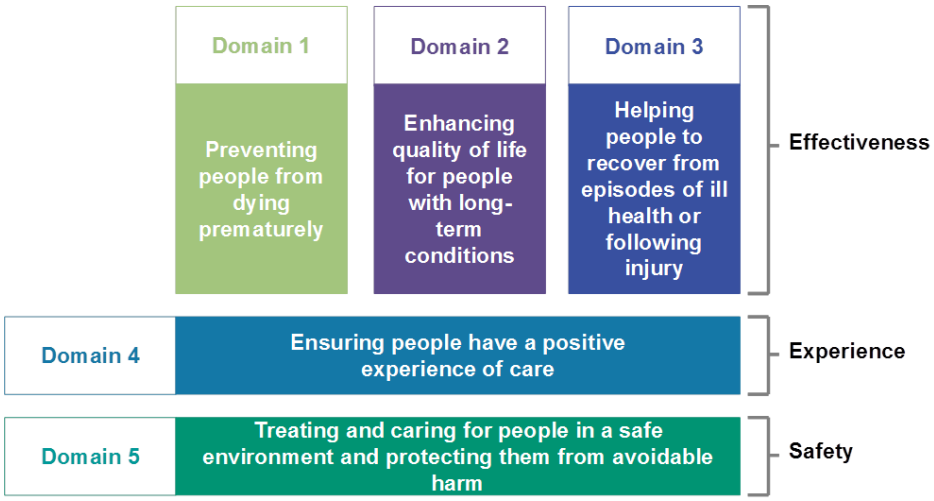

Figure 5.0 NHS Outcomes Framework 2010/2011 (130)

The original ST is a point of care survey that is carried out on 100% of patients within the chosen wards or organisation on the chosen day of the month. It has predominantly been nursing and healthcare assistant staff that have been involved with collecting data for the original ST. Staff use the original ST to

first collect data about simple patient demographics (age group and gender), and second, data about how many patients have suffered from the four harms on that day (125). To date, it has been used to perform over 10 million patient surveys, over 8 years (132).

The original ST was introduced under the Commissioning for Quality and Innovation (CQUIN) scheme, which uses financial levers, in addition to baseline funding, to incentivise healthcare organisations to reach certain targets (133). Organisations with baseline data can therefore compare their previous data to current data to measure improvement. Improvements are incentivised using the CQUIN target payments. Improvement had to be demonstrated by evidence of special cause variation (SCV), as summarised in Table 3.0, to receive payment for achieving the improvement CQUIN goal (134). The incentivisation for using the original ST has continued, and the most recent NHS Standard Contract guidance states that organisations must report the results of the original ST data collection, together with analysis of trends and action taken (135).

Table 3.0: Run Chart Rules for Special Cause Variation (136)

System Shifts	Eight or more consecutive points above or below the mean line
Trends	Seven or more consecutive increasing or decreasing points
Too many/too few runs	The number of times data crosses the mean line is too many or too few (based on the total number of observations) [9]
Astronomical points	Data points outside control limits

3.4.2 Evaluation of the Original Safety Thermometer

As previously when the original ST's steering group started developing the original ST, their aim was "to set up a low-cost pragmatic system to provide monthly data on four harms across care settings and produce measures that could be used locally for improvement but also aggregated to determine the burden of harm nationally"(118, 128). The review suggested that the aforementioned aim had been achieved, stating that "it was possible to develop a system for measuring harm nationally through standardisation and merging of locally reported data" achieved (118).

However, whilst a tool for data collection had successfully been developed, unexpected issues had arisen by using the original ST in regards to improving healthcare, as was identified by a subsequent qualitative evaluation led by independent researchers from the University of Leicester (128). The evaluation highlighted that whilst measurement to ensure a safe, high quality healthcare system was important and that the original ST was helping organisations to do this, there was also some tension between blame and accountability when using collecting data (128). The introduction of the original ST was *"an attempt to shift our focus from blame to learning"* (128, 137) however the evaluation of the original ST found NHS staff using the original ST saw the NHS-ST primarily as a blame allocation device, informed by their previous experiences of performance management and accountability. Armstrong et al. proposed that the focus in healthcare organisations on accountability had not allowed the aforementioned shift of focus from blame to learning to occur (128). Armstrong et al.'s evaluation of the original ST was an important step for identifying that the tool was not achieving the aim of moving away from a blame culture in NHS cultures, and has encouraged stakeholders to consider how the use of the original ST could be used. The evaluation was led by independent researchers not involved with the development of the MedsST, which is an important aspect for evaluation initiatives so that the findings are understandable for people who have not been involved in the development and do not have the background knowledge developers do. Furthermore it helps to ensure that collected data can stand independently so that another trained researcher could analyse the same data in the same way and come to essentially the same conclusion (138).

Following the roll-out of the original ST there were requests for similar ST tools to be developed to help measure other speciality areas of healthcare where measurement tools did not exist, and the next section discusses the 'next generation' Safety Thermometers that were developed. Independent evaluation programmes for the next generation of Safety Thermometers have also been introduced since 2013, and this PhD programme evaluates the use of the MedsST (See Section 3.5).

3.4.3 The Next Generation Safety Thermometers

Four 'Next generation Safety Thermometers' were developed from 2012 onwards forming the "Safety Thermometer Family (Figure 6.0). The four areas that they covered were: mental health, paediatrics, maternity and medication safety to measure and prevent harm (23). This programme of work focuses on the ST that measures medication safety only (the MedsST), and the other three areas measured by STs will not be considered in this programme of work.

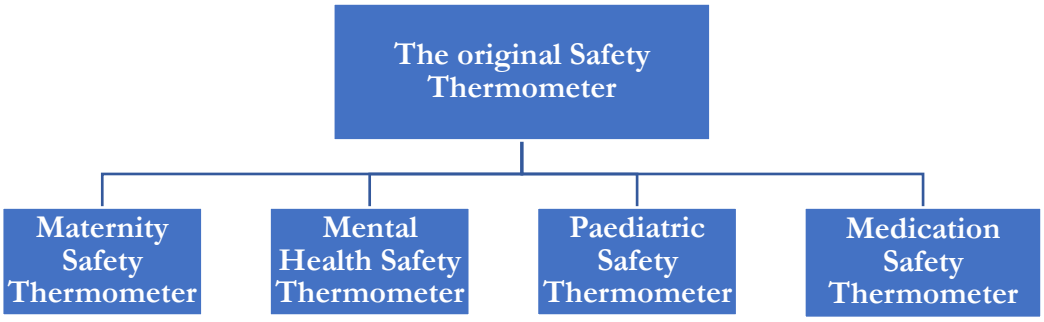

Figure 6.0 The Safety Thermometer Family

After the original ST, the most widely used next generation ST has been the MedsST, which has been used to survey over 200,000 patients. Unlike the original ST, nurses and pharmacists have equally been involved with the development and implementation of the MedsST. Study One (Chapter Six) briefly highlights differences in how different healthcare professionals attribute harm to ME and previous studies have reported differences in attitudes to reporting (139).

3.5 The Medication Safety Thermometer

The introduction of an ST to focus on safe medication use was deemed appropriate considering that medication incidents have been identified as one of the main causes of preventable patient harm, as mentioned in Section 2.2 (18, 29). Therefore, following the rollout of the original ST, many healthcare professionals called for a next generation ST to focus on medication safety. These calls were actioned upon and in 2011 a steering committee was formed to develop the MedsST (23).

3.5.1 Development of the Medication Safety Thermometer

The national steering group led by David Cousins started the development of the MedsST by investigating whether it was possible to measure harm from MEs in a similar way to the original ST (23). The steering committee aimed to develop a tool with the overall purpose of providing snapshot data about the burden of harm due to medication by focusing on four high risk medication groups. It has been suggested the simple act of collecting data should not be underestimated and, as data are mainly collected at the point of care by the multidisciplinary team (MDT), this process alone may help to improve safety culture and awareness at a local level (140).

The MedsST was designed to be used on a monthly basis and the data for measuring medication safety and related improvement over time.
The design, development and national implementation of the tool has been reported in Study 1 (Chapter Six). A number of improvement science methods were used such a driver diagrams and PDSA cycles, examples of which have been given the aforementioned study.

In summary, the steering committee decided to focus the MedsST on potential harms, such as medication omissions, and actual harms related to four classes of drugs that can cause patient harm if not prescribed, dispensed or administered appropriately: anticoagulants, injectable sedatives, insulin and opiates. All of these had been identified and reported to the NRLS as the most likely classes of drug to cause death and severe harm between 2005-2010 (18). The data collected can be used to highlight areas that require further investigation by organisations, for example, to see if policies are being followed or need updating. Although not all medications are included, collecting data about high risk medication groups allows organisations to get a 'snapshot' of the level of harm that is occurring and can measure improvement (23). During the development phase numerous PDSA cycles were used to decide the operational definitions for each measure's operational definitions (see Chapter Six, Study One).

3.5.2 The Current Medication Safety Thermometer Tool: Version 16

The current tool (version 16) was rolled out in August 2014 and involved 3 steps. Furthermore, since 2014 there are two sub-versions, one for acute settings (Version 16a, Appendix 1.0) and one for community settings (Version 16b, see Appendix 2.0). Version 16a (for acute settings) has been used more predominantly than version 16b (for community settings). The steps of the two tools are the same: Step 1 collects information about patient demographics about each of the patients on the ward or nursing home. Step 1 also asks questions about each patient's medication in the last 24 hours, in order to enable detection of critical medication. For example, the number of regular medicines, allergy status, medication omissions and the number of critical medicine omissions. If a patient is receiving any of the listed high-risk medicines then the data collector is prompted to move to Step 2.

Steps 2 and 3 focus on harm free care. Step 2 involves assessing each of the patient's high-risk medicines and aims to detect potential problems. If the answer to any of these questions about ADEs is "Yes", then these act as a trigger of potential harm and the patient should be discussed in Step 3 through an MDT huddle as described previously.

Step 3 involves a MDT huddle where the patient and the trigger of potential harm are discussed between a nurse, pharmacist and doctor. In community settings, this may take the form of a phone call to the GP practice. The discussion should determine whether harm has been caused by ME, and the group then report the level of harm, record learning (i.e. how to improve practices to prevent reoccurrences) from the discussion and whether or not an incident report has been or should have been completed. The three steps of the MedsST have been summarised in Table 4.0.

Table 4.0 – Steps of the Medication Safety Thermometer Version 16 (Adapted from Cousins et al.) (23)

Step:	**Step 1**	**Step 2**	**Step 3**
Patients surveyed:	All Patients.	Patients on high risk medicines.	Patients who have any signs of harm from high risk medicines.
Suggested data collectors/staff involved:	Ward Nurse and Pharmacist.	Pharmacist.	Ward Nurse, Pharmacist and doctor looking after patient.
Data collected/actions taken	• Patient demographics. • Medicines reconciliation initiation. • Allergy status completion. • Omissions. • Reasons for omissions. • Whether patient take any high-risk medicines*. • If patient is on high-risk medicines Step 2 is triggered.	Does the patient have any indicators of harm from the high-risk medicines? E.g. If the patient is taking an anticoagulant: • Have they had a bleed? • Have they been administered Vitamin K? • Are their INR** levels outside of limits (>6).	If the patient has any indications of harm from high-risk medicines, a multi-disciplinary huddle (discussion) should occur to discuss whether a harm has actually occurred due to the high-risk medicines. If so: • What is the level of harm? • What are the learning points?
*High risk medicines include: Insulin, Injectable Sedatives, Anticoagulants and Opioids, **INR: International Normalised Ratio			

Currently version 16 of the MedsST is in use (since October 2013), and since 1st April 2014 the testing phase has been completed for Steps 1 and 2 (23)

3.5.3 MedsST Guidance

Guidance for the MedsST was provided by the development steering committee, specifically for hospitals in the Greater Manchester region when a CQUIN financial scheme was in place to receive payments for collecting data (first six months) and then for showing signs of improvement (last six months) (see Section 3.5.4). The guidance described the purpose of the MedsST as:

"(the MedsST) can be used to: measure across the health economy, raise awareness of medications safety, engage nurses, pharmacists and medical staff in improving medication errors and understand the burden of harm from medication errors."(23)

Organisations that use the MedsST use have been provided various forms of guidance by facilitating NHS organisations including NHS England, Haelo and NHS Improvement. The guidance has included guides that are accessible via the website, webinars, one to one meetings and there was an event specifically about the launch of the MedsST in Bolton in January 2014. However, there have not been any more recent events. Since early 2017, MedsST data collected has been submitted to Quality Observatory team at South, Central and West Commissioning Support Unit on behalf of NHS Improvement (132). Despite the change in management the same guidance from 2013 have been provided to users and no changes in the MedsST has occurred since 2013. This guidance recommends that the sample for data collection on one day of each month is as follows:

- For acute services: 100% of patients on 5 surgical wards and 5 medical wards each month (the same wards should be used each month)
- For community services, 100% patients on one day each month, up to 200 patients. The same wards or teams should collect data for each month for consistency.
- Similarly to the original ST, data collection occurs on one day of each month.

3.5.4 CQUIN Targets

CQUIN targets are financial levers in addition to baseline funding, to incentivise healthcare organisations to reach certain targets (133). All NHS organisations were offered financial incentives to use the original Safety Thermometer through the CQUIN mechanism between April 2012 and March 2013. However, only regional and local financial incentives have been provided for organisations to use the MedsST. Only the Early Adopters (EA) of the MedsST (who joined the national programme during the alpha-testing phase, between January 2013 and March 2013) based in the Greater Manchester region, received a regional financial incentive for using the MedsST, between April 2013 and March 2014. The sole remaining EA organisation that was based outside of Greater Manchester, and Late Adopter (LA) organisations, who joined during the beta-testing phase or after (April 2013 onwards), have not received financial incentives unless they were separately agreed with their local commissioning groups.

3.5.6 Medication Safety Thermometer Data

Originally all data collected were submitted to Haelo, who managed the data collection between 2013-2017. However as mentioned previously, the management of the MedsST data has been transferred from Haelo to the Quality Observatory team at South, Central and West Commissioning Support Unit on behalf of NHS Improvement (132).

Since 2013, MedsST data collected has been openly available for organisations to view and download online at www.SafetyThermometer.nhs.uk. Downloaded data is presented in a dedicated dashboard and allows organisations to view data at national, organisational and ward levels. Data has been compiled for both acute settings and non-acute settings, however, there has been much more data collection in acute settings (141). Whilst patient level data is anonymous, the name of the organisation data are submitted for are not anonymised. The fact that organisations can access this information may lead to organisations competing with each other and "gaming" the system as has been suggested to occur with other national hospital data such as mortality rates (142) and original ST data(128). Gaming the system could include being

selective about which patients to collect data on and which data to submit (142).

3.5.7 Evaluation of the Medication Safety Thermometer and Use of its Data

Whilst data generated by the original ST has been used for a number of studies, and the use of the tool has been evaluated qualitatively, there is a lack of knowledge about the MedsST and its data, and how they can be used.

Whilst some of the lessons learnt from the evaluation of the ST is transferable to use of the MedsST, there are also large differences in how the original ST has been taken up by organisations in comparison to the MedsST. For example, Buckley *et al.* (2014) have published in their paper that the original ST has been a success in their organisation (126), despite this they have not been using the MedsST. Buckley's trust trialled the MedsST for one month and decided not to use it after this. A striking difference is that pharmacists are inevitably much more involved with the development, use and commissioning of the MedsST and previous research has suggested that different healthcare professionals have different attitudes to reporting incidents

As highlighted in Chapter Two, improving medication safety is a large aspect of addressing patient safety overall, and medication-related injury has posed a significant burden to healthcare resources. The overall purpose of the MedsST is to measure improvement over time. However, medication safety initiatives are not just about the development and roll out of a tool, it is also important to evaluate the use of the tool, in particular whether improvement is occurring as a result of an initiatives introduction, and 'what works for whom in what circumstances' (143). As Dixon-Woods *et al.* found when evaluating the programme 'Matching Michigan' (see Section 3.3), it is important to explore social and cultural aspects, rather than solely assessing whether a programme is 'working'. Understanding these aspects helps understand how and why programmes work (123)

There is no published research about the MedsST, and in addition there is a lack of research about the social and cultural aspects of data collection tools

that attribute harm to ME. It is also apparent that there is no universal definition for ME, making it difficult to assign one definition to ME that is suitable across settings, countries and time. However, it is important that a tool has clear operational definitions that can be used by frontline and senior healthcare staff and stakeholders.

As mentioned previously (section 3.5.3) there is guidance and published materials detailing how the MedsST is supposed to be used, little is known about the MedsST is actually used. Furthermore, little is known about the use of medication safety measurement tools as a whole because measurement of medication safety has not traditionally occurred in healthcare settings. The general guidance about the STs specifies that "it is not just about counting – it's caring", highlighting that the STs are designed to be used as part of a culture shift (132) moving away from a blame culture "counting" errors but towards a culture that focuses on improving systems and therefore outcomes for patients regardless of who's fault an error may be.

3.6 Summary of Chapter

Medication related harms are a large cause of overall harm to patients in healthcare. However, it is difficult for organisations to know whether improvement has occurred within their organisations as medication safety is not measured.

The increase in the use of Improvement Science for tackling healthcare issues has been beneficial for developing new innovations to help improve various aspects of healthcare. However, if innovation programmes are not evaluated and improved they can lead to wasting of resources. As qualitative research focuses on understanding meanings and experiences it is particularly useful for unpacking some of the complex issues inherent to improvement initiatives such as the MedsST (144), therefore this programme of work will mainly use qualitative approaches, the methods for this programme of work are discussed in Chapter Five.

Although literature exists evaluating the original Safety Thermometer and other large-scale patient safety systems, to date there is very little evidence evaluating patient safety measurement systems that focus specifically on measuring medication safety, which can be a more complex endeavour (22) as stated by the developers who have described the MedsST as the most difficult ST to develop (personal communication with Haelo and NHS England, 2014). Using implementation theory to evaluate the implementation would also help understand the relevance to how a similar tool to the MedsST may be implemented in other healthcare settings. Many difficulties can arise from the measurement of medication safety (22), and the MedsST measures are far more complex than the original ST measures and the MedsST involves more steps and staff involvement. There are similarities and differences between the MedsST and the original ST. For example, they both aim to improve patient safety by preventing patient harm, data is collected in a similar manner and in terms of development similar feedback systems have been in place for users of the MedsST.

In conclusion, it is important to use the learning from the original ST when researching the MedsST, but there are major differences between the tools and it is evident that separate research to assess the use of the MedsST is warranted. Hence, the overall aim of this programme of research being as follows:

To evaluate the use of the MedsST, with focus on how it has been designed, developed, implemented and can be used at both national and local levels.
A programme of research consisting of four studies (submitted for publication as four journal articles) was conducted in order to address this overall research aim. The structure of this programme of research is discussed in Chapter Three.

Chapter Four – Thesis Aim

As mentioned previously, the overall aim of this thesis is to evaluate the use of the MedsST, with focus on how it has been designed, developed, implemented and can be used at both national and local levels.

In order to evaluate an intervention, an understanding of how it has been developed is required, therefore the initial segment of this programme of work aims to understand the design, development and implementation of the MedsST both at national levels, and local levels within various healthcare organisations. This programme will then explore how the MedsST can be used to learn about medication safety and aid improvement. The specific objectives are as follows:

1) To investigate how the MedsST has been designed, developed and implemented into practice nationally, to help thoroughly understand the tool and its purpose.
2) To understand how the MedsST has been implemented into practice at a local level, and the barriers and facilitators associated with its implementation.
3) To identify whether MedsST data have been used to influence and measure improvements in medication safety in, and if so how.
4) To identify positive practice associated with use of the MedsST to aid medication safety improvement.
5) To explore how nationally aggregated MedsST data can be used to learn more about medication safety at scale within the NHS.
6) To make recommendations for up-scaling positive practice, and for general best use of the MedsST and its data.

SECTION TWO: METHODOLOGY

Section Two Introduction

The first section of this thesis provided an outline of the organisation of this thesis and introduced this programme of research (Chapter One). Chapters Two and Three provided background about patient safety, medication safety and improvement science as a facilitator for improving patient safety. A detailed background of the MedsST was also provided in Chapter Three. The thesis aims and objectives highlighted that this programme of research seeked to address the knowledge gap regarding evaluation of the MedsST.

As highlighted in Chapter Two and Three, evaluation of complex quality improvement initiatives requires various approaches, including qualitative and quantitative methods to consider both the social and cultural aspects of tools such as the MedsST. Therefore, a mixed-methods approach was chosen for conducting this programme of work which is discussed in Section Two which consists of Chapter Five only. Chapter Five presents a detailed description of the philosophical stance or paradigms in conducting mixed-methods research.

Descriptions of the four main paradigms used in research studies are highlighted in section 5.1. This is followed by stating the pragmatist paradigm has been used in this programme of work and the rationale for its selection (Section 5.2). Section 5.3 provides background information about mixed-methods before Section 5.4 gives the rationale for using a mixed-methods approach. Section 5.5 provides a more detailed information about various mixed-methods research designs and 5.6 gives the rationale for the mixed-methods research design used in this programme of work.

Sections 5.7 and 5.8 describe the qualitative and quantitative research methods used in this programme of work, respectively. Finally, Section 5.9 discusses the key methodological issues and ethical considerations related to this programme of work.

Chapter Five:
Methods

This programme of work employed a mixed-methods approach, where both quantitative and qualitative methodologies were used. To discuss the methodologies used in this programme of work, it is essential to explain first the underlying philosophical assumptions of research studies. This will then strengthen the rationale for selecting a mixed-methods approach, given the chosen paradigm.

5.1 Paradigms

A paradigm refers to a distinct set of beliefs, concepts or thought patterns, to guide a researcher's actions and beliefs. This set of beliefs relates to the existence and nature of reality (ontology), the perceived relationship with the object being studied that is considered real (epistemology), the process of knowing something considered to be real (methodology) and the ethical considerations required to conduct related research (axiology) (145). These fundamental principles of ontology, epistemology, methodology and axiology guide, inform and shape how a researcher sees the world and acts accordingly (146). Researchers must recognise the paradigm that guides their work because it enables them to identify their own roles in the research process, determine the course of any research project and decide other perspectives (147).

A large number of paradigms have been proposed by researchers, but four main paradigms are commonly used to underpin research studies (148, 149) . The four paradigms, also referred to as 'philosophical worldviews', include: postpositivism, constructivism, transformatism, and pragmatism. The following sub-sections discuss each of these paradigms.

5.1.1 Postpositivism

Postpositivism has been most commonly associated with quantitative research (148, 150). This paradigm has also been referred to as the 'scientific method' or doing science research (149). Studies guided by postpositivism often begin with a theory, then collect data that either supports or rejects the theory and

revise the theory accordingly before performing additional tests if necessary (148). Postpositivist researchers' approach includes gaining knowledge of what can be seen and measured. Knowledge of anything beyond that, a positivist would hold, is impossible (146). Postpositivism derives from positivism, but extends the traditional concepts associated with positivism, which concern the absolute truth of knowledge (149). Postpositivism was developed as positivist researchers realised that they cannot be positive about their claims of knowledge when it comes to studying the attitude and behaviour of people (149), and what might be the truth for one person or cultural group may not be the truth for another.

5.1.2 Constructivism

Constructivism is usually associated with qualitative research and is also referred to as interpretivism (149). Constructivist researchers investigate, interpret and describe social realities (145, 149). In contrast to postpositivism, researchers guided by constructivism (constructivists) propose that reality is subjective and socially constructed by its participants, therefore constructivist researchers aim to rely as much as possible on the participants' views of the situation being studied (149). Constructivists believe that individuals look for an understanding of the world in which they work and live. Individuals acquire subjective meanings of their experiences, and meanings focussed on objects and situations. These meanings are diverse and multiple, which lead the researchers to look for the complexity of interpretations instead of narrowing the meanings into a few ideas (149). Constructivist researchers recognise that their backgrounds, cultures and experiences shape the way they interpret the meanings, so they generate a theory rather than starting with a theory as postpositivists do (149).

5.1.3 Transformatism

The transformative paradigm is mainly associated with qualitative research, but can also be a foundation for quantitative research (149). The transformative paradigm provides a framework for examining assumptions that explicitly address power issues, social justice and cultural complexity throughout the research processes (151). The research contains an action agenda for reform

that may transform the lives of the participants, institutions where people work or live and the researcher's life (149). The transformative researcher uses a programme theory of beliefs about how the programme works and why problems of oppression, domination and power relationship exist (152).

5.1.4 Pragmatism

Pragmatism, which has guided this programme of work, is associated with mixed-methods research consisting of both qualitative and quantitative research. This paradigm is relatively new compared to the paradigms described previously. Pragmatism was developed in response to the disputes between quantitative and qualitative paradigms, and uses philosophy to enhance use of both qualitative and quantitative approaches to gain a practical solution (153). Pragmatist researchers use different methods to understand a problem (i.e. mixed-methods), instead of focusing only on one method (149). Pragmatist researchers focus their attention on a research problem and then use mixed-methods approaches to develop knowledge about the problem (147). The pragmatist researcher has the freedom to choose methods, techniques and procedures of research to meet the purpose of the study. The pragmatist researcher looks to the 'what' and 'how' to research based on the intended consequences. Therefore, they have their justifications for mixing approaches, and reasons for why quantitative and qualitative data need to be mixed (154). Pragmatism holds characteristics allied with both the positivist and constructivist paradigms (148, 149).

5.2 Use of the Pragmatist Paradigm to Guide this Programme of Work

The pragmatist paradigm was chosen to underpin this mixed-methods programme of work because it allowed use of both qualitative and quantitative methods to explore the research questions.

In this study, the researcher believed that the pragmatist paradigm was more appropriate than other paradigms for achieving the study aims. Pragmatism allows researchers to be free from mental and practical constraints by the "forced choice dichotomy between postpositivism and constructivism" (155). Pragmatist researchers have the flexibility in choosing the methods and

procedures that best fit the research question and aim. Thus, pragmatism opens the door to multiple methods, different worldviews and different assumptions from the other paradigms (149). The use of the pragmatist paradigm also allowed for use of different forms of both qualitative and quantitative data collection and analysis methods (149). This use of both qualitative and quantitative methods is referred to as mixed-methods, which is further defined in Section 5.3.

5.2.1 Reflexivity

The use of the pragmatist paradigm allowed greater "reflexitivity". Reflexivity has been described as researchers having an ongoing self-awareness during the research process which aids in making visible the practice and construction of knowledge within research in order to produce more accurate analyses (156). For example, different theoretical approaches were used, the initial qualitative strand of this programme of work incorporated elements of a constructivist grounded theory approach (see Section 5.7.2). Constructivist grounded theory has pragmatist roots (157) which make it a useful method for evaluating a tool such as the MedsST. Pragmatism offers different ways to think about evaluating a phenomena and constructivist grounded theory offers strategies for doing it (157).

The grounded theory approach relies on the assumption that social reality is constructed and, therefore, the researcher is an inherent part of that reality, which should be taken into account during the stage of analysis. This means that researchers should be aware of their preconceptions and reflexivity in order to ensure accuracy in analysing the data (158). During the initial stages of qualitative data collection and analysis, the main researcher purposely did not acquire knowledge of psychological theories, a process described as bracketing (159). This reflexive approach helped to ensure that the "true" meaning of data were explored and data were not forced into predefined categories. Once data collection was complete emergent themes were compared against existing implementation theories and frameworks, which led to the use of Normalisation Process Theory (NPT)(160) (See section 5.7.4).

5.3 Mixed-Methods Methodology

Creswell (2014) has defined mixed-methods research as *"an approach to an enquiry involving collecting both quantitative and qualitative data, integrating the two forms of data and using distinct designs that may involve philosophical assumptions and frameworks. The core assumption of this form of enquiry includes the combination of qualitative and quantitative approaches that provide a complete understanding of the research problem than either using one approach alone*"(page 4) (149).

Although adopting mixed-methods methodology is challenging and time-consuming, as it needs extensive data collection and analysis, it has been recognised as providing added value to research programmes at various levels. At the general level, choosing mixed-methods has its strength of drawing on quantitative and qualitative research, and overcoming the limitations of both approaches. At the practical level, it is an ideal method for researchers who have the need for, or access to, both types of data. At the procedural level, adopting a mixed-methods methodology is a useful strategy for obtaining a comprehensive understanding of the research problem (149).

5.4 Rationale for Using a Mixed-Methods Approach

The rationale for using a mixed-methods approach to evaluate the MedsST was to allow the use of a variety of methods to achieve the research aims mentioned in Chapter Four, in summary these were to:

- Gain an in-depth understanding of how the MedsST has been designed, developed and implemented nationally (Study One, Chapter Six).
- Explore how the MedsST has been implemented within healthcare organisations (Study Two, Chapter Seven).
- Explore how the collected MedsST data has actually been used for improvement within organisations (Study Three, Chapter Eight).
- Investigate how the collected data can be aggregated and used for medication safety research by focussing on the prevalence, nature and causes of patients experiencing omissions as an exemplar (Study Four, Chapter Nine).

Both qualitative and quantitative methodologies were required to achieve the above aims and objectives. The background chapters (Chapters Two and Three) highlighted that routine medication safety measurement within organisations is rare, and prior to the MedsST there has not been a tool to collect medication safety data routinely used by different NHS healthcare settings. Combining qualitative and quantitative approaches can enable a more detailed interrogation and understanding of the processes involved in using medication safety measurement tools, which was previously an underdeveloped research area.

5.5 Types of Mixed-Methods Research Designs

A number of mixed-methods research study designs exist, which have been summarised by Johnson and Onwuegbuzie (161) (see Figure 7.0), their summary highlights that mixed-methods research must make two primary decisions: whether one wants to operate largely within a qualitative or quantitative paradigm or not, and whether one wants to conduct the phases concurrently or sequentially.

		Time Order Decision	
		Concurrent	**Sequential**
Paradigm Emphasis Decision	**Equal Status**	QUAL + QUAN	QUAL → QUAN QUAN →QUAL
	Dominant Status	QUAL + quan QUAN + qual	***QUAL → quan*** qual → QUAN QUAN → qual quan → QUAL

Note. "qual" stands for qualitative, "quan" stands for quantitative, "+" stands for concurrent, "→" stands for sequential, capital letters denote high priority or weight, and lower case letters denote lower priority or weight. The approach taken in this PhD programme of work is highlighted.

Figure 7.0 Mixed-methods Design Matrix (161)

As highlighted in Figure 7.0, this programme of work used a sequential mixed-methods approach with a dominant focus of qualitative methods, the decision for using this approach has been explained in the following section.

5.6 Rationale for Using Sequential Mixed-Methods Approach

As this research involved the evaluation of a novel tool, it was important to first understand the tool, how it was developed and the proposed purpose of the tool. This was explored using various qualitative data, including data from previous versions of the tool, notes from steering committee meetings and input from members of the steering committee group (Study One). It was then important to understand how the tool has been implemented into practice, this was also explored using qualitative data, but in the form of interview data to share the subjective realities of the participants using the tool (Study Two). Study Two highlighted that whilst participants understood the purpose of the MedsST for helping to improve medication safety, they did not understand how this could be done. Leading to Studies Three and Four (Chapter Eight and Nine, respectively). Study Three explored how data had been used by using both quantitative and qualitative data from three organisations that had used the tool for the longest period of time. Study Four was a quantitative study that presented an exemplar of how nationally aggregated MedsST data could be used to learn about medication safety. Study Four focussed on medication omissions, which were highlighted by Studies Two and Three to be a problematic area of medication safety that was a priority area for improvement for participants' hospitals.

As highlighted above, qualitative approaches were used initially in this programme of work to understand what the MedsST was and how it had been implemented (Studies One and Two) this was followed sequentially by a qualitative study informed by quantitative MedsST data (Study Three) and quantitative (Study Four) study to explore how data were being used and can be used. The next sections will describe the qualitative and quantitative approaches used in this research

5.7 Qualitative Strategies Used in this Research

In general, qualitative research refers to types of research that produce findings that were not arrived at by means of statistical procedures or other means of quantification (162). Qualitative research uses a naturalistic approach that seeks to understand phenomena in context-specific settings where the researcher does not attempt to manipulate the phenomenon of interest (163). Unlike quantitative researchers who seek causal determination, prediction, and generalisation of findings, qualitative researchers seek instead illumination, understanding, and extrapolation to similar situations (164). As mentioned previously, the mixed-methods approach used in this programme of work had a dominant focus on qualitative approaches. Whilst the overall programme of work employed the pragmatic approach, the qualitative strand of this programme employed the constructivist approach in which individuals construct knowledge based on their experiences. This means that knowledge is socially constructed by multiple realities and may, therefore, be context and time specific (165). For example, whilst the MedsST may be aiding improvement in one setting, it may not be in another. Likewise, whilst data may be useful at national levels, it may be less useful, or vice versa at local levels. To account for these different realities, a mixed-methods approach of data collection was required to understand the realities constructed out of the experience of different participants in this programme of research.

The majority of studies in this programme of research are based on qualitative research. A qualitative approach was considered an appropriate method to address the objectives. For example, qualitative research allowed for participant selection that involved purposeful sampling, prioritizing inclusion of information-rich cases from which one can learn much about issues of central importance (see Study Three, Chapter Eight) (147). The qualitative documentary analysis and the theoretical underpinnings of the qualitative strand of this programme of work have been discussed in the following sub-sections.

5.7.1 Qualitative Documentary Analysis

Study One involved a qualitative documentary analysis that enabled the researcher to build a narrative about how the MedsST was designed, developed and implemented. This involved use of various sources of qualitative data, including data from 16 versions of the tool, notes from steering committee meetings and input from members of the steering committee group. The use of these multiple sources of data allowed triangulation. For example, changes identified between versions of the MedsST could be investigated using meeting notes to understand why they occurred and this could be confirmed by talking with members of the steering committee involved with the changes. Examples of such changes are given as PDSA examples in the Tables of Study One.

The use of documentary analysis for this study was particularly beneficial for a number of reasons. Documents are often the only source of data at an early stage of a healthcare innovation and they do not present the problems (practical, ethical, interactive) associated with research involving human subjects of research which can be time-consuming to overcome (166). On the other hand, documents about the development of a healthcare improvement tool such as the MedsST, are often partial or superficial, representing plans rather than realities (166). The scope for analysis can therefore sometimes be limited and subjective (166). However, the researcher used a reflexive approach and worked with a variety of the MedsST steering committee group members to overcome any subjectivity and to ensure that a range of perspectives about the "design, development and implementation" were merged into a single narrative that all contributors agreed on.

5.7.2 Underpinning Theories for the Qualitative Strand of Research

A theory refers to 'a set of concepts, definitions, assumptions and principles interrelated to each other" (167). Theories aim to explain and predict phenomena (168). As the use of the MedsST is a novel research area, the initial theoretical underpinning of this programme of work was derived from grounded theory (Section 5.7.2) which was used to develop themes which were later found to overlap with the four domains of NPT (Section 5.7.3).

5.7.3 Use of Grounded Theory

The initial qualitative component of this study used elements of grounded theory. Grounded theory has been defined as a "general methodology for developing theory that is grounded in data systematically gathered and analysed" (162). Using a grounded theory approach is particularly helpful for evaluation of tools, such as the MedsST, and allows researchers to help staff and decision makers understand how a programme functions and why it functions as it does (147). As the MedsST tool was a novel tool, elements of grounded theory were used to develop themes generated for the qualitative data in the sense that the initial themes developed were grounded within the collected data that was collected using an inductive process.

As mentioned previously, during the initial stages of qualitative data collection and analysis, the main researcher purposely did not acquire knowledge of implementation theory, a process described as bracketing (159). This approach allowed greater reflexivity. Bracketing occurred to ensure the true meaning of data were explored and data were not forced into predefined categories. Once data collection was complete emergent themes were compared against existing implementation theories and frameworks (160). It was found that there was strong resonance between the data, emergent themes, and the NPT constructs, and it made sense to extend the analytical process by mapping the emergent themes onto the four NPT constructs (169, 170). Therefore, NPT was used for Studies Two and Three.

5.7.4 Use of Normalisation Process Theory

After the constant comparative method was used to analyse data, which were constantly compared with earlier collected data, to form the themes grounded within the data. The second stage involved a deductive theory-driven analysis of the data. The constructs of NPT, and the relevant themes from the thematic analysis. Emergent themes from Study Two data mapped onto the four NPT constructs. The constructs of NPT and the relevant themes from the thematic analysis are presented Table B.1 of Study Two, Chapter Seven, alongside working definitions of the NPT constructs for this specific programme of work.

It was identified that the use of the tool required further research, leading to Study Four which extended the use of the NPT themes related to use of the MedsST and its data (Table C.2, Chapter Nine).

Previous quality improvement evaluation research has suggested it is not just about assessing whether a programme is 'working', it is also important that the system behind a programme is assessed, as it is crucial to understand how and why programmes work (123). In terms of evaluating the MedsST, looking at the system includes looking at how the activities involved using the MedsST are linked to improvements in medication safety, and how specific contexts interact with use of the MedsST.

Understanding the system behind a programme is vital to advancing the science of improvement. Implementing an initiative, such as the MedsST, over a wider region, simply because it is successful at reducing harm in some trusts, without understanding the social processes and mechanisms that produced the outcomes, can lead to a waste of resources, money and time (123). If the programme is extended to other healthcare organisations without understanding what makes it successful, new users of the programmes will not know what must be done to make the program effective or how they should direct their efforts and resources. If the social processes are not investigated, if the program does not result in improvement in other trusts, it is difficult to know why this is and whether this was due to faulty theory (the wrong thing was done), flawed implementation (the correct thing was done, but in the wrong way), or some combination of both (123).

5.8 Quantitative Strategies Used in this Research

Quantitative research allows the researcher to familiarize him/herself with the problem or concept to be studied, and perhaps generate hypotheses to be tested. In quantitative uses, data that are in the form of numbers that can be quantified and summarised and final results are expressed in statistical terminologies (163). As this programme of work assessed a tool that surveys patients, it was deemed necessary to use collected data to conduct survey

research. Survey research is a type of quantitative research that can be conducted to provide a quantitative or numeric description of a population, by studying a sample of the population (149). One of the stated aims of the developers of the MedsST was to develop a tool that provides baseline measurement of medication safety issues and use data for improvement (23), and the possibility of this was explored in Study Four (Chapter Nine) by using aggregated MedsST omissions data as an exemplar.

5.9 Key Issues in this Programme of Research

A number of issues arose during the programme of research, which have been discussed in the sub-sections below.

5.9.1 Reliability and Trustworthiness of the Research

Reliability in quantitative research refers to gaining results that are similar, consistent, regardless of the number of times the method is repeated (171). The statistical tests and methods that were used in the quantitative methods (Studies Three and Four) were repeated with the same data set to ensure and checked by other members of the research team to ensure accuracy.

As the term 'reliability' in quantitative research is used for testing repeatability, it can be an irrelevant measure in qualitative research (172) and demonstrating 'trustworthiness" of qualitative research is generally more appropriate (165). It has been stated that trustworthiness in qualitative research relates to how well a particular study does what it is designed to do (173). Trustworthiness in this programme of research was demonstrated using a number of methods. In Study One a variety of members of the original steering committee were collaborated with to ensure accurate reporting of the design, development and implementation of the MedsST. In Study Two, several interviews were conducted, which were audio-recorded and transcribed verbatim by the researcher or a University of Manchester approved transcriber. Interviews were conducted until data saturation was reached, themes were compared to previous implementation theories and the supervisors also confirmed and developed the findings. In Study Three, qualitative data were compared against quantitative data to confirm and explore the emerging findings. Although

interviews took place in Study Three they were not recorded, as frontline staff in Study Two had indicated they were more comfortable with discussing use of data for specific incidents, such as judicial inquiries if they were not recorded.

An audit trail was recorded for all three studies with qualitative components (Studies One, Two and Three); this included management of collected data, noting how data were collected and how themes emerged from the data, to ensure consistency and demonstrate dependability in the research. In addition, members of the research team for each study conducted peer examination to check the plausibility of emerging themes and interpretation of data. For example, when conducting Study Two (Chapter Seven), the main researcher's supervisory team reviewed data and emergent themes to ensure consistency and reliability. Furthermore, the published qualitative studies have undergone peer-review.

5.9.2 Ethical Issues

A number of ethical issues were considered during the design and conduct of this programme of research. These included participants' informed consent, coercion and the confidentiality of the individual participants, and the organisations that they were from. Some of the research did not require ethics approval as it involved secondary analysis of open-access data, or constituted service evaluation, however, university ethics approval was obtained for the interviews that required it (Appendix 5.0).

To ensure ethical research is conducted it is important that research participants are fully informed about the purpose of the research, risks associated with their participation and how research data will be used (174). To ensure this, all potential participants who were interviewed were provided with a participant information sheet, that was sent with the recruitment e-mail (Appendix 6.0) or provided in paper copies prior to interviews. Two participant information sheets were used, one for MedsST Leads (those leading the implementation of the MedsST in their organisations [see Appendix 7.0]) and MedsST users (frontline MedsST data collectors [see Appendix 8.0]) that outlined the aims, requirements and duration of the research, what happens to

the data collected and, if participants change their mind after data has been collected, how confidentiality is maintained, where the research will be conducted and details on what to do if the participant experiences any issues regarding the research. Potential participants were also given the opportunity to contact the researcher if they had any further enquiries before committing to their involvement. This ensured participants were not coerced into participation and that they had the freedom to decide whether they would like to participate or not. Participants were asked to sign consent forms (Appendix 9.0) or provide verbal consent prior to interviews commencing.

It was also vital to ensure that confidentiality was maintained by keeping manual and electronic data secure. Data were safeguarded in compliance with faculty procedures from the University of Manchester. All interview data collected in Study Two were recorded on an encrypted Dictaphone and were transferred to the researcher's university secure network drive, which is encrypted and recordings were deleted from the Dictaphone. Notes from interviews in Study Three were only shared between the research team, and the participants who had been interviewed were sent their own data to clarify the accuracy and meanings in the notes.

Polgar and Thomas state that "the risks of identifying individuals in research are increased in the study of small, specialised sub-populations and in qualitative studies where direct quotation of the words of the research participant may be used in the publications" (174). Participant names in Study Two and Study Three were anonymised by marking them with a pseudonym or reference number. In Studies Three and Four, any data, such as colleague names that were accidentally mentioned by the participant were deleted and have been replaced with ellipses (…) in the study publications.

5.9.3 Ethical Approvals

Studies One and Four did not require any ethical approvals, as they did not collect data and only involved secondary analysis of anonymous data. Studies Two and Three recruited various NHS staff who were involved with either

leading the implementation of the MedsST, using the MedsST to collect data or using the data collected by the MedsST.

Using the NHS ethics tool, it was confirmed that Study Two did not require NHS ethical approval. Instead, it required University Research Ethics Committee (UREC) approval, which was obtained from The University of Manchester Research Ethics Committee 3 on the 25th November 2015 (reference number 15479).

Study Three did not require approval from either an NHS Research Ethics Committee or the university's Ethics Review Panel because it involved service evaluation rather than research. This was confirmed by the university's Research Practice Governance Manager.

The university uses the following criteria for determining whether service evaluations require ethical review:

- "Data are collected without personal identifiers, the participants are not asked for confidential or sensitive information, the issues being researched are not likely to upset or disturb participants.
- The research involving interviews with participants on subjects deemed to be within their professional competence."

The work reported here meets the above criteria and sought to evaluate an existing service. No personal or upsetting questions were asked and the MedsST does not collect patient-identifiable data. Verbal consent for interviewing was obtained from all participants.

SECTION THREE: INVESTIGATING HOW THE MEDICATION SAFETY THERMOMETER HAS BEEN DEISGNED, DEVELOPED AND IMPLEMENTED NATIONALLY AND LOCALLY WITHIN ORGANISATIONS

Section Three Introduction

Section Two provided background about the main paradigms used in research (Section 5.2), and a rationale for the pragmatist paradigm used in this mixed-methods programme of work (Section 5.2). Furthermore, the various designs of mixed-methods research were summarised, and the use of the sequential mixed-methods approach was rationalised (Section 5.4). The theories used throughout this programme of work were also described, including grounded theory and NPT (Section 5.7). Methodological issues and ethical considerations in this programme of research were also highlighted.

As this thesis is presented in the alternative format, this section (Section Three) and the next section (Section Four) present the four research studies conducted in this programme of work as journal articles. Each study's journal article has stated the specific methods used within the study. In summary:

- Section Three explores how the MedsST has been designed, developed and implemented into practice and includes Studies One and Two (Chapters Six and Seven, respectively).
- Section Four explores how the MedsST and its data can actually be used to for medication safety improvement and includes Studies Three and Four (Chapters Eight and Nine, respectively).

Chapter Six:

Study One

Chapter type:	**Journal article**
Article title:	**Learning from the Design, Development and Implementation of the Medication Safety Thermometer**
Authors:	**Paryaneh Rostami, Maxine Power, Abigail Harrison, Kurt Bramfitt, Steve D. Williams, Yogini Jani, Darren M. Ashcroft, and Mary P. Tully**
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Note. As this paper has been published, the formatting, referencing and layout are consistent with the requirements for the journal. The abbreviations used may also differ. For this chapter, references, tables, figures and appendices will be placed at the end of the chapter rather than at the end of the thesis.

Learning from the Design, Development and Implementation of the Medication Safety Thermometer

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Abstract:

Quality Issue: Approximately 10% of patients are harmed by healthcare, and of this harm 15% is thought to be medication related. Despite this, medication safety data used for improvement purposes are not often routinely collected by healthcare organizations over time.

Initial Assessment: A need for a prospective medication safety measurement tool was identified.

Choice of Solution: The aim was to develop a tool to allow measurement and aid improvement of medication safety over time. The methodology used for the National Health Service (NHS) Safety Thermometer was identified as an approach. The resulting tool was named the 'Medication Safety Thermometer'.

Implementation: The development of the Medication Safety Thermometer was facilitated by a multidisciplinary steering group using a Plan, Do, Study, Act (PDSA) method. Alpha and beta testing occurred over a period of 9 months. The tool was officially launched in October 2013 and continued to be improved until May 2016 using ongoing user feedback.

Evaluation: Feedback was gained through paper and online forms, and was discussed at regular steering group meetings. This resulted in 16 versions of the tool. The tool is now used nationally, with over 230000 patients surveyed in over 100 NHS organizations. Data from these organizations are openly accessible on a dedicated website.

Lessons Learned: Measuring harm from medication errors is complex and requires steps to measure individual errors, triggers of harm and actual harm. PDSA methodology can be effectively used to develop measurement systems. Measurement at the point of care is beneficial and a multidisciplinary approach is vital.

Key words: medication errors, harm, measurement, PDSA

Quality Issue

Approximately 1 in 10 patients are harmed by healthcare [1–3]. It is thought that 15% of these harms are associated with medication related incidents [3], which remain the single largest source of repetitive healthcare error [4]. Despite these statistics, there is a lack of tools to routinely measure medication safety in healthcare organizations over time.

Initial Assessment

Previous research indicates that harm to patients involving medication is often preventable [5]. Therefore, interventions aimed at reducing medication errors have the potential to make a substantial difference to improving patient safety [3]. In order to prevent medication errors and reduce the risks of harm, organizations must detect and measure errors [6], and analyse the information collected to understand what is happening and why. Medication errors are currently under-reported, often because they are corrected before reaching the patient [7]. Nonetheless, the small proportion of errors that do reach the patient may potentially cause severe harm, including death [8].

Most medication safety data are obtained through either research studies or, more commonly, voluntary reporting. The latter has been the mainstay of learning from medication safety incidents within the UK's National Health Service (NHS). However, voluntary reporting underestimates error [8–12], and even though the number of reports has continually increased since the National Reporting and Learning System (NRLS) was established [13], the numbers and quality of reports from individual organizations remain variable [12]. Data collected for research studies are more reliable than voluntary reports and can be used for learning 'and' measuring. However, such data collection methods are rarely used in practice, as they are time-consuming, labour-intensive and expensive [14, 15]. Hence, they are not sustainable or practical in the long term for busy healthcare environments.

Previous literature has suggested that it is time to review and update data collection methods with 'fresh eyes' [10]. Therefore, NHS England commissioned Haelo (an independent innovation and improvement science

centre hosted by Salford Royal Hospital NHS Foundation Trust) [16] to explore whether the NHS Safety Thermometer approach could be applied to collect medication safety data, which could be used for learning and measurement, and to support organizations in decreasing the risk of harm from medication error over time.

Choice of Solution

The NHS Safety Thermometer, developed in 2010 as part of a national safety improvement programme in England, is a tool that has enabled organizations to collect data on common harms on 1 day each month and to track improvement over time [17]. The original NHS Safety Thermometer measures harm from pressure ulcers, falls, venous thromboembolism and urine infections in catheterized patients. It also provides a composite measure of 'harm free' care, defined as the absence of the measured harms [18].

Following the national rollout of the Safety Thermometer specialist groups and frontline teams identified that this methodology could be used for additional patient safety issues. Four 'next generation' Safety Thermometers were developed for maternity, mental health, children and young people and, the subject of this paper, the Medication Safety Thermometer (MedsST).

A national multidisciplinary steering group was commissioned by NHS England and facilitated by Haelo. This group initiated the development of the MedsST, an instrument that aimed to support local measurement of harm from medication, and related improvement. The MedsST also needed to allow for data to be aggregated and assessed at regional and national levels, in line with the NHS Outcomes Framework, which requires a focus on the 'incidence of medication errors causing serious harm' [19].

The steering group adhered to the Safety Thermometer design principles, that the tool would: have clinically valid definitions, be efficient, be used wherever the patient is treated, provide immediate access to data over time, measure all harm experienced by the patient regardless of preventability, measure harm at

the patient level enabling a composite measure of 'harmfree' care and be easy to aggregate [18, 20].

Approach to Implementation

A plan for developing the MedsST was constructed using a driver diagram framework (Figure A.1). Alpha-testing (from January 2013 to March 2013) involved very early tests with eight alpha-sites in Greater Manchester and one alpha-site in London. Beta-testing ('the pilot phase') ran from April 2013 to September 2013. In addition, a 6-month regional Commissioning for Quality and Innovation (CQUIN) payment target was introduced from April 2013 to March 2014 to incentivize the Greater Manchester organizations to continue testing the tool. CQUIN targets are used as financial levers in addition to baseline funding for organizations in the NHS [21]. Participation in the beta testing phase was open to all organizations and led to 43 sites joining the pilot phase. The national rollout of the MedsST occurred in October 2013 and collection of feedback for improving the MedsST has continued.

Agreeing on Operational Definitions

It was decided to focus on harm due to high-risk medicines and develop measures of harm related to errors involving these (Tables A.1–A.3).

Technical Development

Initially, a paper-based prototype instrument was tested in alpha-sites; data were entered into a spreadsheet and e-mailed to Haelo. Monthly feedback was used to design the next iteration of the form.

Guidance for Instrument Use and Data Collection

Safety Thermometers have been designed to be used as part of routine healthcare, in acute and community settings to encourage continuity of care [22].

The NHS Safety Thermometer data collection is made at the point of care by a healthcare professional who reviews the patient's documentation and performs a physical examination where necessary. For example, the presence of a

pressure ulcer, when the skin is inspected, is classed as a 'harm' in the original Safety thermometer. Early discussions between the steering group and the first tests of change revealed difficulties with this methodology when measuring harm from medicines. In particular, harm from medication may not be apparent at the time of review. This 'uncoupling' of the error from the harm required a stepped approach to measuring error and harm. This characteristic is unique to the MedsST and differentiates it from the original NHS Safety Thermometer.

Guidance documents were developed to support teams in testing the tool [20]. It was recommended that Step 1 data (process errors) were collected by nurses, and Step 2 data (triggers of harm) by pharmacists and nurses together. The third step involved a multidisciplinary 'huddle' to discuss if harm had actually occurred. In hospital settings, this would involve at least the nurse, pharmacist and junior doctor looking after the patient on the ward, and in the community, this may involve a phone call from a nurse or pharmacist to the GP overseeing the patient's care.

Feedback and Satisfaction with the Instrument

The main methods of feedback to the steering group included: monthly meetings via a virtual conferencing platform, monthly surveys and regular phone calls and e-mails with volunteers who had tested the tool. The data collected using the tool, and the feedback and satisfaction data were discussed regularly within the steering group. Once changes were agreed, a new version of the tool was circulated. The development team hypothesized that, with increased satisfaction and ease of use, the number of patients surveyed and the number of organizations using the tool would increase.

Ethics

Data were collected for NHS service improvement rather than research; therefore, research ethics committee approval was not required. No patient identifiable data were collected. The data were collected monthly as part of routine care, therefore causing no burden to patients and the burden on the staff was evaluated using surveys and identified as minimal.

PDSA Testing and Instrument Refining

Safety Thermometers have been developed using improvement science, in particular, Plan, Do, Study, Act (PDSA) cycles, which provide a structure for iterative testing of changes to improve quality systems. Each measure and definition included was developed using numerous cycles.

To date (May 2016), there have been 16 versions of the MedsST with multiple small changes per version, with each version tested for 2–3 months. Version 16 has now been used for over a year, with no current plans for Version 17. Version 16 includes subversions for acute and community settings. The most recent version of the MedsST is available from www.safetythermometer.nhs.uk [23].

Agreeing on Operational Definitions

In order to measure outcomes of harm from medication, proxy measures were identified, but early tests revealed that this approach alone would not provide clinically valid definitions of harm. Attributing harm to medication error was complex due to several factors. For example, there may be some time between an error occurring and the harm being apparent (such as omission of an anticoagulant) or it may be difficult to establish if the error alone had caused the harm (such as confusion due to opiate overdose, which could also be due to a competing cause, for instance, a severe infection). To ensure only a manageable proportion of the most high-risk patients were triggering Step 2, each operational definition was refined several times (Table A.1). In addition, process measures that may indicate potential harm were also focused on including medication omissions, allergy status and medicines reconciliation completion.

Technical Development

As the number of users increased, an online version using SurveyMonkey® replaced the spreadsheet method. Once feedback indicated that the form was suitable, online platforms were developed, including a dedicated web tool and an application that could be used on phones or tablets, which also allowed

offline data collection. This reduced the data collection time and anecdotal feedback suggests most organizations take <2 minutes per patient (excluding interruptions and when Step 3 is triggered).

Recommendations for Use and Observations of Use

Through testing, the steering group agreed a recommended sample for data collection: all patients on five surgical wards and five medical wards per hospital, on the same day each month and all patients (up to 200) in community settings. However, organizations could choose to scale up their collection sample over time. Suggested dates for data collection were published in the MedsST guidance [20] and were used by the majority of organizations.

Feedback from surveys and observations revealed that data have been collected by a variety of professionals (Tables A.1 and A.2). Anecdotal feedback suggested in some, but not all organizations, Steps 1 and 2 data were regularly analysed at ward and senior management levels. For example, at some sites, MedsST was analysed to see which wards were showing most improvement. Additionally, not all organizations have used Step 3 and, when it has been used, there have been challenges with completing it at the point of care. In hospitals, for example, the patient surveyed may have left the ward by the time the huddle could be arranged. In those organizations that have used Step 3, it has encouraged voluntary incident reporting of harm to allow local investigation and identification, in turn promoting a culture of safety [24].

Feedback and Satisfaction with Instrument

Virtual conference meetings allowed users and developers to discuss and suggest improvements based on testing and learning. It was often highlighted that organizations were experiencing similar problems, for example, problems with high numbers of referrals from Step 1 to Step 2, due to codeine-based medication post-surgery (Table A.2). There has been a steep increase in the number of hospitals using the Web tool and, more recently, the mobile application. Some hospitals have stopped using the MedsST. Anecdotal feedback suggests some hospitals have stopped using the MedsST due to lack of time and resources.

Setting

The MedsST has predominantly been used in secondary care hospitals; however, has also been used in community settings, including community hospitals, domiciliary care and nursing homes.

Lessons Learned

Repeated PDSA cycles confirmed that attributing harm to medication error at a single time point is highly complex [4, 9], and it is necessary to use different steps to observe errors, triggers of harm and actual harm. The original plan was for the MedsST to involve a simple bedside point of care audit, similar to the NHS Safety Thermometer, which focused on harm as an outcome of medication error. However, the resulting instrument extends this and focuses on both potential and actual harm due to medication [10].

Adverse events are often multifactorial, and it can be challenging to attribute harm to a medication [9]. By using a number of steps, this complexity was partially addressed, as only those patients that triggered potential harm indicators were investigated for actual harm. Previous tools, such as the IHI global trigger tool, have demonstrated the need for using numerous steps [4]. Although various steps are required, trigger tools must be as time- and resource-efficient as possible [25, 26]. A previous study, using the IHI global trigger tool for Adverse Drug Events (ADEs), reported that 20 minutes was required to screen a single patient's record, and the study required a doctor and pharmacist to spend one-half to one day per site retrospectively reviewing a random sample of charts that contained triggers [26]. The study used a 39-item ADE trigger tool and only nine of the 39 triggers used accounted for 94.4% of ADEs detected [26]. Focusing review on triggers more predictive of an adverse event, as the MedsST does, is a better use of resources and may be more likely to improve patient safety [25, 26].

PDSA methodology can be effectively used to develop a measurement system As previous research has suggested, it is occasionally necessary to simply 'get on with it' to assess the outcomes and the methods by which we can learn and

improve a system [27]. However, this should not be a 'quick and dirty process' and requires an efficient plan, which may be constantly revised [27]. As indicated in Table A.1, some definitions were expanded and then retracted to the original definition over several versions because, until changes are tested, it is difficult to know their impact.

The overarching aim to develop a tool to allow measurement and aid improvement of medication safety over time was achieved. Feedback from organizations using Step 3 suggests the MedsST triggers have been useful to identify actual harm from high-risk medications, and may have contributed to increased incident reporting and encouraged multidisciplinary teamwork. However, the focus on actual harm was expanded to also include potential harm (using process measures) and some organizations have focused on potential harm only. Although the focus of the MedsST may differ to what was originally planned, the PDSA cycle approach is quality driven and learning from 'failed' tests is equally as important as learning from success, and often the most valuable lessons are learnt from failure, which enables course correction [28].

Measuring medication error and harm at the point of care is beneficial and a multidisciplinary approach is vital. The data collected and analysed provide a baseline to establish whether further improvement work impacts medication safety and if it is maintained [12]. The simple act of collecting data should not be underestimated and, as data are mainly collected at the point of care by the multidisciplinary team (MDT), this process alone may help to improve safety culture and awareness at a local level [29].

Although more complex than anticipated, it was possible to collect similar medication safety data in different settings. Testing revealed that the MedsST needed to be different in community and acute settings, as the resources in each setting are considerably different.

Lessons Learned from the Data

The focus on medicines reconciliation helps to improve continuity of care between healthcare settings [22]. Some of the medicines reconciliation rates observed from the national MedsST data are similar to rates from previous research. For example, national MedsST data show that ~73% of patients are having medicines reconciliation within 24 hours (Figure A.2a). This figure is similar to findings from a previous study evaluating medicines reconciliation rates in one UK hospital (n = 70%) [30]. The aforementioned data, however, indicate that the standard of 95%, previously suggested by the National Institute for Health and Care Excellence for medicines reconciliation within 24 hours [30, 31], is not being met. Organizations should be encouraged to use the MedsST when assessing further improvement work to increase medicine reconciliation completion rates.

Other MedsST data have varied from data collected in previous research. For example, MedsST data suggest 22% of patients have at least one dose omission per day (Figure A.2b) and 5.7% of patients experience an omission of a critical medication (Figure A.2c). These omission data are lower than omission rates from previous research studies, which estimate that 80% of patients have an omitted dose [32]. This variance is may be due to a number of factors such as whether studies measure the rate of omissions of doses, or the rate of patients with omitted doses [33]. Other reasons include: studies examining different drug classes or whether data are collected from electronic prescribing and administration systems, which have the potential to impact omissions and identifying the rate of omissions [34]. Therefore, standardization of how omissions are measured is required and in the context of the MedsST, local improvement has been encouraged, rather than comparison between organizations.

Lessons learned from the data provide many opportunities for further improvement work, which can be presented in a variety of ways. The Pareto Chart in Figure A.2d shows that 80% of critical omissions were with only two of the four critical risk medications (anti-infectives and opioids). Therefore, the most parsimonious approach of reducing omissions may be to focus

improvement efforts on reducing omissions of anti-infectives and opioids in the first instance.

Data collected by the MedsST are presented in run charts on the website [23]. This allows users to study variation in data over time and understand the impact of changes with minimal mathematical complexity [35]. The run charts make data accessible and understandable to a range of different healthcare professionals. Special cause variation occurred in August 2014 (Figure A.2b and c), when there was a decrease in the number of omissions coincident with the introduction of Version 16. This was due to a change in the way omissions data were collected and the operational definitions that were first implemented in Version 16 (Table A.1). To address this, further guidance and support was provided to organizations. This was done by producing additional guidance and providing support via group WebExes, and one-to-one phone support to certain organizations. The data stabilized from September 2014 onwards, suggesting that challenges with data collection had been somewhat resolved.

Over 230000 patients have been surveyed using the MedsST in over 100 organizations (June 2016). As the number of patients surveyed using the MedsST has increased, the denominator for each of the medication safety measures is larger, which has reduced variation. A decrease in variation occurred in early 2015, as illustrated in Figure A.2a-d; in January 2015 the number of patient surveyed was 7425 compared to 5271 patients in December 2015. Furthermore, the hypothesis, that the number of organizations and patients surveyed would increase as the satisfaction and ease of use increased, was correct. This is also suggested by the fact that the majority of Greater Manchester organizations chose to continue using the MedsST, despite no longer receiving CQUIN payments after April 2014.

However, some organizations have stopped using the MedsST. Detailed analysis of such cases is warranted for further learning. Individual organizational data published online [29] demonstrates that, despite the constraints of using a tool that is relatively new, some organizations have improved [29]. This suggests that solutions to common problems may exist in

the user community. Certain MedsST users, who are positive deviants, may have knowledge that can be generalized and, if the solutions have been generated within the MedsST user community, they may be more readily adopted in other organizations [36–38].

Suggestions for Future Work

Further research is required to explore how the MedsST is used in practice and to evaluate its utility. A mixed-method approach may be suitable for this. Investigation of variance in the use of the MedsST is warranted, for example, to explore the barriers preventing some organizations from using Step 3. Investigation of variance of the actual MedsST data is also warranted. Lessons can be learnt from organizations who have shown improvement in their MedsST data. The positive deviance approach may be useful to explore how the MedsST can successfully be used for improvement.

Conclusion

The MedsST provides a refined methodology for measuring medication safety and its improvement over time. The PDSA approach has been particularly helpful in developing the tool. The increased engagement may be due to the refinement of the tool relying on regular feedback from frontline users; however, further research is required to ascertain this. The MedsST is inherently practical and easy to use, and has been used by over 100 healthcare organizations across the UK. To the best of our knowledge, it is the only tool measuring medication safety on a monthly basis. Data collection has led to demonstrable improvement in some organizations, but not all, indicating the need for further development and evaluation.

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Study One Figures

Figure A.1: Project Plan Framework - Adapted from Power et al (18)

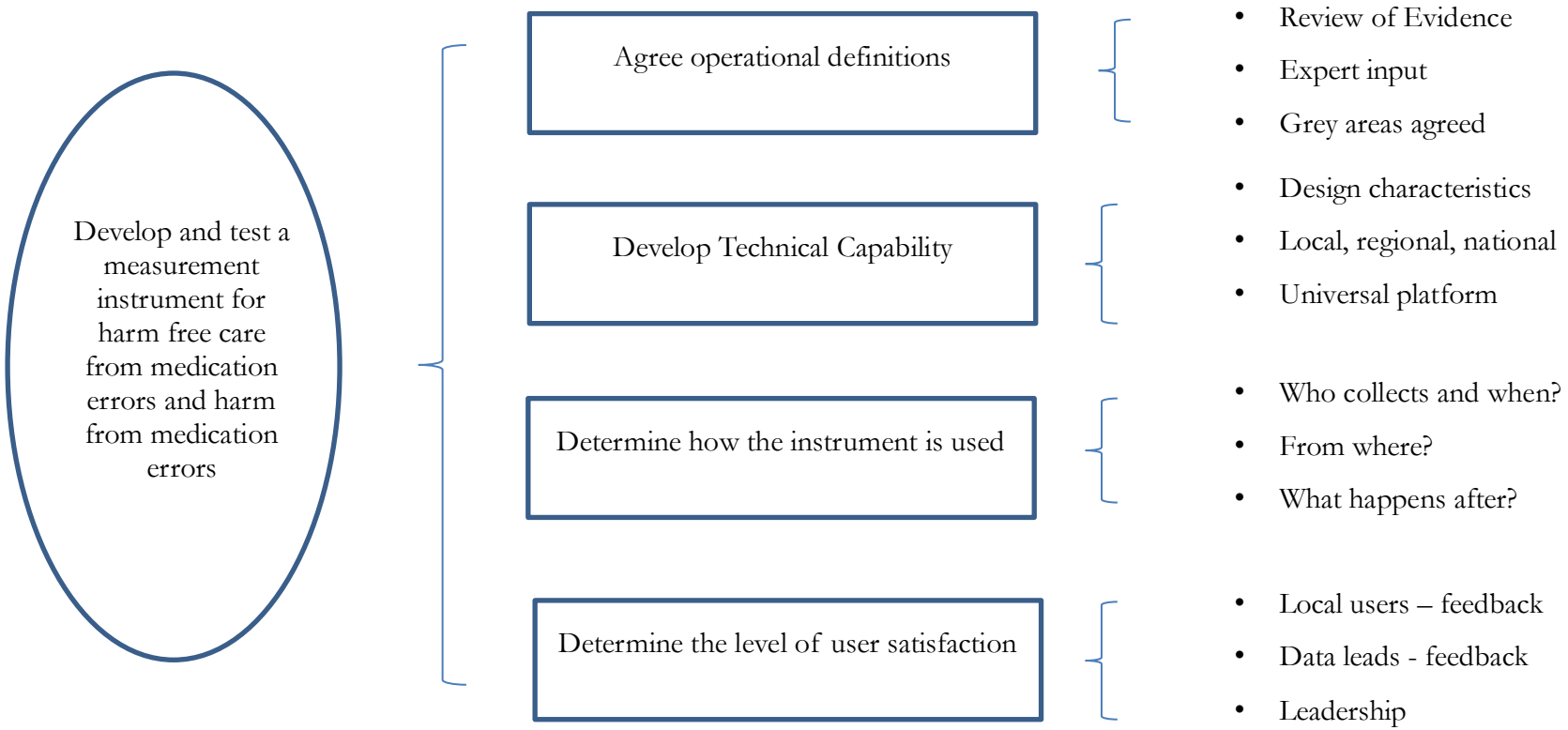
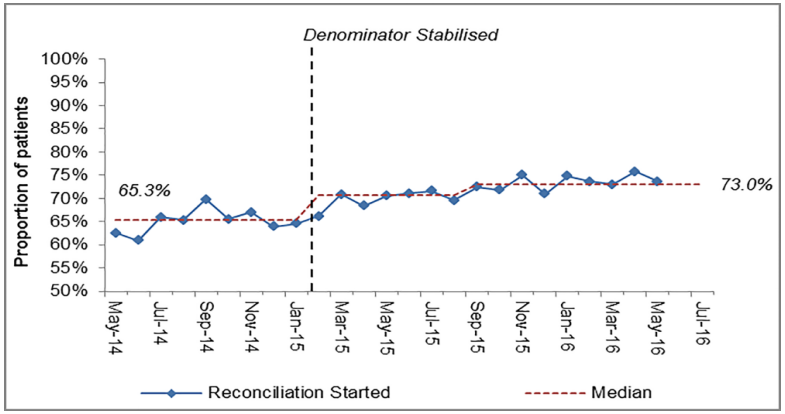
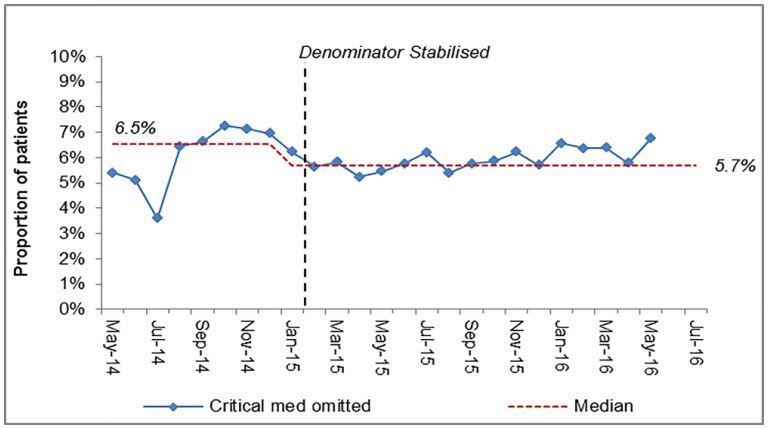


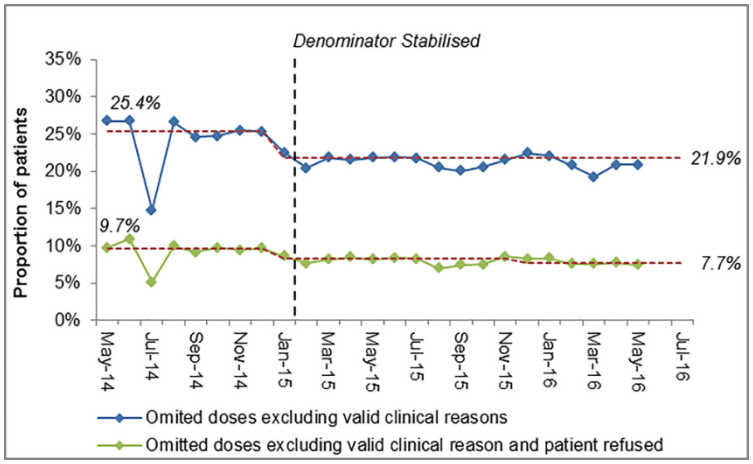
Figure A.2: Medicines Reconciliation and Omissions Data over Twenty-Four Months



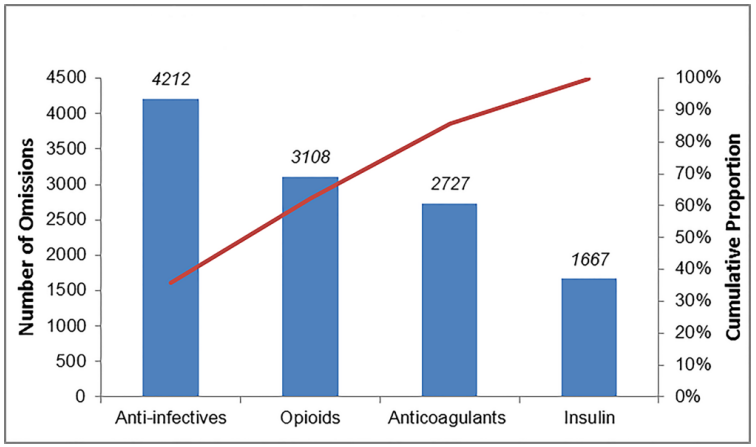
A.2a: Proportion of Patients with a Medicines Reconciliation Started in the First Twenty-Four Hours of Admission to Setting.



A2b: Proportion of patients with Omissions of Critical Medicine(s) in the Last Twenty-Four Hours[1].



A.2c: Proportion of Patients who have had an Omitted Dose in the Last Twenty-Four Hours[1].



A.2d: Number of Critical Omissions by Medication Class (between October 2013 and April 2016). The red line denotes the cumulative frequency of omissions.

[1] The last 24 hours from the point of data collection [2] Anti-infectives include: antibiotics, antifungals, antivirals and antimalarials

Study One Tables

Table A.1 - Changes in operational definitions over time (using Version 1, 8 and 16 for illustration).

Step 1 of Versions 1 and 8 have been provided in Appendix A.1 and A.2

Note: The most recent version on the MedsST is available from www.safetythermometer.nhs.uk

Measure/ step	Step	Version 1	Version 8	Version 16*
Allergy status documented	**1**	Was the medicine allergy status documented in the clinical record in this care setting (including no known allergies)?	Was the medicine allergy status documented in the patient's clinical record in this care setting (including no known drug allergies) e.g. on prescription or Medication Administration Review and Request (MARR) chart?	Same as version 8.
Medicines reconciliation initiated		Were all medications documented as reconciled within 24 hours of admission to this care setting?	Was medicines reconciliation for all medicines undertaken (started) within 24 hours of admission to this care setting?	Same as version 8.
Omission of medication		Had the patient had an omitted dose of any medication in the last 24 hours?	Had the patient had an omitted dose of any medication in the last 24 hours (excluding food supplements)?	Was the patient on any of the following medications: anticoagulants, opioids, insulin or anti-infectives (excluding food supplements & oxygen). If so, had any of these (or "any other prescribed medicines") been omitted and for what reason? **Reasons**: Patient refused, outstanding reconciliation, medicine not available, route not available, patient absent at medication round, not documented or other.
Omission of high risk medication		Not included in Version 1.	Were omitted doses (see above) any of the following: anticoagulant, insulin, opiate, anti-infective (antibiotics, antifungals, antivirals and antimalarials)?	

Inclusion criteria and triggers for harm from anticoagulants	**2**	All anticoagulants were included. **Triggers:** If the patient had a bleed, vitamin K administered or INR outside the following limits -less than 2, higher than 6.	Heparin, LMWH, Warfarin and NOACs (excluding VTE prophylaxis) were included. **Triggers:** A bleed of any kind or VTE, administration of vitamin K, protamine or clotting factors e.g. octaplex, or an INR greater than 6 or APTT ratio greater than 4	Heparin, LMWH, Warfarin and NOACs (excluding VTE prophylaxis) were included. **Triggers:** A bleed of any kind or VTE, or administration of vitamin K, protamine or clotting factors e.g. octaplex.
Inclusion criteria/trigger for harm from opiates		All opiates were included. **Triggers:** Was the prescribed dose more than 50% higher than the previous dose? Was the prescribed starting dose usual for the route to be used? Was the patient showing any symptoms of an overdose or common side-effects?	All opiates included. **Triggers:** Common complications (including sedation, respiratory depression, confusion), administration of naloxone, increased early warning score or respiratory rate below 12 breaths per minute.	Opioids excluding oral codeine, dihydrocodeine and tramadol. **Triggers**: Administration of Naloxone, respiratory rate is less than 8 breaths per minute.
Inclusion criteria/trigger for harm from sedatives		All sedatives were included. **Triggers:** If the patient had any history of dementia or delirium, had administration of Flumazenil or had had a fall.	The following injectable sedatives were included: midazolam, lorazepam, diazepam, clonazepam. **Triggers:** Common complications of over sedation (hypotension, delirium, respiratory depression, reduced Glasgow Coma Score), administration of Flumazenil or increased early warning score.	IV or SC sedatives: Midazolam, Lorazepam, diazepam, clonazepam were included **Triggers:** Common complications (see version 8) or administration of Flumazenil.
Inclusion criteria and Triggers for harm from insulin		All insulin included. **Triggers:** If an intravenous syringe or a non-insulin syringe used for insulin preparation or administration? Was the patient's insulin unit dose and frequency clearly documented? Had the patient had any omitted doses of insulin in the last 24 hours?	All insulin was included. **Triggers:** Common complications (capillary blood sugar < 4mmol/L, symptoms: anxiety confusion, extreme hunger, fatigue, irritability, sweating or clammy skin, trembling hands), administration of IV dextrose or glucagon, or diabetic ketoacidosis or hyperosmolar hyperglycaemic state	All insulin included. **Triggers:** Common complications: capillary blood sugar < 4mmol/L or symptoms of hypoglycaemia, administration of IV dextrose or glucagon, or diabetic ketoacidosis or hyperosmolar hyperglycaemic state.

	3	If any of the above (harms) were identified, the team was to refer to Step 3, which involved a Multi-Disciplinary Team (MDT) root cause analysis to determine whether there was harm from medication error. **The form for Step 3 was to be confirmed.**	If triggered, organisations were recommended to perform an MDT huddle. This would involve a discussion with the doctor, nurse and pharmacist taking care of the patient to ascertain whether harm had occurred. **The form for Step 3 was to be confirmed.**	If triggered, organisations were recommended to perform an MDT huddle using **a supplementary page for facilitation.** The form recorded: who was involved with the MDT huddle, their roles and involvement with the patient's care. If harm had occurred, it also recording of the level of harm based on NPSA harm scale (8) and learning and outcomes of Step 3.

*Version 16 consists of two sub-versions; acute and community. The acute sub-version has been used for illustration purposes in this table, as it is used more predominantly.

Table A.2: Summary of PDSA Cycles Involved in Developing Step 1.

Plan	Step 1 would focus on error potential and be completed for all patients. It involves collecting demographic data regarding the patient, their medications, omissions and drug allergy documentation, and identify patients taking any of the four classes of medicines reported to the UK's National Reporting and Learning System (NRLS) as most likely to cause death and severe harm between 2005 and 2010 (8) if not prescribed, dispensed or administered appropriately: anticoagulants, injectable sedatives, insulin and opiates. Step 1 was the first stage of a proxy harm measurement system, and if a patient was on any of the aforementioned medications, Step 2 would be triggered (Table 3). Prediction: Step 1 would be collected by nurses and they would be comfortable using Step 1, if they were not, this would be highlighted in user feedback. Step 1 would refer a small proportion of patients who were on high risk drugs to allow a manageable "snapshot" of the level of harm from medication errors. Testing would confirm if the high-risk drug class definitions were appropriate for this, or whether they were under- or over-sensitive.
Do	Testing was gradually scaled up as the tool improved, based on feedback from each test. First, very small tests on one patient were undertaken, then one ward, multiple wards, alpha sites (9 hospitals), beta sites (43 hospitals), and finally all sites continued to feed back after the official testing phase ended. Frontline teams collected data and fed back their experience of using the form, for example, how easy data collection was and how long it took. Feedback was collected at regular intervals and assessed at biweekly steering group meetings, facilitated by the development team, to ascertain the most efficient method of collecting data. Feedback platforms included online forums and surveys, verbal reports and meetings. Observations were also undertaken to better understand the impact of problems, such as the order of questions in regard to ease of data collection.
Study	The prediction was not entirely correct as some definitions were not appropriate, for various reasons highlighted below. The main learning points from testing were: • In addition to nurses, Step 1 data were also collected by pharmacists, pre-registration pharmacists, clinical auditors and healthcare assistants. • The wording of some questions in Step 1 was not relevant or appropriate for community care settings. • The conceptual order of the questions did not enable the easiest and quickest collection of data, and was not necessarily taking less than 10 minutes per patient. The order, although seemingly logical, actually meant that

	most teams were looking for data in one place for the first question, moving somewhere else on the record to get the data for the next questions, and then going back to their original source for data for the third question.
Act	• A large number of patients who were at a very low risk of harm were triggering Step 2 due to being on opioids. Qualitative feedback from testers indicated that they felt that patients on low doses or low risk opioids were going through to Step 2 unnecessarily, as there was very little risk of harm occurring and that this was very time consuming and disengaging. This was mostly due to low dose codeine, usually compounded with paracetamol as co-codamol. This had often been prescribed as 'when required' and not always necessarily used by the patient. • There was a need identified for an appropriate denominator to understand the proportion of omissions of high risk medication. In early versions, data about the number of patients who had had omissions of high risk medications was collected, however, data about the number of patients who were on the high-risk medications initially were not collected. This meant that users were using the whole population of patients surveyed as a denominator, as opposed to the population of patients on a high-risk medication, leading to sampling bias.
	Actions taken in response to study of tests included: • Development of a community sub-version, in which the wording was amended to make Step 1 more relevant to practice in community. • Individual definitions were revised to make the tool more practical. For example, it was decided to exclude oral codeine, dihydrocodeine and tramadol, as the problems they were causing in data collection outweighed the benefit of keeping them. The concept of the Medication Safety Thermometer is to give a *snapshot* of harm and it is not possible to include all medications, even though they all have the potential to cause harm.

	• The form was reordered so that questions were grouped together around the likely source of information. Multiple PDSAs were conducted to re-design all of the questions, thus increasing ease of data collection and reducing the time required. • A new question was introduced about the number of patients on critical medication.
Unresolved issues	Feedback from users has highlighted that the wording remains unsuitable for community settings; further refining is required. Some organisations are still taking longer than 10 minutes to survey each patient; further investigation is required to explore the potential reasons for this.

Table A.3 - Brief Summary of PDSA Cycles Involved in Developing Step 2

Plan	The plan was for Step 2 to be completed for all patients triggered in Step 1 due to receiving one or more of the high risk medications. Step 2 was the second stage of a proxy harm measurement system mentioned in Table 2. For example, if a patient identified in Step 1 as being on an anticoagulant, and then in Step 2 it was established that they had had a bleed, these two factors together would be classed as a harm. Similarly to Step 1, PDSA methodology was used to develop the measures so that data would be simple to collect, the burden of data collection is minimal and measures are easily understood and clinically valid. **Prediction: Step 2 would be collected by nurses and pharmacists together, who would be comfortable with identifying the harms listed. The definitions used for the triggers of harm from medication error would be appropriate for identifying potential harms. Feedback from users would identify if the definitions used were appropriate or not.**
Do	Data were collected on all patients identified in Step 1 who were on any of the drugs from the four high risk classes. These patients would go through to Step 2 where a nurse and pharmacist would collect data on whether the triggers of harm had occurred. First, very small tests on one patient were undertaken, then one ward, multiple wards, alpha sites (9 hospitals), beta sites (43 hospitals), and finally all sites continued to feedback after the official testing phase ended. Frontline teams collected data and fed back on their experience of using the form, for example, how easy data collection was and how long it took. Feedback was collected at regular intervals and assessed at biweekly steering group meetings, facilitated by the development team to ascertain the most efficient method of collecting data. Feedback platforms included online forums and surveys, verbal reports and meetings. Observations were also undertaken to explore the feedback and better understand the impact of problems, such as the order of questions regarding ease of data collection.
Study	The prediction that teams would be comfortable with identifying harms was not entirely correct, and a need for revisions was confirmed as each definition went through multiple PDSA cycles. Qualitative feedback from several PDSAs indicated that the attempt to define harm related to medication errors was extremely complex and that the measures were not representative of actual medication harm. Some of the key individual issues identified were: □ Instead of Step 2 being collected by a nurse and pharmacist as recommended, it was mainly collected solely by a pharmacist or in some cases solely by a nurse. In addition, other professionals, such as pharmacy technicians were collecting data for Step 2. □ Certain terminology was not understood by all data collectors depending on their professional background. For example, one of the triggers of harm from injectable sedatives included assessing the patient's "early warning score". However, feedback indicated that most of the data for Step 2 was being collected by the pharmacy team who, as opposed to nurses, were not

	familiar with this term. In addition, different organisations had different definitions of "early warning scores" and not all organisations used them. • Attributing a harm to a medication error using a trigger was difficult. It is absolutely vital to have multi-disciplinary discussions to ascertain the likelihood of whether harm has occurred due to a medication error. In many cases, it was not possible to be certain that a harm was only related to medication. There could be other factors to consider, making it difficult to decide if a harm could be classed as a medication harm.
Act	Definitions of each individual measure were refined and tested through PDSA cycles numerous times, resulting actions included: • Refinement of Step 2 to exclude certain triggers. For example, the use of an "early warning score" as a trigger of harm was removed in version 8. • There was strong consensus from the steering group and the testers that, in order to understand if a harm was caused by a medication, there needed to be a multidisciplinary discussion involving nurses, doctors and pharmacists when collecting data on medication harms. This lead to official testing of Step 3, in volunteering organisations, after the launch date (October 2014) when Step 2 was more refined and stable.
Unresolved issues	The argument for continuing to include 'when required' opioids. Some harm may be missed, as harm may occur from low dose opioids. Many organisations have not been using Step 3 and referring harms from Step 2 for MDT discussion. Further qualitative exploration is required to find out why organisations are not using Step 3.

Study One Appendices

Appendix A.1 -The Medication Safety Thermometer Version 1 (Step 1)

Patient Information Step 1		
Gender	Male / female	
Age group	<18, 18 – 70, >70	
Were all medications documented as reconciled within 24 hours of admission to this care setting?	Yes / no	
How many regular medicines is the patient prescribed?	1-3, 4-7, 8-11, 12-15, 16-19, > 20	
Is the medicine allergy status documented in your clinical record in this care setting? (including no known drug allergies)	Yes / no	
Does the Patient have a Medication Alert Card	Yes/No	
Has the patient had an omitted dose of any medication in the last 24 hours?	Input number	**Select reason** *Medicine not available* *Patient 'Nil By Mouth'* *Route (e.g. IV) not available* *Patient not present (e.g. patient in diagnostic department)* *Dose refused by patient* *Outstanding reconciliation query* *Other - please specify reason* *Valid clinical reason*
Is the patient on any of the following drugs?	*Anticoagulants* *Insulin* *Opiates* *Sedatives* *Nonsteroidal anti-inflammatory* *Diuretics* *Antiplatelets*	**Yes/No** **If yes move to step 2**

Appendix A.2 – The Medication Safety Thermometer Version 8 (Step 1)

Medications Safety Thermometer V.8

Each question should be answered by circling the response

Step 1: Medication review for all patients

This section should be completed by the nurse or primary carer using the medication administration or prescription chart, information from clinical records and dialogue with the patient / carer. The focus of this section is on the fundamentals of safe medication use. It should be completed for ALL patients surveyed.

1.1 Gender	Male				Female		
1.2 Age	< 18		19-40		41 – 69		>70
1.3 Was medicines reconciliation for all medicines undertaken (started) within 24 hours of admission to this care setting?	Yes				No		No- patient still within 24 hour period at point of survey
1.4 How many regular medicines is the patient prescribed? (Not including PRN , stat doses or IV fluids)	0	1-4	5-8	9-12	13-16	17-20	>20
1.5 Is the medicine allergy status documented in your clinical record in this care setting? (including no known drug allergies) e.g on prescription or MAR sheet	Yes				No		

1.6a Has the patient had an omitted dose of any medication in the last 24 hours? (*excluding food supplements)* (insert number of omissions using available information e.g. 3 omissions as patient refused and 2 route not available)	Valid clinical reason e.g. low BP	
	Outstanding reconciliation	
	Medicine not available	
	Route not available (e.g NBM, IV line tissued)	
	Patient absent at meds round	
	Patient refused	
	Not documented	
	Other	

1.6b Were these omitted doses any of the following: (Insert Yes or No)	Anticoagulant	
	Insulin	
	Opiate	
	Anti-infectives *	

1.7 Has the patient received any of the following medicines in the last 72 hours? *Anticoagulants(Heparin, LMWH { Excluding VTE Prophylaxis}, Warfarin and NOACs*)* *Insulin* *Opiates* *IV or SC Sedatives* **	**Yes** Patient on **high risk** medications **Proceed to section 2**	**No** Safety thermometer complete. No need to proceed further.

*(Warfarin , Sinthrome, Phenindione, Newer Oral Anticoagulants (NOACs), Dabigatran (PRADAXA) Apixaban (ELIQUIS), Rivaroxaban (XARELTO) LMWH: Dalteparin (FRAGMIN), Tinzaparin (INNOHEP), Enoxaparin (CLEXANE)

* Anti-infectives (antibiotics, antifungals, antivirals & antimalarials)

** IV or SC Sedatives Midazolam, lorazepam, diazepam, clonazepam

Progression from Study One to Study Two

As this research involved the evaluation of a novel tool, it was important to first understand the tool, how it was developed and the proposed purpose of the tool. Therefore, Study One addressed the first objective of this programme of research: to investigate how the MedsST has been designed, developed and implemented into practice nationally, to help thoroughly understand the tool and its purpose.

Study One highlighted the recommendations for implementation of the MedsST at local levels. However, further research was required to investigate how the MedsST had actually been implemented in practice and understand whether the proposed recommendations developed by the steering group had been followed. Therefore, the findings from Study One led to the development of Study Two which explored the implementation the MedsST at local levels, within different healthcare organisations.

Chapter Seven:

Study Two

Chapter type:	**Journal article**
Article title:	**A Formative Evaluation of the Implementation of a Medication Safety Data Collection Tool in English Healthcare settings: A Qualitative Interview Study Using Normalisation Process Theory**
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Note. As this paper has been published, the formatting, referencing and layout are consistent with the requirements for the journal. The abbreviations used may also differ. For this chapter, references, tables, figures and appendices will be placed at the end of the chapter rather than at the end of the thesis.

A Formative Evaluation of the Implementation of a Medication Safety Data Collection tool in English Healthcare Settings: A Qualitative Interview Study using Normalisation Process Theory

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Abstract:

Background: Reducing medication-related harm is a global priority; however, impetus for improvement is impeded as routine medication safety data are seldom available. Therefore, the Medication Safety Thermometer was developed within England's National Health Service. This study aimed to explore the implementation of the tool into routine practice from users' perspectives.

Method: Fifteen semi-structured interviews were conducted with purposely sampled National Health Service staff from primary and secondary care settings. Interview data were analysed using an initial thematic analysis, and subsequent analysis using Normalisation Process Theory.

Results: Secondary care staff understood that the Medication Safety Thermometer's purpose was to measure medication safety and improvement. However, other uses were reported, such as pinpointing poor practice. Confusion about its purpose existed in primary care, despite further training, suggesting unsuitability of the tool. Decreased engagement was displayed by staff less involved with medication use, who displayed less ownership. Nonetheless, these advocates often lacked support from management and frontline levels, leading to an overall lack of engagement. Many participants reported efforts to drive scale-up of the use of the tool, for example, by securing funding, despite uncertainty around how to use data. Successful improvement was often at ward-level and went unrecognised within the wider organisation. There was mixed feedback regarding the value of the tool, often due to a perceived lack of *"capacity"*. However, participants demonstrated interest in learning how to use their data and unexpected applications of data were reported.

Conclusion: Routine medication safety data collection is complex, but achievable and facilitates improvements. However, collected data must be analysed, understood and used for further work to achieve improvement, which often does not happen. The national roll-out of the tool has accelerated shared learning; however, a number of difficulties still exist, particularly in primary care settings, where a different approach is likely to be required.

Keywords: Medication Safety, Measurement, Normalisation Process Theory, Quality Improvement

Background

One in ten patients are harmed by their healthcare and research indicates that 15% of this harm is medication related [1]. Large-scale epidemiological studies provide important insights into the problem, but are time-consuming and expensive to conduct. Voluntary incident reports have formed the mainstay of medication safety data within England's National Health Service (NHS); however, whilst reports are vital for learning, they do not allow measurement and tracking of improvement over time. In order for healthcare organisations to know if they are reducing medication-related harm, medication safety must be routinely measured to provide a baseline and to track improvement. In order to address the lack of routine medication safety data, England's NHS introduced an improvement tool called the "Medication Safety Thermometer" (MedsST) in 2013 [2] and developed it via a large-scale multi-disciplinary collaborative, facilitated by Haelo (an independent innovation and improvement centre hosted by Salford Royal NHS Foundation Trust, England).

The MedsST was developed based on a similar tool called the "original Safety Thermometer", which routinely measures harms from pressure ulcers, falls, venous thromboembolism and urine infections in catheterised patients [3]. Following the national rollout of the original Safety Thermometer, four further Safety Thermometers were developed for maternity, mental health, children and young people and, the subject of this paper, the MedsST. The MedsST consists of three steps to measure individual errors, triggers of harm and actual harm related to medication safety. Details of the MedsST tool and how it has been designed and developed are described in a previous paper [2].

An evaluation of the original Safety Thermometer identified that it is possible to establish nationally used measurement systems to aid patient safety improvement, via large-scale collaborations. However, there were considerable challenges, for example changes to organisational policy at local and national levels, such as loss of funding for use of the intervention [4]. All NHS organisations were offered financial incentives to use the original Safety Thermometer through the Commissioning for Quality and Innovation (CQUIN) mechanism between April 2012 and March 2013. However, only

regional and local financial incentives have been provided for organisations to use the MedsST. Only the Early Adopters (EA) of the MedsST (who joined the national programme during the alpha-testing phase, between January 2013 and March 2013) based in the Greater Manchester region, received a regional financial incentive for using the MedsST, between April 2013 and March 2014 [2]. The sole remaining EA organisation that was based outside of Greater Manchester, and Late Adopter (LA) organisations, who joined during the beta-testing phase or after (April 2013 onwards), have not received financial incentives unless they were agreed with their local commissioning groups [2]. The availability of financial incentives is an external contextual factor [5], and one of many differing contextual variables regarding how the MedsST has been implemented and used in comparison to the original Safety Thermometer. Another example of a contextual variable is the greater variety of healthcare staff that have been needed for development and use of the MedsST, due to the complexity of identifying medication-related harm [2], which has also been identified as a factor that influences successful implementation of a patient safety intervention [5].

Although literature exists evaluating the original Safety Thermometer and other large-scale patient safety systems, to date there is very little evidence evaluating patient safety measurement systems that focus specifically on measuring medication safety, which can be a more complex endeavour [2]. Using implementation theory to evaluate the implementation would also help understand the relevance to how a similar tool to the MedsST may be implemented in other healthcare settings.

Given the potential for medication safety measurement to help reduce medication related harm and, therefore, improve patient safety, and the lack of theory-based evidence relating to the implementation of routine medication safety measurement tools, particularly with a national focus, the aim of this study was to explore healthcare staff's experiences of implementing the MedsST in England, using Implementation Theory [6].

Methods

Ethical Considerations

University ethical approval was received from The University of Manchester Research Ethics Committee 3 on the 25th November 2015 (reference number 15479). Written consent was gained from participants prior to interviews.

Design

As the research question is descriptive and concerns "how" the MedsST has been implemented, a qualitative approach was used to allow collection of data that could be used to gain an in-depth understanding of this phenomenon [7]. Interviews were used, which allowed rich data to be obtained by purposively recruiting a number of respondents that was small enough to permit in-depth qualitative analysis, but displayed wide diversity in perspective (i.e. a 'maximum variation' approach). Normalisation Process Theory (NPT) was used as an underlying concept for data analysis [8]. NPT is a theory of healthcare implementation and offers a structure for understanding practices that enable or constrain the integration of an intervention into routine care [9]. Reporting of this study is in line with the Consolidated criteria for reporting qualitative research (COREQ): and a COREQ checklist can be found in S1 File of the Supporting Information files[10].

Sampling

Participants were recruited from various healthcare organisations in England, and included EA and LA organisations. Staff were purposely sampled to recruit staff who were leading the implementation of the MedsST (MedsST leads) and frontline users collecting data for the tool (MedsST users) based in healthcare organisations that had used the MedsST for at least 3 months consecutively, and that were based in England (where the MedsST has been exclusively developed and implemented). MedsST leads are appointed representatives of their organisations, who have been involved with the implementation of the MedsST at their organisations. MedsST leads are usually senior pharmacists; however, middle-grade pharmacists, pharmacy technicians and nurses may also be MedsST leads. MedsST users are usually nurses and pharmacists, but may also be pharmacy technicians, pre-registration pharmacists and clinical auditors. To determine sample size, the data

saturation approach was used, where the researchers determine when the data collected from the interviews becomes redundant and it is estimated that the inclusion of more study subjects would add little to understanding of the study phenomenon [11].

MedsST leads were recruited by e-mail, using a database of existing contacts known to Haelo. This recruitment was followed up with snowball sampling, in which the MedsST leads were asked to forward the e-mail to MedsST users within their organisation. Some participants were known to the researcher through professional networks prior to the study.

Data Collection

Fifteen in-depth semi-structured interviews were conducted between December 2015 and September 2016 by PR, as part of her PhD project evaluating the use of the MedsST. The interview schedule (see S2 File) was based on three main topics drawn from the recommended national guidance about the MedsST (the most recent guidance is available from www.safetythermometer.nhs.uk) [12]; engagement with the purpose of the tool, data collection and the use of data by the organisation. To better understand what enables and constrains the implementation of a large-scale intervention in different settings, contexts were also considered by focussing on "how implementation processes differ between settings" [8], for example, questions about whether financial incentives were attached to use of the MedsST. The resulting interview schedule was piloted with a pharmacist before data collection began. New topics were added to the interview schedule, for subsequent interviews, as they arose in earlier interviews. Interviews were conducted in person, at the participants place of work, or by telephone, ranged in length from 32 to 99 minutes (average, 63 minutes), and were digitally recorded and transcribed verbatim. Field notes were also made and used to clarify the meaning of the interview data, such as the specialty of wards mentioned by the participants.

Data Analysis

The interview transcripts were imported into the qualitative data analysis management software

QSR N-Vivo version 11.0. The first author (PR) conducted the data analysis, which was conducted in two stages, the co-authors (MPT and DMA) provided advice and input throughout the analysis process. The first stage involved an initial inductive thematic analysis of data, where data were coded, categorized and similar categories grouped into themes emerging from the data[13]. The constant comparative method was used, where the data analysed were constantly compared with earlier collected data, to form the categories and to explore variations in the data. The end result was the identification of 10 descriptive themes, shown in the second column of Table B.1.The second stage involved a deductive theory-driven analysis of the data. Once the thematic analysis was complete, emergent themes were compared against existing implementation theories and frameworks [6]. Strong resonance was identified between the data, emergent themes and the NPT constructs, and it made sense to extend the analytical process by mapping the emergent themes onto the four NPT constructs [8, 9]. The constructs of NPT and the relevant themes from the thematic analysis are presented in Table B.1, alongside working definitions of the NPT constructs for this specific study.

The co-authors contributed to the analysis in discussion of data, themes and constructs, to ensure that all perspectives were covered. Quotes were chosen to best illustrate each theme and to display a range of varying opinions. Words in parenthesis have been added to quotes by the authors to clarify meaning, and ellipses (…) have been used to indicate the removal of unrelated text or information that may lead to identification of participants. Participant details are presented in Table B.2.

Results

Fifteen participants were recruited from ten organisations, including five EA organisations and five LA organisations (Table B.2). The ten organisations were located across six different English counties. Participants consisted of eight MedsST leads and seven MedsST users. At the beginning of the study period (December 2015), staff from sixty-five organisations were eligible for the study according to the inclusion criteria, therefore 15% of eligible organisations were represented in the study. Participant roles included seven secondary care pharmacists, two primary care pharmacists, three secondary care nurses, one pre-registration pharmacist, one pharmacy technician and one clinical auditor. Despite considerable efforts, only two participants working in primary care were recruited, and both were pharmacists and MedsST leads. Openly accessible data online indicates that many primary care organisations had stopped using the MedsST prior to this study [12]. Implications of, and reasons for, primary care organisations stopping the use of the MedsST were explored during interviews with all participants, as certain secondary care organisations worked closely with associated primary care organisations.

Factors Influencing Implementation of the MedsST

The findings are presented within the NPT framework, using study-specific definitions (see Table B.1) and supported by illustrative quotes. The source of each quotation is indicated by participant number, profession and whether they are from an EA or LA organisation.

Coherence: Understanding the Purpose of the MedsST and its Data

Regarding the views on the purpose of the tool, the study analysis highlighted that a common understanding existed, concerning the rationale for measuring medication safety for learning and improvement. However, in order to have confidence to engage with the MedsST implementation, NHS staff required clarification on the operation of the tool, such as; how data should be collected and by whom, and available support networks that could be used to facilitate this. All participants were in agreement that the MedsST's purpose was to aid improvement of medication safety by enabling organisations to quantify medication safety issues and providing a "base-line" (P10, Nurse, EA) to

monitor improvement. Specifically, it was used to identify the most problematic hospital wards and work with them to improve medication safety.

Most organisations had previously used yearly audits to measure medication safety. Staff with training or passion for quality improvement truly understood the benefits of monthly medication safety data, as opposed to yearly data from the traditional medication safety audits collected by most organisations.

Only one organisation had collected monthly medication safety data prior to implementing the MedsST, using an internally developed tool. The MedsST lead from this organisation reported that their medication safety data tool had been replaced by the MedsST, because of its national focus, and the ability to use the learning they had gained from their previous tool to contribute to the MedsST's development, as this MedsST lead had joined the steering group who were leading the development of the MedsST. The MedsST lead preferred the previous tool, due to greater data "granularity" (P12, Pharmacist, EA). However, the MedsST user in the same organisation preferred the MedsST over the previous tool, because it involved nurses, saved time and provided immediate feedback for wards.

> *There was a clunky internal system before that resulted in our lead pharmacist having to plug away hours and hours and hours of data collation, and pulling together and feeding that back to us. That's clearly not a robust way…(and the Medication Safety) Thermometer for our organisation is brilliant…it has slightly made our data collection better, I'd argue.* P13 (Nurse, EA)

Participants reported an initial lack of understanding about how data could be used for improvement, particularly in LA organisations, where data collection was initiated prior to gaining a full understanding of how it should be used. Some participants felt strongly that the MedsST should not be used for pin-pointing individuals and for staff to have *"the finger pointed at them."* (P3, Clinical Auditor, LA). Nonetheless, one pharmacist (P2, LA) stated that MedsST data had been used for pin-pointing poor practice of nurses and subsequent performance management. Most nurses agreed with participant 2 that MedsST

data should be used for monitoring performance of nurses and that practice cannot be completely *"blame-free",* as certain *"stupid"* individuals could cause errors; however, they also believed that errors are actually caused by system problems that need to be addressed by supporting individuals. Although national online guidance specifically states that the tool has not been developed to blame individuals [12], the study analysis highlighted that cognitive dissonance may exist regarding whether staff believe medication errors are due to specific individuals, or system problems. Although it was stated that errors may be due to individuals, it was also stated that the errors individuals make are usually due to system problems.

> *It can't be completely blame-free, because obviously some people are just stupid. But what you're not trying to do is beat them with a big stick, and look for trends, because usually when an error occurs it tends to be the system and not the person*. P9 (Nurse, EA)

Although more junior staff understood the purpose of the MedsST was to collect medication safety data, they were unsure about how data were actually used. Lack of coherence was reported to be a problem in primary care, where data were mainly collected by junior staff. One MedsST lead from primary care believed that junior staff may not understand the value of MedsST data and reported a culture of "looking for mistakes" (P4, Pharmacist, LA), rather than looking for harm (regardless of how it occurred), which may have led to missed learning opportunities.

> *I wonder if the people there are quite junior…(and) are just doing what they are told by senior staff and…implementing it (MedsST)…not really thinking about the value of it…and thinking, 'no that's not an error, we haven't done anything wrong'…I tried to explain…it's not just about error.* P4 (Pharmacist, LA)

Although now based in primary care, Participant 4 had previous secondary care experience and quality improvement training. Therefore, they felt the culture of looking for errors, rather than harm, may be more predominant in the primary

care settings, where there may not be organisational readiness for quality improvement tools, such as the MedsST.

Cognitive Participation: Engagement with the MedsST and its Data

In order for healthcare staff to engage with the MedsST, they had to have ownership of their organisation's medication safety, by being involved with the medication process, for example, the clinical auditor (P3) was not involved with the medication process and showed less engagement as reported below. Furthermore, in organisations where staff displayed coherence with wider quality improvement projects, greater engagement and organisational readiness for implementing the MedsST was reported, and the use of the MedsST appeared to have "normalised" into routine practice more easily [14]. Involvement with the MedsST strengthened medication safety ownership and led to improvements in participants' own practice.

> *When I do come across a drug chart that hasn't been dated, I get quite frustrated because at the end of the day it is trust policy…with me having more involvement with this (the MedsST), I am really aware of it now.* P5 (Pharmacy technician, LA)

Although difficulties with engaging ward senior management were reported, their involvement with data collection led to greater trust in and ownership of medication safety data.

> *I think if I'm the ward sister and someone tells me…'You've got 10% dose omissions' and they've done the audit, it's useful…but if I've actually done it (collected MedsST data), then I know that it was John in bed one and Barbara in bed three.* P13 (Nurse, EA)

It was evident from the data that strong support networks, internally and externally to organisations, seemed to be fundamental for impetus for improving medication safety. In particular the formation of the Medication Safety Officer (MSO) network in 2014 [15] provided a helpful support network for MedsST leads who were also the MSO for their organisation (an allocated

member of staff to support local medication error reporting and learning [15]). Although external support did improve impetus for using data for improvement, this impetus was decreased if there was a lack of support internally, particularly from senior management (at ward and organisational management levels). Where senior management staff displayed a lack of ownership of the MedsST a knock-on effect could occur, where frontline staff would show less engagement. Furthermore, management staff had to be *"pro-active"* (P9, Nurse, EA) to ensure that ward staff were aware of the MedsST data, and for further improvement work to be conducted. Lack of engagement from management staff was associated with decreased awareness of the MedsST within organisations and, therefore, lack of use of data for improvement. It was reported that more junior staff, such as pre-registration pharmacists, collecting data displayed less engagement, feeling it was "pushed" onto them.

> *As a group we feel like no-one wants to do it (collect data), so they just pushed it towards the pre-reg (pre-registration pharmacists), we won't complain, we'll just do it…(but) it would make more sense for a technician…to collect the data because they're doing the meds rec (medicines reconciliation) every day. So they're familiar with the chart, they're familiar with the patient.* P15 (Pre-registration Pharmacist, EA)

As mentioned previously, the Clinical Auditor (P3, LA) who was interviewed was the only participant who was not directly involved with medication dispensing or administering in the rest of their work, and reported that they had been *"borrowed"* by the pharmacy department to help collect data. Therefore, they demonstrated a lack of ownership of medication safety improvement and did not feel inclined to view or act on the data they had collected. Furthermore, their lack of involvement in the medication process, led them to feeling like a "lonely worker" who was not part of "the bigger picture". Some MedsST leads also felt unsupported in improving medication safety, particularly if they had no one else in their teams.

> *In terms of governance and medication safety…I'm a bit of a one-man band…because…There isn't any other people (in my team)* P1 (Pharmacist, LA)

This feeling of lack of support had detrimental effects on impetus for improving medication safety, some MedsST leads had overcome this lack of support by forming or joining external medication safety networks, where they could learn about how to use the MedsST and its data for improvement. The support networks were often developed by pro-active MedsST leads, and enabled wards, organisations and regions to share innovative methods of using data for improvement, in addition to learning how challenges with data collection could be overcome. In most organisations the MedsST lead was also an MSO, however, in one organisation the MSO was not involved with the MedsST and the role of MedsST lead had been offered to a pharmacist with personal interest in quality improvement. This participant had unsuccessfully attempted to contact other organisations to learn how they had implemented the MedsST in primary care settings. Without internal or external support networks, the MedsST role had proven burdensome for the pharmacist who felt unsupported and that they were not being *"listened to"* (P4, Pharmacist, LA) about how the MedsST data could be used for further improvement work.

> *I am very aware that it shouldn't really be my role…and I keep telling them that…"Yes I can implement this for you, I can tell you what the problems are etcetera, but you need to take it on".* P4 (Pharmacist, LA)

Many organisations had not experienced the benefits of a multi-disciplinary approach, as described by other participants, as nurses were not involved with data collection. Nonetheless, even participants from organisations where only the pharmacy staff were collecting data, believed that measurement and improvement of medication safety required a multi-disciplinary approach. It was generally reported that senior nursing staff said they did support the use of the MedsST; however, they did not show this support and had often used *"lack of capacity"* (P6, Pharmacist, LA) as an excuse for not allowing nurses to be involved with MedsST data collection. Furthermore, it was highlighted that involvement of nursing staff at ward level was important for fostering multi-disciplinary ownership of medication safety.

> *People see pharmacy…(and think) drugs. But…as nursing staff, we give them…They (pharmacists) don't actually administer them so there's no point (pharmacists) coming along thinking, 'I'll fill all this, and I know what we're doing'. Yes, it's dead easy for you to fill it in, but then there's no ownership at ward level and then the nursing staff don't get to know what's going on, they don't actually see it.* P9 (Nurse, EA)

Generally, there was a lack of cognitive participation with Step 3, which involves a multi-disciplinary huddle to ascertain whether medication related harm has occurred, and the majority of organisations were not using it. Participants reported difficulties with gathering the pharmacist, nurse and doctor for a multi-disciplinary huddle. However, some organisations, despite facing similar staff and funding issues, reported that they had no issues with performing the huddle for Step 3 once people understood that it is a simple conversation between the nurse and junior doctor looking after the patient and the pharmacist collecting data.

> *I think the term MDT (multi-disciplinary) huddle has made people think that that's some kind of super 'I need to get it sorted out by e-mail, I need to get the consultants in' and no, that isn't like that, and that is why I say,… 'Look, just grab the junior doctor, grab the primary nurse and see if they agree, and then put it in the incident system. If that needs investigation then we might need to get the consultant in and we might need to get the ward manager in'.* P8 (Pharmacist, EA)

Mixed feelings were displayed about performing MDT huddles in primary care settings, the main benefit highlighted was the team-working between the pharmacist and a patient's GP to review a patient's safety in a novel way. However, there were practical difficulties with contacting the GP and making them aware of why they were being contacted.

> *Initially they (the GPs) started off (saying) 'what the hell are you ringing me about'…but when I explained it (the MedsST) to them, yes they could see that*

there was a value and a point to it. So yes, that was positive. P4 (Pharmacist, LA)

Primary care NHS staff were generally supportive of the concept of the MedsST, but believed some questions were not applicable for their setting, and that using an alternative community version (version 16b) would not improve the issues faced. Of the four high risk drugs monitored using MedsST, only insulin had triggered MDT huddles in primary care settings, leading to primary care organisations reviewing the suitability of these triggers. One primary care organisation had stopped using the MedsST for this reason, as reported by a participant from this organisation's associated secondary care organisation.

The uptake in community (primary care settings) is really poor. We've stopped doing it in community because…what was the point in doing it if we weren't detecting anything? Therefore, we are clearly asking the wrong questions. P8 (Pharmacist, EA)

<u>Collective Action: Actions Taken to Normalise Use of the MedsST into Routine Practice</u>

Many activities were reported to have been undertaken to scale up implementation of the MedsST within organisations, including increasing the number of wards data were collected from, and securing additional funding and staff for this. Non-financial incentives existed for staff for their involvement in collection of data, such as protected time for overseeing data collection and analysis, involvement with related research projects and attendance at medication safety meetings.

Local financial incentives for organisations to use the tool, had often been organised at the suggestion of the MedsST lead to the local Clinical Commissioning Groups (CCGs) who set financial targets for healthcare organisations in England [2]. The introduction of financial incentives were referred to by participants as a *"turning-point"* (P6, Pharmacist, LA), and had led to management staff giving the MedsST data "*greater respect"* (P8, Pharmacist, EA); and more senior staff involvement with data collection to ensure accuracy of data. Although it was difficult to involve senior staff, as they already had

high work-loads, doing so had led to increased ownership and passion for improving medication safety and, therefore, supporting analysis of MedsST data.

> *After…CQUIN (payments became available), obviously we had reports to do, every quarter we had to say why we hadn't achieved, there were penalties and no financial gain and that's probably where the turning point was and because of that I started really looking at the data.* P6 (Pharmacist, LA)

Although financial incentives were reported to help drive data collection and scale-up of MedsST use, it was important to MedsST leads that they worked with local CCGs when introducing financial CQUIN payments, to ensure targets were realistic.

> *The problem is CCGs get hold of something and they don't actually understand it, they just tell us to use it. So we have a potential CQUIN (financial incentive target) with one of the CCGs and my report has to actually…tell them how useful (the MedsST) is…and how much time it takes.* P4 (Pharmacist, LA)

Locally commissioned financial incentives appeared more successful than regionally commissioned financial incentives, and there was general agreement that national financial incentives should not be introduced. However, large-scale implementation nationally was described as a "great thing" (P2, Pharmacist, LA), but it introduced various complexities in different wards, organisations and regions, especially if they were still unsure of how to use the data for improvement. Participants discussed their organisation's plans for scaling up use of the MedsST to all wards, which had been delayed multiple times, due to resistance from senior and ward level staff. Where organisations had successfully scaled up use of the MedsST to all wards, there was increased engagement of staff, and the MedsST had been embedded into routine practice to the point that it 'disappeared' from view (i.e., it was normalised) [14]. By contrast, in organisations where only some wards were collecting data, there was increased ward level resistance to implementation and by clinical

champions (frontline users who take action to forward the implementation process) used personal friendships to overcome this.

> *(The ward sister) was really against doing it and she used to rant and rave at me every time we talked about rolling it out… I said, 'Look, I know (you don't want to do it). But, you're going to do it for me anyway aren't you?', and she said, "Yes because you are my friend, but otherwise, no, I wouldn't".* P9 (Nurse, EA)

Although communication between MedsST leads with ward staff was occurring in most organisations to engage more wards to initiate use of the MedsST, communication was not occurring between senior organisational management, MedsST leads and ward level management regarding actually using the data collected, hindering the impetus for improvement using the collected MedsST data. For example, in organisations where data were analysed, the feedback was e-mailed to wards and not all frontline staff accessed e-mails. Additionally, for feedback to be acted upon, strong leadership was required from ward managers to create impetus for further improvement work.

> *It has to be coming from a hierarchy saying, 'We need to develop something'. (If you) send out an e-mail…only ward managers read it and…not every ward manager is 100% proactive.* P9 (Nurse, EA)

Furthermore, there was a lack of education and training for healthcare staff about how to make best use of the data to inform quality improvement. Training was provided for data collection, but even this was problematic, with participants reporting a lack of funding and resources to train more staff. Most MedsST users had learnt how to collect data by shadowing other MedsST leads or users, and by using national guidance. One organisation had developed standard operating procedures in order to create a shared understanding between staff of how to collect consistent data, but these activities required extra funding. Many MedsST leads reported an inability to influence implementation to a greater extent, due to lack of funding, resources and support from senior levels who prioritised other areas of safety improvement.

For example, it was reported that collecting data on electronic tablet devices (rather than paper-based) had halved data collection time; however, establishing the use of electronic tablets as a resource and gaining appropriate permissions presented challenges, and had taken 3 months in one organisation.

Reflexive Monitoring: Reviewing Use of the MedsST and Embedding Changes

To successfully embed the MedsST into routine practice, staff had to review their experiences of implementation and adapt the MedsST to suit local circumstances as necessary. Use of data included reviewing, analysing and trying to learn lessons from collected data. Although all participants were aware that they could access MedsST data via a dedicated website; however, very few had done so. Reasons for not viewing or using data included: technical difficulties (such as the website crashing), believing another department would view and act upon the data (such as the Quality Improvement department), time and resource constraints, communication issues and staff feeling ill-equipped or supported to analyse data.

Mixed feelings existed about the usefulness of data presentation on the dedicated website. For example, one MedsST user disliked the run charts used to display data and indicated preference for a written summary of change, which would require more management staff input.

> *It would be nice to have a little summary to say, "This actually shows that 40% of patients have had their medicines" or something. Because… if you are not used to the…graph… (it's) like "What's that line there for?" and "What does that mean there?".* P9 (Nurse, EA)

Conversely, senior management staff preferred even more detailed displays, such as Statistical Process Control charts [16]. However, it is possible that frontline staff would not have the appropriate skills to interpret more detailed graphs, as they already reported difficulties understanding the simpler run charts, as indicated above. Staff who had quality improvement training or a personal interest, particularly from EA organisations, were more confident using MedsST data. EA organisations generally displayed better understanding

and ownership of the MedsST, indicating that involvement of users with early development of an intervention can positively impact implementation of it.

Generally, the majority of participants did feel the run charts used to display data on the website were useful for visualising progress over time, and that the immediate access to these run charts was beneficial and time-saving, for example, in response to freedom of information requests.

> *We had a freedom of information request about insulins: 'How (many) omitted doses have we had in the last quarter?' Just like that, it was so brilliant, at a push of a button I could say, 'Oh yes, I know how many insulin doses were missed out of this proportion of these number of patients'.* P2 (Pharmacist, LA)

Where participants understood the data presentation, they successfully used run charts to monitor improvement, and identify patterns and trends. Furthermore, collecting data on a monthly basis had been vital for identifying and investigating certain trends, such as the impact of staffing shortages on medication safety in December every year, or the impact of system changes on medication safety (for example, the introduction of electronic prescribing). When investigating changes in data, input from ward staff was reported as vital.

> *She (the ward sister) actually gave me reasons of why there was peaks in drug omissions. She said, 'Around that time we had a lot of agency staff'…so that makes sense because agency staff obviously don't have that ownership (of good practice) that a permanent member of staff do.* P6 (Pharmacist, LA)

In addition, having routine medication safety data allowed users to demonstrate improvements at ward level, for example, for judicial inquiries.

> *(We needed) to be able to prove … that things have actually improved since (an incident occurred). …(So I thought) I'll pull all the data off…so long as it looks good then we will send it, if it doesn't look good, let's not send it. But it did show that the ward (staff) were actually making strides to improve.* P9 (Nurse, EA)

MedsST data also allowed healthcare staff to identify specific areas of medication safety for further improvement work, for example, a medication omissions awareness project had been conducted by one organisation, as they had realised their rate of omissions was higher than the national average according to the MedsST data. Mixed feelings existed about using MedsST data for benchmarking and comparison between organisations, departments and wards. Some participants agreed it should happen; however, some participants felt that comparison data between organisations would be beneficial, but not between wards, as wards should be "working together" (P3, Clinical auditor, LA). However, other participants argued that comparison between different wards' data did encourage wards working together by increased sharing of learning between wards. This culture of learning from each other was more apparent in EA organisations.

> *Data on wards was being reviewed by other teams both internally and externally, and MedsST data was encouraging people to ask each other, "How did you get it right?"* P13 (Nurse, EA)

LA organisations had more recently started sharing lessons learnt from using the MedsST and related improvement projects, particularly between organisations. Although there are platforms, such as online forums, available for sharing information about how the MedsST has been used and received within organisations, some participants (particularly nurses) were not aware of them and felt there were communication issues between organisations.

> *What goes on here might be brilliant, but unless someone is shouting about it from the rooftops, other wards might not be able to get to know about it.* P9 (Nurse, EA)

Communication between primary care MedsST leads was problematic and they reported a lack of awareness regarding how to contact their peers.

I do think there might be potential (in primary care) but…I would like to speak to other community trusts to see how they are using it…and have looked at redesigning the triggers. P4 (Pharmacist, LA)

Discussion

This study has found that implementing medication safety measurement into routine practice is possible; however, collected medication safety data must be used for further local improvement in order to reduce medication-related harm, and this is not happening in most settings. A two-stage analysis approach was used, consisting of thematic analysis and an NPT framework, to better understand the barriers and facilitators experienced by English NHS staff who have implemented the MedsST into routine practice. The first stage of this two-stage approach, used in previous similar studies, helped to avoid forcing of data into predetermined conceptual categories and thus ensured our interpretation remained data-driven [17]. In the second stage, all themes from the first stage of analysis were mapped onto the NPT constructs, confirming the suitability of NPT as a suitable theory for evaluating patient safety interventions, such as the MedsST. However, as other researchers have found, there are challenges in differentiating the four NPT constructs [18]. The various elements of NPT interact in a complex adaptive system, where significant changes at a micro-, meso- or macro-level manifest over time [8], highlighting the importance of factoring in context when evaluating interventions using NPT.

C*oherence* with routine medication safety data collection was achieved despite local context variation. Across all ten organisations there was agreement that the MedsST was useful for enabling routine medication safety measurement, and appropriate resources were in place to enable staff to *cognitively participate* with MedsST data collection, but not necessarily for using data for improvement. There were differences between settings regarding the *collective actions* that had occurred to upscale use of the MedsST, mainly due to the differences in resources, such as funding for extra staff. The study analysis confirmed findings from previous research that clinical champions are vital for successfully implementing and normalizing use of an intervention into routine

practice, and that their key activities are to educate, advocate, build relationships and navigate boundaries [4, 19]. Our results suggest that clinical champions must not only build relationships, but utilise existing relationships to help implement improvement programmes. Through *reflexive monitoring* staff were able to evaluate how the MedsST can be improved and what changes were required. This ties into the methodology of MedsST development, which relied greatly on user feedback via Plan-Do-Study-Act cycles [20]. EA organisations were more able to influence improvement of the MedsST during development, which may explain the greater understanding of, and engagement with, further improvement work. The national focus was useful for organisations to learn from each other's experiences of implementation; however, the implementation processes had to be adapted for each setting (ward, department or organisation). Each setting was an adaptive system that formed a dynamic environment(s) with different contexts [21]. Variation between these contexts contributed to determining intervention fidelity [8], therefore the varying contexts need to be considered and implementation processes adapted accordingly. The findings regarding the variations in how data are collected between settings, highlight the importance of being cautious when using MedsST data for comparison purposes, and understanding that contextual differences between settings may impact the data. However, the ability to share lessons learnt and view other settings' data for learning purposes has been useful and this should be encouraged.

It was clear that in organisations where staff had greater knowledge and experience of quality improvement projects, due to a stronger quality and safety infrastructure [5], normalization of the use of the MedsST was simpler. A greater understanding of quality improvement concepts may lead to staff feeling more equipped to use improvement data, such as MedsST data, supporting previous calls for integration of quality improvement concepts into healthcare professionals training curricula [22]. One particular quality improvement concept that requires more awareness is the role of the system in the occurrence of errors. As previous research has highlighted, healthcare staff often may not understand the difference between a learning and a blame

culture, and there is a lack of education provided enabling staff to differentiate between the two [23].

Lack of understanding about how data could be used for quality improvement, and who was responsible for reviewing and using data, existed and was due to communication issues. Clearer communication is required to make clear that all staff can review data and use it. This could help create a common culture and feeling of shared ownership of MedsST data, in turn increasing formative use of quality indicators [24].

Regular evaluation of interventions identifies barriers to normalising the use of an intervention as they occur and identifies whether improvement has occurred following changes. Technical issues resulting from misunderstanding definitions, highlighted the importance of communication about standardised definitions [2, 25]. Notably, users expressed that communication required major improvement, including awareness of support networks internally (within organisations) and externally (regionally and nationally), as the national focus is useless, if participants feel they have to "shout from the rooftops" about improvements they have made that could be generalised to other settings.

Participants agreed that there is a requirement for medication safety measurement in primary care settings, and most understood the need for routine data. However, participants felt that the medication classes used for the triggers of the MedsST [2] were not appropriate for most primary care settings (excluding community hospitals and intermediate care facilities), leading to discontinuation of the use of the tool by many primary care organisations.

One of the reasons for the difficulties in using the MedsST in primary care was the differences in infrastructure between primary and secondary care, and even between primary care sub-settings. For example, one pharmacist can cover a very large geographical area in the district care sub-setting, but there may be more than one pharmacist in a community hospital setting. Furthermore, within each type of primary care sub-setting, each organisation should adapt

the MedsST to suit local contexts, and there is evidence of this occurring. For example, a recent study reported that a hospice in England was using the MedsST only for patients with more than ten medications [26], which saved resources yet helped to prevent harm in those patients considered most susceptible to medication-related harm.

Despite changes to the way the data were collected, the MedsST has still been deemed unsuitable for some primary care settings, where use of the tool has stopped. Participants felt this was due to the inappropriateness of the harms focussed on for primary care. It may be argued that the four high-risk medicines that the MedsST focuses, in particular, are inappropriate for most primary care settings. They were chosen based on all national incident reports, regardless of whether they were from primary or secondary care organisations [2], and previous research has found that most national medication-related reports are received from secondary care settings [27].

For the reasons highlighted above, it may be beneficial to redesign the community (primary care) version of the MedsST, and to combine use of the MedsST with the routine use of evidence-based initiatives currently used in primary care that are recommended by the National Institute of Clinical Excellence in the medicines optimisation guideline [28] in order to measure improvement over time. Many of these initiatives involve using electronic health records to identify the most prevalent potentially hazardous medication safety indicators that are specific to primary care [29-33]. Furthermore, sub-settings within primary care may require different sub-versions with specific measures. For example, measuring the number of patients who have been administered the wrong dose of medication, would be a relevant problem to measure for care homes [34] but probably not for district nursing settings (where nurses provide care to patients at their homes).

Conclusion

Healthcare staff believed that standardised routine medication safety monitoring is a fundamental part of improving medication safety. However, medication safety can only be improved if data are analysed for learning

purposes and lessons learnt are acted upon, which is not necessarily happening. This may be due to a lack of understanding about how data can be analysed and used. Developing quality improvement education for healthcare staff may help staff to become more confident with analysing data and using the findings for further improvement work. It may be beneficial to allocate further funding to improve medication safety, as organisations who have secured extra funding and staff for medication safety improvement reported the most improvement. However, an economic evaluation is required to ascertain this. Within organisations, there is a need to improve communication between multi-disciplinary teams from different wards, departments and management staff for more efficient use of the MedsST and its data for improvement. Greater communication between organisations is also required to spread best practices for implementation, and learn what works best for different contexts and save resources. Alternative approaches for measuring medication safety are required in different primary care settings, and participants perceived the current tool to be inappropriate for most primary care settings.

Implications

There was great variation in participants' awareness of whether their organisation had shown improvement of medication safety. Organisations could use the findings of this study to trigger further improvement work and investigation of collected MedsST data. For example, it may be useful to explore which organisations (or wards or settings) are showing improvement in medication safety, which may help us to understand the variation in practice and offer opportunity for learning and improvement. It is possible that variation exists in the prevalence of medication related harm between patient groups, settings, specialities and over time, and individual organizational data published online [29] demonstrates that, despite the constraints of using a tool that is relatively new, some organizations have improved [29]. This suggests that solutions to common problems may exist in the user community. Certain MedsST users, who are positive deviants, may have knowledge that can be generalized and, if the solutions have been generated within the MedsST user community, they may be more readily adopted in other organizations [35]. The standard methodology of the MedsST setting may be generalizable to other

healthcare organisations internationally, but it is likely to require amendments to suit local contexts, for example, regarding who collects data. As alternative approaches for measuring medication safety are required in different primary care sub-settings, the tool may also need to be amended to suit different primary care sub-settings, and further work is required to ascertain the potential of the MedsST for different primary care sub-settings.

Strengths and Limitations

To the best of our knowledge this is the first study to use explore views and experiences of staff using a medication safety measurement tool with a national focus.

Detailed insights were provided by a range of healthcare professionals holding a range of roles and levels of experience from a variety of healthcare settings and specialties. It may be argued that the work may have been strengthened by interviewing MedsST users in primary care settings; however, both MedsST lead participants from primary care settings had also acted as MedsST users and been involved with data collection within their organisations, enabling us to get an insight into how data collection actually occurs in primary care settings.

One of the main limitations of this study was that only staff who had volunteered were interviewed, indicating that they may be more proactive with medication safety improvement. However, it would be unethical to coerce participants and there were many negative opinions shared, suggesting that a range of views were represented.

As mentioned previously, no further data were collected after fifteen interviews because it appeared that data saturation regarding the implementation of the tool in hospital settings (where the tool is predominantly used) had occurred after 12 interviews. It is possible that data saturation regarding implementation of the tool in community settings did not occur; however, the most important finding in community settings was that the tool is not considered to be appropriate for these settings (excluding community hospitals). Although

guidelines for sample size in qualitative research are varied and debatable, it is acknowledged that qualitative research typically involves the intensive study of a small group of people and tends to focus on depth rather than breadth [36].

Organisations that had used the tool for less than 3 months consecutively were excluded, in order to explore how MedsST use had been established and adopted over time. This may have led to the omission of some barriers that organisations faced, which resulted in their discontinued use of the MedsST. However, some participants were from organisations that had previously stopped using the MedsST and provided views about barriers to implementation.

The qualitative findings of this study highlight the importance of contextual factors in shaping how medication safety measurement can be implemented and normalised into practice, in different healthcare settings. These findings should help inform policymakers and organisations on how to optimise implementation of the MedsST into practice. Furthermore, the findings can also be used to develop and implement similar patient safety measurement tools internationally.

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Study Two Tables

Table B.1. Descriptive Themes and their Definitions

Normalisation Process Theory Construct	Descriptive Theme	Definition
Coherence: Understanding the Purpose of the Medication Safety Thermometer and its Data	**Views on purpose**	Views on what the Medication Safety Thermometer is and how it should be used, as perceived by participants.
	Operation	How the Medication Safety Thermometer data were being collected, which represents the understanding of the wider teams within organisations regarding how the Medication Safety Thermometer should be used.
Cognitive participation: Engagement with the Medication Safety Thermometer and its Data	**Organisational readiness**	The culture within organisations prior to using the tool, with respect to patient safety, auditing and quality improvement.
	Ownership and engagement	Ownership of medication safety overall and engagement with Medication Safety Thermometer data collection and use of data, for further improvement work.
	Leadership and support	Views on the impact of having individuals who lead implementation of the MedsST, and relevant support networks for those leading implementation and frontline users, at organisational, regional and national levels.
Collective action: Activities Undertaken to "Normalise" Medication Safety Thermometer use into Routine Practice	**Scaling up**	Actions taken, or planned, to scale up use of the tool.
	Time and money	Time and money as influences on collecting MedsST data and subsequent improvement work using the data
	Education and training	Details of associated training for staff involved with the use of the Medication Safety Thermometer
Reflexive monitoring: Reviewing Medication Safety Thermometer Use and Embedding Changes	**Use of data**	How the data were actually used within organisations.
	Reviewing and amending use of the tool	Changes to the process of collecting Medication Safety Thermometer data to suit individual contexts. Including suggestions for the future.

Table B.2 – Participant details

Organisation (EA/LA)	Participant	Implementation Role (Lead/User)	Profession	Setting Type
1 (LA)	1	Lead	Pharmacist (MSO*)	Secondary care
2 (LA)	2	Lead	Pharmacist (MSO)	Secondary care
	3	User	Clinical Auditor	Secondary care
3 (LA)	4	Lead	Pharmacist	Primary care
4 (LA)	5	User	Pharmacy Technician	Secondary care
	6	Lead	Pharmacist (MSO)	Secondary care
5 (LA)	7	User	Pharmacist	Secondary care
6 (EA)	8	Lead	Pharmacist (MSO)	Secondary care
	9	User	Nurse	Secondary care
7 (EA)	10	User	Nurse	Secondary care
	11	Lead	Pharmacist	Secondary care
8 (EA)	12	Lead	Pharmacist (MSO)	Secondary care
	13	User	Nurse	Secondary care
9 (EA)	14	Lead	Pharmacist (MSO)	Primary care
10 (EA)	15	User	Pre-registration Pharmacist	Secondary care

*__MSO:__ Medication Safety Officer. __EA:__ Early adopter (joined in the alpha-testing phase [January–March 2013]). __LA:__ Late Adopter (joined in the beta-testing phase or after [April 2013 onwards]) (1).

Study Two Appendices

Appendix B.1 – Approximate Interview Schedule

This is an approximate list of topics and may be amended during the study, to collect other relevant data about the use of the Medication Safety Thermometer (MedsST) within interviewee's organisations.

Introduction: My name is Paryaneh Rostami and I am a PhD student researching the use of the MST, at the University of Manchester. This study is an exploratory study, and is the first study of my PhD project. The research is funded by Haelo and your participation is entirely voluntary. It aims to get an idea of your experiences and perceptions of using the MST in your organisation. There are no right or wrong answers to the following questions as I am interested in **your** experiences and perceptions of using the MST.

Background Details of Participant:

What is your organisation name and type of organisation (if not previously established)?
What is your present job title and how long have you been in this position?

Engagement

In your view, what is the purpose of the Medication Safety Thermometer?
Is it being used for this purpose?
Was any data on medication error collected by your organisation prior to using the MST?
If yes, how was this done?
Why did you decide to use the MST?
What training did staff have prior to being involved with the MST data collection?
Online or in person?
How long did this last?

What is happening – Data Collection

Can you talk me through the process of collecting the data in your organisation? (for those who do the data collection themselves)

- When is the Medication Safety Thermometer used?
- Who collects the data?
- Who else is involved with data collection?
- How is data recorded and submitted (paper/PC/iPad/both)?
- What data sources do you use?
- Does anyone check the data before it is submitted?

Who decided who would collect the data?

Appendix B.2 - COREQ Checklist for Interviews and Focus Groups

COREQ Category	COREQ Explanation	Response
Interviewer/facilitator	Which author/s conducted the interview or focus group?	Paryaneh Rostami (PR). Detailed in the methods, under "data collection".
Credentials	What were the researcher's credentials? *E.g. PhD, MD*	This is detailed in the information for the submitted manuscript on the title page.
Occupation	What was their occupation at the time of the study?	PhD student and pharmacist by background. Detailed in the method under the heading "data collection".
Gender	Was the researcher male or female?	This is not relevant for this study as the issues are not gender specific.
Experience and training	What experience or training did the researcher have?	As a PhD student, PR has completed a Qualitative Research Methods module, and attended qualitative research training provided by the university of Manchester and is a practicing pharmacist. Furthermore, the other members of the research team Darren M Ashcroft (DMA) and Mary P Tully (MPT), who are very experienced qualitative researchers who have undertaken many qualitative studies, contributed to the design of the study protocol and interview schedule. Furthermore, all authors input into analysis and writing of the manuscript, and MPT and DMA reviewed successive drafts of the paper. Authors' contribution and training were provided at the submission stage.
Relationship established	Was a relationship established prior to study commencement?	No relationship was established prior to study commencement. Detailed in methods, under "sampling".
Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research*	This was explained to the participants via the information sheet and at the start of interviews. This information is included in the topic guide that can be included as a supplementary file if requested.

Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	The reasons for researching this area and using implementation theory are described in the introduction. Information relating to the profession of the interviewers can be found under "data sampling" in the methods section. Bias and assumptions are discussed in the strengths and limitations section of the discussion.
Methodological orientation and theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	Interview guides were based on the recommendations for use of the intervention from national guidance. Analysis consisted of two stages; an initial general thematic analysis, followed by a secondary analysis underpinned by Normalisation Process Theory. Details and reasons for this two-stage approach are included in both the methods and discussions sections.
Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Participants were purposively sampled, and this is stated in the method. Staff leading the implementation of the intervention, from all eligible organisations, were invited to take part in the study. Details of the sampling have been provided in the methods section under the heading "sampling".
Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email*	MedsST leads were recruited through snowball sampling using existing contacts known to Haelo. And this approach is described in the sampling section.
Sample size	How many participants were in the study?	This has been described in the results section, in terms of number of participants and organisations that participated, as well as the proportion of eligible organisations that participated.
Non-participation	How many people refused to participate or dropped out? Reasons?	No-one dropped out of interviews. The poor participation rate from primary care staff is most likely due to primary care organisations

		stopping use of the tool. This has been described and discussed in the methods, results and discussion sections.
Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace*	The interviews were conducted by telephone or in person (at the participant's place of work). This is mentioned in the data collection sub-section of the methods.
Presence of non-participants	Was anyone else present besides the participants and researchers?	No.
Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	The period in which interviews took place in and is included in the methods. In addition, it is stated that organisations from six different counties took part to highlight the variation; however, these counties have not been named to preserve anonymity.
Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Provided as Supplementary file 2 (S2).
Repeat interviews	Were repeat interviews carried out? If yes, how many?	No repeat interviews were conducted.
Audio/visual recording	Did the research use audio or visual recording to collect the data?	The interviews were audio recorded and this is noted in the method.
Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were made, but were not used during the analysis phase.
Duration	What was the duration of the interviews or focus group?	Interviews ranged in length from 32 to 99 minutes (average length, 63 minutes). This information is in the data collection section.
Data saturation	Was data saturation discussed?	Data saturation regarding implementation of the tool was reached as no new themes emerged after the 13th interview. Data saturation has been discussed in the methods section and the strengths and limitations.
Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No, due to the busy nature of healthcare professional's jobs, and the high-quality of

		recordings, it was felt that this would not be a useful exercise.
Number of data coders	How many data coders coded the data?	This is detailed in the data analysis section of the method.
Description of the coding tree	Did authors provide a description of the coding tree?	No, but this can be provided on request. Themes from the thematic analysis, and how they map onto Normalisation Process Theory constructs can be found in Table B.1.
Derivation of themes	Were themes identified in advance or derived from the data?	Themes were derived from the data and mapped onto NPT constructs. This is explained and referenced in the data analysis section of the method.
Software	What software, if applicable, was used to manage the data?	Qualitative data analysis management software QSR N-Vivo version 11.0 was used, and this is detailed in the data collection section.
Participant checking	Did participants provide feedback on the findings?	No – we did not think this would be suitable for this study.
Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.*g. participant number*	Yes and they have been identified by participant numbers, profession and whether they are from an Early or Late Adopter organisation (depending on which stage of testing of they adopted the intervention).
Data and findings consistent	Was there consistency between the data presented and the findings?	Yes, this is clear from the text and the inferences drawn from the data are described in the discussion.
Clarity of major themes	Were major themes clearly presented in the findings?	Yes – this is clear from both the text and Table B.1.
Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Although we have not labelled the themes as major and minor, this is clear from the text and Table B.1. The major themes are the NPT constructs and the minor themes are the themes from the thematic analysis (see Table B.1 of the manuscript). In addition, the inferences drawn from the data are described in the discussion.

Progression from Study Two to Studies Three and Four

Study Two met the second objective of this programme of work: to understand how the MedsST has been implemented into practice at local levels, and the barriers and facilitators associated with its implementation. Study Two also helped somewhat to address objectives Three and Four: to identify whether MedsST data have been used to influence and measure improvements in medication safety in and to identify positive practice in terms of using the MedsST to aid medication safety improvement.

Study Two found that MedsST data collection had been implemented effectively by most organisations and that positive practice was seen in some organisations, for example, in terms of clinical champions leading MedsST data collection implementation. However less understanding was displayed about how organisations could and did review and use collected data for medication safety improvement purposes. This lead to Studies Three and Four (Chapter Eight and Nine, respectively) that focussed on how data has been, or could be used, for learning about medication safety and improvement purposes.

SECTION FOUR: EXPLORING THE USE OF THE MEDICATION SAFETY THERMOMETER DATA

Section Four Introduction

As mentioned previously, Section Three explored how the MedsST had been designed, developed and implemented into practice and includes Studies One and Two (Chapters Six and Seven, respectively). The results of Study Two (Chapter Seven) highlighted that whilst all staff using the MedsST understand the purpose of the MedsST to enable medication safety improvement measurement, there is less understanding about how the MedsST and its data can actually be used for improvement. Furthermore, staff using the MedsST did not believe the MedsST was appropriate for primary care settings and do not trust data collected in primary care settings.

As Study Two identified a knowledge gap about how MedsST data can be used to learn about medication safety and facilitate improvements, Section Four explores this knowledge gap and consists of two separate studies (Studies Three and Four). Study Three (Chapter Eight) explored how the MedsST and its data have been used for medication safety improvement within hospitals and Study Four (Chapter Nine) used national MedsST data that had been aggregated to learn about a specific area of medication safety, omissions as an exemplar of how MedsST data could be used. Omissions were chosen as a focus because Study Two highlighted that the improvement of omissions are a priority for many organisations.

Chapter Eight:

Study Three

Chapter type:	Journal article
Article title:	A qualitative study exploring how routinely collected Medication Safety Thermometer data have been used for Quality Improvement purposes, using case studies from three UK hospitals
Authors:	Paryaneh Rostami, Abigail Harrison, Gareth Parry, Darren M Ashcroft, Mary P Tully
Article Type:	Original Research
Status:	Accepted for publication

Note. As this paper has been submitted for publication, the formatting, referencing and layout are consistent with the requirements for the journal. The abbreviations used may also differ. For this chapter, references, tables, figures and appendices will be placed at the end of the chapter rather than at the end of the thesis.

A Qualitative Study Exploring how Routinely Collected Medication Safety Thermometer Data have been used for Quality Improvement Purposes, Using Case Studies from Three UK Hospitals

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Abstract:
Objectives: The Medication Safety Thermometer (MedsST) is a medication safety data collection tool, which has been used by over 100 UK healthcare organisations to enable measurement of medication safety for improvement purposes. This study aimed to explore whether, and how, data collected by the MedsST have been used in organisations to facilitate medication safety improvements.
Design: Routine MedsST data collected between October 2013 and July 2016 were analysed using run charts. Identified changes were investigated using interviews with staff from each hospital trust. The interviews were analysed using a framework based on Normalisation Process Theory, focussing on use of the MedsST and its data.
Setting: Three NHS hospital trusts in the North West of England which have used the MedsST for the longest period.
Participants: Eight interview participants, purposely sampled based on their involvement with the MedsST, included pharmacists, pharmacy technicians and nurses.
Results: Improvement was often at ward-level and focussed on particular areas of medication safety, led by clinical champions. The most sustainable improvements involved changes to systems, such as introducing new guidelines. Although some improvement occurred, internal communication about improvements was poor and large amounts of data remained unused, often due to a lack of ownership of data review and use.
Conclusions: Simply collecting data is not sufficient, a system of data collection, review and use for improvement is required. Issues with such systems may have been recognised and averted if implementation theory had been used in the early stages of national development and implementation. However, implementation theory could be used within organisations to fix issues locally, particularly to increase ward-level ownership of this system, which could lead to considerable improvements.

Key words: Patient Safety, Quality Improvement, Medication Safety, Measurement

Article Summary

Strengths and Limitations of this Study

- This is the first study to use Medication Safety Thermometer (MedsST) data with qualitative interviews to explore whether quality improvement has occurred in different hospitals, with specific examples demonstrating how.
- A small sample size was used consisting of three sites with the most experience with the MedsST. Whilst the small sample size does not allow generalisation to occur, this study demonstrates potential for successful quality improvement using MedsST data.
- Using implementation theory, it was found that one of the causes for data being unused was that more focus had been given to implementing data collection, rather than the holistic system of collection, reviewing and use of data.
- Only one member of nursing staff was interviewed, compared to five pharmacy staff, however, this was representative of staff using the MedsST, who have predominantly been pharmacy staff.
- Audio-recording of conducted interviews did not occur, however, notes from two interviewers were merged and meanings of notes and quotes from participants were clarified with participants after interviews, addressing potential inaccuracies.

Background

Failures within healthcare systems serve as reminders of the need to focus on improving patient safety, for example, the much-publicised failures at the Mid-Staffordshire National Health Service (NHS) Foundation Trust in the UK [1 2]. Reports have consistently identified medication safety as a priority area of improvement within healthcare systems [2 3]. It has been recommended that improvements are not just made in response to serious incidents, but that routine measurement should occur to enable organisations to proactively seek potential problems before they lead to significant incidents [3].

Since 2013, several English healthcare organisations have used a tool called the Medication Safety Thermometer (MedsST) to routinely measure medication safety [4 5]. The most recent version of the MedsST[5] has three steps measuring: process errors (such as medication omissions), triggers of harm (such as hypoglycaemic attacks in diabetic patients), and actual harm from medication (i.e. establishing whether a high [>6] INR for a patient on anticoagulants was due to medication issues or a patient's deteriorating condition) [4]. Step 1 data is collected for all patients. If a patient is receiving any high-risk medicines (anticoagulants, injectable sedatives, opioids or insulin) then the data collector is prompted to move to Step 2. Step 2 involves assessing each patient's high-risk medicines and aims to detect potential problems. If a trigger of potential harm is detected, the potential harm and the patient should be discussed in Step 3 through a multi-disciplinary huddle between a nurse, pharmacist and doctor. The discussion should determine whether harm has been caused by medication issues, and the level of harm occurred. Associated learning (i.e. how to improve practices to prevent reoccurrences) from the discussion and whether or not an incident report has been completed must also be recorded in Step 3. According to the national guidance, collected data from the MedsST and other Safety Thermometers can then be used to *"obtain a baseline, understand variation within your organisation or across multiple organisations, set an improvement goal and measure improvement"* [6].

The design, development and implementation of the MedsST have been reported in a previous study[4], and a second qualitative study evaluating the

MedsST's implementation has been conducted using Normalisation Process Theory (NPT)[7]. The latter study found that staff using the MedsST displayed understanding of why medication safety measurement is required (*coherence*) and engagement with the tool (*cognitive participation*). Conversely, there was a lack of awareness regarding how to review the use of the tool and its data (*reflexive monitoring*) and to scale up use of the tool for medication safety improvement (*collective action*) [7]. Nonetheless, all healthcare staff interviewed displayed interest in improving medication safety and many had attempted to learn from other organisations, but with limited success. The study suggested that only some hospitals had support from Quality Improvement departments with analysis of MedsST data and only some organisations used data for board level reports. One participant from a hospital who had only recently started using the tool suggested that data should be used for "bench-marking through the back door" to compare organisations[7]. However, there was no evidence of this happening currently and many participants were unsure whether data were even being used, and how they could be used. In fact, some participants in the previous study were unaware submitted data was collated and presented in charts openly available for download online [5].

To date, only one study has reported how MedsST data have been used as part of further improvement work [8]. Phippen *et al.* describe how data can be used in residential care settings to assist prioritisation of patients requiring urgent medicines reconciliation. However, the MedsST has predominantly been used in hospital settings and little is known about whether the data collected are being used [7].

To address this knowledge gap, this study aimed to identify whether MedsST data have been used to influence and measure improvements in medication safety in hospitals that were *"early adopters"* of the MedsST, and if so, how. Early Adopters of the MedsST were hospitals who joined the national programme during the alpha-testing phase, between January 2013 and March 2013 [7].

Method

The MedsST was piloted and implemented through Manchester Academic Health Science Centre (MAHSC) and the tool has since been used by over 100 English healthcare organisations. MAHSC was a partnership between The University of Manchester and six NHS healthcare organisations. The three NHS hospital trusts within MAHSC, which are the focus of this study, have used the MedsST since its inception in 2013 and were 'alpha-sites' (contributing to the development of the MedsST during initial "alpha" testing) [4, 7].

A mixed-methods study design was used, with two stages: identification of Special Cause Variation (SCV) by analysis of existing data, followed by interviews to investigate SCV and explore how the MedsST and its data were used at each hospital (Appendices 1-4). Interviews were analysed using NPT and case studies were created to give specific examples of how data had been used for improvement. Although this is a research study, it is sharing knowledge of quality improvement initiatives. Therefore, reporting of this study is in line with the Standards for Quality Improvement Reporting Excellence (SQUIRE) criteria for reporting quality improvement work and a SQUIRE checklist has been provided in the supplementary material (Appendix C.5) [9].

Stage 1: Identification of Special Cause Variation

MedsST data that had been collected between October 2013 (when the MedsST was nationally rolled-out)[4] and June 2016 were reviewed. Firstly, openly accessible MedsST data collected by staff at each of the hospitals were downloaded from **www.SafetyThermometer.nhs.uk** [5]. Data were analysed at both ward- and organisational-levels. Throughout the data collection period, data analysts checked the accuracy of data and worked with hospital staff where issues had arisen. For example, if astronomical data points occurred (see Table C.1), this would be investigated to see whether any issues with data collection or input had occurred.

Time-series analysis was performed using Run Chart methods [10] using Excel 2013. Standard criteria for SCV and system shifts (Table C.1) were used to determine whether observed changes were due to specific assignable causes [10-12]. New control limits and centre lines were calculated when a system shift was observed. SCVs were noted and used to develop questions to include in interviews.

Stage 2: Interview Data Collection and Analysis

Qualitative interviews were used to investigate the highlighted variation and contextual factors regarding how the MedsST and its data had been used. A purposive sample of staff (n=8) from the three hospitals was interviewed, including a combination of leads (senior members overseeing the use of the tool) and users (frontline staff collecting data). Originally, this study had aimed to interview senior staff only, to get a snapshot of the way that data had been used across the hospitals, but it was discovered that most improvement occurs at ward-level, and therefore we expanded our inclusion criteria to recruit ward-level staff. This was difficult as many ward-level staff do not have frequent access to e-mails, unlike senior staff, and it was challenging to identify the ward-level staff involved with MedsST use. Snowball sampling was used where the identified contacts were unavailable, or to contact staff on specific wards where SCV had occurred. A range of staff were recruited including pharmacists, nurses and pharmacy technicians. In the UK pharmacy technicians are healthcare staff who are registered with the UK General Pharmaceutical Council (GPhC) and have relevant qualifications that are accredited by the GPhC.

Interviews were conducted by the first author and assisted by a project manager. An approximate interview schedule was used which included specific questions about SCV variations, and questions regarding contextual factors, such as the types of wards which used the MedsST. Interviews were not recorded as our previous study exploring the implementation of the MedsST found that staff were more comfortable discussing the use of the MedsST when not recorded [7]. However, notes were taken by both interviewers, and summaries of participants' own interviews and the final study report draft were

sent to participants to clarify meanings and for approval. Not recording interviews help to maintain a more conversational interview tone and make the frontline staff more comfortable, to help prevent inadvertently inhibiting responses [13].

As mentioned above, a previous study highlighted that staff displayed understanding of *(Coherence)* and engagement with *(Cognitive Participation)* the MedsST [7]. However, engagement often declined due to a lack of understanding about how to review the data and use of the MedsST (*reflexive monitoring*), and how to scale-up use (*collective action*) of it. Therefore, this study focussed on questions related to the latter two of the four constructs of NPT, and the framework in Table C.2 was used to analyse data [7]. Notes from interviews were coded by hand, categorised and similar categories grouped into themes emerging from data. The deductive approach was used, where data analysed were constantly compared with the descriptive themes displayed in Table C.2.

The hospitals and wards were given pseudonyms of A-C and 1-11 respectively. Quotes were chosen to illustrate a range of varying opinions about each theme. Words in parentheses have been added to quotes to clarify meaning, and ellipses (…) have been used to indicate the removal of unrelated text or information that may lead to identification of participants.

Ethical Consideration

According to the NHS research ethics decision tool [14] and the ethics guidance of the main author's university [15], this work was service evaluation rather than research, therefore approval from an NHS Research Ethics Committee or the university's Ethics Review Panel was not required.

The university uses the following criteria for determining whether service evaluations require ethical review:

- *"Data are collected without personal identifiers, the participants are not asked for confidential or sensitive information, the issues being researched are not likely to upset or disturb participants.*
- *The research involving interviews with participants on subjects deemed to be within*

their professional competence."

The work reported here meets the above criteria and sought to evaluate an existing service. No personal or upsetting questions were asked and the MedsST does not collect patient-identifiable data. Verbal consent for interviewing was obtained from all participants.

Patient and Public Involvement

Patients were not involved in the development of the research question, outcome measures or study design. A study report with the results have been shared with each participating organisation, and a presentation summarising results has been presented to MAHSC leaders at a MAHSC Population Health and Implementation Domain Meeting.

Results

The results have been separated into "MedsST data" and "interview data". MedsST data describes the quantitative data which were analysed (Appendices 1-4) and interview data provides results of the interviews using quotes for illustration purposes. The case studies created have been presented in Table C.3.

Medication Safety Thermometer data

Data were collected on 29 mainly medical and surgical wards across the three hospitals, using both the MedsST application (app) and paper-based collection forms. The run chart presenting aggregated data from all three hospitals showed the following SCV (presented using absolute values):

- The rate of medication omissions had reduced by 15% (from 40% to 25%)
- The rate of medicines reconciliation initiated within 24 hours of patient admission had improved by 7% (from 78% to 85%)
- The proportion of patients with a trigger of harm had reduced by 1.5% (from 2.0% to 0.5%)

Appendix C.1 presents MedsST process measure data for each hospital. Individual ward-level data from each hospital has also been provided (Appendices C.2-C.4). Medication omissions, medicines reconciliation initiation and allergy status data have been presented at both organisational- and ward-levels. Step 2 data (triggers of harm) have only been provided at organisational-level, as these data were not collected by many wards. Reasons for this were explored in the interviews.

Small system shifts were observed in all measures at organisational-levels, however, at ward-levels a handful of wards displayed greater system shifts. This suggested that improvement often occurred at ward-levels and a small selection of wards were driving SCVs at organisational level. For example, in Hospital C overall omissions had reduced from 34% to 32%, however five wards showed no reduction over time. The decrease was driven by six wards, with the biggest reduction of 23% in Ward C10 (from 38% to 15%).

Interview Data

A total of eight participants were interviewed, including pharmacists (n=3), pharmacy technicians (n=4) and a nurse. The lack of participation was due to a low response rate from nurses as it was difficult for them to take time off from their patient-facing roles. Pharmacy staff were involved with MedsST use at all organisations and had more availability for meetings after their ward rounds, therefore were more likely to be selected for interviews. Interview data have been presented under each theme from the framework presented in Table C.2.

<u>Collective Action:</u>

Scaling-Up

Healthcare staff had scaled-up the use of the MedsST and its data in different ways. For example, personal relationships between ward sisters were used to scale-up its use. Scale-up of data collection had been led by clinical "champions" (frontline users who acted to forward the implementation process). This was observed at both organisational and ward-levels and relied on champions' *"enthusiasm"* for MedsST use.

"*There are differences in views about the MedsST between wards. For example, Ward … shows major improvement and omissions seem to be … (very low) – this may be because … (the ward manager) is very enthusiastic about using the MedsST."* (Participant 1, Pharmacist)

Impetus was lost when champions left organisations. In one organisation, a "champion" who was also a Medication Safety Officer (MSO) had retired, and participants from this organisation reported *"waiting"* for the appointment of a new to take ownership of using data for improvement (a designated member of staff who supports medication error reporting and learning) [16].

"After … (the Medication Safety Officer) left, not much has happened with data, we are waiting for the new Medication Safety Officer … to start." (Participant 3, Pharmacy Technician)

Time and Money

A range of staff had acted as champions and taken ownership of the use of the MedsST and its data, including those who were involved with the MedsST as part of their main role, such as MSOs. However, there were also voluntary champions, who had taken ownership of the MedsST in addition to their main roles. For example, a nurse ward manager had arranged their working pattern to ensure they would be working on days where data was scheduled to be collected, they had also used their non-working time, including lunch breaks, to print data to display on the wards for all staff and patients (Table C.3, Case study 1 and Figure C.1). This was sustainable at ward level, as a ward manager was focussing on their own data. However, it was less sustainable if one person, such as a non-ward-based pharmacist, focussed on several wards' data, in addition to their routine work, and often these staff had used their own time to conduct further improvement work. Even where funding was provided for using MedsST data for related improvement work, it created an extra burden on top of day-to-day duties and the champion needed to have a personal interest to volunteer to be involved. Furthermore, good professional relationships with senior colleagues were required for obtaining funding for improving medication safety.

"The lead clinician said to me (the ward pharmacist) 'Do you want this money to improve medication safety on your wards?'. And I said 'Yes'. Otherwise he would have given it to … (another pharmacist)." (Participant 8, Pharmacist)

Organisations' complex systems created barriers for more time-efficient MedsST use; for example, where individuals had to pre-book iPads and acquire relevant permissions prior to data collection, even though it was reported iPads saved staff *"hours of time"* (Participant 4, Pharmacy Technician). Additionally, "*Wi-Fi dropout (connectivity issues)"* also acted as a barrier to use of the iPads.

Education and Training

Many staff reported training themselves on how to use MedsST, using online resources but that there was *"no formal training"* within hospitals. Contrarily, it was highlighted that MedsST collection training had merged into nurse and pre-registration pharmacist induction training at two organisations.

"(In terms of training, there is) nothing formal at any time…Training (for using the MedsST) is included in pre-reg(istration) pharmacists' induction on an annual basis." (Participant 6, Pharmacy Technician)

In one case, a ward pharmacist had used online resources to learn how to interpret MedsST data. This was in response to colleagues, including doctors and nurses, enquiring about what the MedsST data meant, after it was sent out to wards via e-mail. This indicated a lack of education about the MedsST across hospitals, for those staff not involved with data collection.

Ward based staff reported that it had been *"difficult"* to attend the WebExes due to the timing and other work commitments and mainly pharmacists had attended the monthly WebExes during the testing stages.

<u>Reflexive monitoring:</u>

Use of the MedsST and its Data

Marked variations were reported between how data were collected and used at organisations. For example, different members of staff collected data at different organisations, including pre-registration pharmacists, pharmacists, pharmacy technicians, pharmacy nurses and ward managers. Generally, ownership and engagement with use of data increased if those who had collected it were more senior, i.e. ward managers or MSOs. Participants from Hospitals A and B reported that the data collected were discussed in some senior patient safety meetings in which safety across the hospital was discussed. However, in Hospital C data were more likely to be reviewed in local patient safety meetings that discussed patient safety on particular wards.

Most collected data were unused for improvement purposes, unless staff involved with data collection had taken ownership of reviewing and using the data for further improvement work. For example, Hospital B's Medication Safety Team who were responsible for ensuring MedsST data were collected, had analysed Step 3 data regarding triggers of harm to see why most reports of harm were related to certain medicines (Table C.3, Case Study 2). There was also evidence of staff not involved with MedsST data collection using data in Hospital C, but this was rare. For example, in Hospital C, a specialist hepatology pharmacist (who had not been involved with data collection) had taken ownership of data collected by lower-grade pharmacy staff to facilitate improvements in medication safety, after becoming aware of the existence of MedsST data (Table C.3, Case Study 3). Identification of special cause variation of two of the hospitals wards led to interviews with the specialist hepatology ward pharmacist who was asked about the special cause variation (see Table C.3, Case Study 3 and Figure C.2). However, the hospitals MSO was unaware of the improvement work undertaken by the specialist hepatology pharmacist suggesting poor communication about improvement work

Where funding had been allocated to improve patient safety it was often "reactive improvement", to show senior staff improvements had been made in response to events that highlighted issues with medication safety. For example, an external inspection in one hospital had identified issues with the medication omissions and according to one participant, the hospital staff had become

more interested in how to show medication safety improvement following the inspection.

"We had an inspection, and one inspector happened to be a pharmacist, (therefore was particularly) interested in medication safety. He had a chat with a patient who said they were self-administering because of the nurses… (who had missed his medication administration). The inspector had fed back these issues to the hospital which led to other staff asking me how to use the MedsST data." (Participant 8, Pharmacist)

Reviewing and Amending Use of the Tool

It was reported that frontline staff felt they received 'little or no feedback' on the results of the collection. Many staff reported uncertainty about whose "job" it was to review data, and staff were unsure who they could contact for support with interpreting data.

"If someone could feed that back to me and explain it (data) as well…(or) maybe someone from the…I don't know, (maybe) the QI (Quality Improvement) team? (If they) could attend the ward and…help me pick out some (information)." (Participant 2, Nurse)

Communication issues existed and a lack of feedback to staff was highlighted on many wards. Some individual wards demonstrated a high degree of local commitment to staff feedback, with some wards displaying data for staff and patients to view. However, this appeared to be sporadic.

"We display our results on our (ward's) whiteboard…I don't think anywhere else (any other wards) do…next door definitely don't display their results". (Participant 2, Nurse)

Awareness-raising of medication safety issues at ward-level seemed to have contributed to improvements on individual wards, but this relied on at least one member of staff to understand and interpret the data to others and it was reported some feedback methods had been *"useless"* (Participant 2, nurse), for example, feedback given via e-mail despite several staff having no access to e-mails.

The tool was adapted within the three hospitals in various ways. For example, at one hospital, many wards did not collect Step 3 data and the hospital had not formally implemented Step 3 of the MedsST. Staff described the reason for this as "*harm from medication would be "covered" by the hospital's incident reporting system*" (Participant 7, Pharmacist). In the other two hospitals, both data collection systems ran in parallel.

Discussion

This study highlights that it is possible to use routine medication safety data for improvement in hospitals, but that collected data often remains unused by hospital staff. There has been more focus solely on data collection, rather than the full system of data collection, review and use. Healthcare staff are familiar with how data are collected and submitted, but less familiar with how the data can be used for feedback and further improvement work. It has been difficult to understand exactly why the implementation of this system has not succeeded due to poor theoretical underpinning of its implementation. However, there are some examples where this system has been successfully implemented and has contributed to improvements, mainly at ward-level. Improvements made to systems, rather than individual behaviour, have been more sustainable.

Prior to national roll-out, the MedsST had undergone two stages of testing; alpha- and beta-testing.[4] The three organisations, within this study, have used the MedsST throughout these stages and have previously had financial incentives attached to collecting data and evidence of using data (April 2013 to March 2014) [4]. Despite these financial incentives and early use of the tool, a system of collecting, reviewing and using data has not been fully implemented across the organisations. Therefore, it is possible that organisations who have started using the tool more recently have had greater issues with the implementation of the above described system. Whilst a significant amount of effort has gone into the development of the tool and collecting data, it seems that there has been less focus on the implementation of the reviewing and use of data aspects of the system. This had led to large amounts of data remaining unused and many staff not involved with data collection were unaware of the existence of data.

A wide range of healthcare data are collected in UK hospitals, ranging from patient feedback [17] to catheter data [11], and various studies have found that data are often underused and not interpreted correctly [7 18-20]. As the quantity of various types of data collected within NHS hospitals grows [18], it is vital that

staff are able to access and interpret the collected data to ensure an efficient use of resources.

There are issues with implementing innovations to improve patient safety without ensuring that staff fully understand the innovations and how to use them to aid improvement of safety [21]. If there is a lack of understanding about how to use an intervention, there is a risk of decline of use of the intervention, leading to difficulties in demonstrating added value of the intervention. Early evaluation of new tools, such as the MedsST, can help avert issues with declining use as evaluations can lead to better understanding of associated system mechanisms and contexts [21].

A variety of quality improvement methodologies have been used to evaluate and refine the tool whilst it was developed. For example, Plan-Do-Study-Act (PDSA) cycles have been useful for iteratively improving the MedsST [4]. However, additional quality improvement and research methods would benefit scale up of the system of data collection, review and use. In particular, there has been a lack of focus on the use of implementation theories, models and frameworks for evaluating this system [22]. If implementation theory had been used during the national roll-out period, it could have aided evaluation of what worked and what did not work in terms of the system of data collection, use and review. There are still opportunities for hospital staff to work with researchers to use implementation theory at local levels to aid scale-up of this system, for example, by reviewing the current system and making improvements (e.g. training staff to use data for quality improvement) and scaling up these improvements using implementation frameworks. Several Academic Health Sciences Centres (AHSCs) have been established in the UK in the last decade [23] they are *"a constellation of functions and organizations committed to improving the health of patients and populations through the integration of their roles in research, education, and patient care"* [24]. AHSCs provide an ideal opportunity for greater collaboration between hospitals and universities to work together to improve the system of medication safety data collection review, using research such as implementation theory. For example, by encouraging further education and training on quality improvement methods across the healthcare system for staff, students and patients. If staff involved with the MedsST have a better understanding of QI

methods, it is likely they will be able to identify special cause variation on their graphs and may be more likely to undertake further improvement work.

Other healthcare systems considering introducing the MedsST or similar tools must focus on the system of data collection, review and use from early stage of introducing the tool, rather than implementing data collection alone This includes UK hospitals considering adopting the MedsST as well as national healthcare organisations who have started using the MedsST more recently such as Hamad Medical Corporation in Qatar (personal communication). Additionally, organisations implementing data collection tools similar to the MedsST must also be cautious about focussing on the implementation of the aforementioned system, for example, organisations implementing the "All Wales Safety Thermometer" in Wales [25] and the "Patient Safety Thermometer" in Saudi Arabia [26].

Whilst data has often remained unused, it is encouraging that healthcare professionals not directly involved with the MedsST are curious about the MedsST and its data. Further education and training is required to ensure all staff are aware of the MedsST within hospitals, as medication safety improvement requires a multi-disciplinary effort [7] from frontline staff, senior staff, Quality Improvement departments (if existent) and others. Furthermore, it should be made clear how each member of staff can have a role in the collection of data and its use to aid improvement. There was evidence of some discrete initiatives, for example, information about the MedsST was included in the introductory training for all nurses at Hospital B and the induction pack for pre-registration pharmacists at Hospital C. Further work is required to investigate the impact of these changes. It is vital that organisations learn from each other and lessons learnt from these changes and other related improvement work must be shared both internally within hospitals and externally. Since 2017, hospital trusts in Greater Manchester have started to merge [27]. The merger plans may provide a greater opportunity for wards to share improvement strategies, if the correct system-level changes are introduced, for example, introducing communication channels between the large number of wards that will result from the merger could aid scaling-up of improvements.

For the lessons learnt to be transferable between settings, it is important that all changes to systems are clear and transparent. For example, there are often no clear procedures for training to use the MedsST and staff may not even realise that training is occurring, making it difficult to tell others how training is occurring. Some UK organisations have introduced guidelines for how to collect MedsST data [7] it may be useful to also introduce guidelines for how to review and use data. The guidelines could also provide contact details about who to contact if there are issues or to get help with data interpreting, such as a hospitals' Quality Improvement team, as frontline staff highlighted they were unsure who they could get help from.

Clinical champions played a fundamental role in scaling up the use of the MedsST, however, there are issues introduced with relying on individual behaviour change, for example, when Hospital B's data were negatively impacted after the MedsST lead left organisation. It was reported that the former MedsST lead played a significant role in encouraging both pharmacy and clinical staff to take an interest and thus appreciate the benefits of regular data collection. Furthermore, most champions were more focussed on scaling-up MedsST data collection. If champions were supported to also provide feedback and action plans for use of data to their colleagues, it may aid the system of using data for improvement. Providing feedback to peers promotes collective behaviour change and previous research has found that if feedback is provided by supervisors or colleagues they are more effective, particularly if feedback is given verbally and in written form, and an action plan is provided [28 29]. Senior staff should also receive feedback from champions about how to improve MedsST use, by helping to overcome barriers such as the lack of resources to collect data, such as introducing more efficient systems for providing iPads for data collection.

Traditionally safety in hospitals has been defined as the absence of harmful incidents or events, in line with "Safety I" approaches [30], and hospitals therefore focus on identifying the causes of negative events and eliminating their reoccurrence. There is evidence of medication safety data being used in this way, for example, when senior staff started to review data in response to a negative incident reported by a hospital inspector. Whilst this reactive data use

is important and can help lead to system improvements, there should also be proactive use of data.

There was also evidence of Safety II approaches to use of data, where participants spoke about exploring "what is going right" with medication safety [30] and which wards had shown improvement. Previous research has showed how Safety Thermometer data (for other areas of patient safety) can be used to identify positive deviants within organisations [31]. Senior staff may use MedsST data in a similar way to identify wards who are positive deviants [31] within their hospitals and share positive practice to other wards before the negative incidents occur.

Conclusion

The collection of routine data can enable hospitals to measure the trajectory of change and aid improvement, but only if data collection is part of a system of data collection, review and use for improvement. Whilst using collected medication safety data may sound like an obvious next step after collecting data, this study has highlighted that it is not simple as it seems due to barriers such as a lack of communication between staff. Visible improvements were made across many participating wards and discrete improvements on wards. Increased focus on the implementation of the complete system of data collection, review and use would have been beneficial in the early stages of the MedsST's development. However, individual organisations can improve this system at local levels, particularly by learning from positive deviants. Further multi-disciplinary work is required between research departments and organisations to support the "champions" who have been using MedsST data to aid improvement of medication safety to share and disseminate their work. Changes made to systems, rather than just individual behaviour must be encouraged, to make improvements more sustainable.

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Study Three Tables

Table C.1: Run Chart Rules for Special Cause Variation

System Shifts	Eight or more consecutive points above or below the mean line
Trends	Seven or more consecutive increasing or decreasing points
Too many/too few runs	The number of times data crosses the mean line is too many or too few (based on the total number of observations) [9]
Astronomical points	Data points outside control limits

Table C.2 -Descriptive Themes and their Definitions

Normalisation Process Theory construct	**Descriptive theme**	**Definition**
Collective action: Activities undertaken to "normalise" Medication Safety Thermometer use into routine practice	**Scaling up**	Actions taken, or planned, to scale up use of the tool.
	Time and money	Time and money as influences on collecting data and subsequent improvement work using data.
	Education and training	Details of associated training for staff involved with the use of the tool.
Reflexive monitoring: Reviewing Medication Safety Thermometer use and embedding changes	**Use of the tool and its data**	How data were actually used within organisations.
	Reviewing and amending use of the tool	Changes to the process of collecting data to suit individual contexts. Including suggestions for the future.

Table C.3 Case studies of how Medication Safety Thermometer data had been used

Case study 1: The general surgery ward of Hospital A had regularly reviewed the MedsST data and displayed them for staff, patients and visitors to consult. On this ward, data were collected consistently by the same ward manager, who ensured that they would be working on days where data was scheduled to be collected, leading to ownership of collection, review and use of data. The ward manager had identified issues with medication safety and he proactively worked with the ward pharmacist to raise awareness of these issues within the team. This activity commenced in Summer 2015, and led to improvements, such as increased rates of medicines reconciliation within 24 hours (Figure C.1), which had increased by 11.6%, whereas the overall rate within the hospital only improved by 2.5% within the study period.

Case study 2: The participants from Hospital B reported investigating triggers of harm (Step 3) by performing multi-disciplinary huddles with junior doctors, pharmacists and nurses involved in the care of that patient. Data from Step 3 were analysed. Two of the lessons learnt included:
Patients with diabetes under palliative care were triggering Step 3 due to hypoglycaemic attacks. By combining MedsST data and information from incident reports it was found that the reason these patients were having hypoglycaemic attacks was that, despite their reduced nutritional intake, insulin doses had not been adjusted. Increased awareness of reviewing and reducing insulin doses for patients with diabetes under palliative care.
2) Elderly patients were triggering Step 3 due to signs of over-anticoagulation. Investigation revealed that the hospital's guidance for anticoagulation was not appropriate for very elderly and frail patients. A new guideline specifically for elderly and frail patients was developed with *"toned down"* loading doses.

Case study 3: In Hospital C, two wards had shown a significant reduction in medication omissions from 40% to 26% (Figure C.2). The MedsST lead was unaware of any changes, however, the lead pharmacist for these wards reported that the multi-disciplinary ward team had made a group effort to improve reporting and foster a culture of 'learning from mistakes'. In addition, the ward's lead clinician had obtained funding for the pharmacist on these two wards to improve medication safety. Therefore, the pharmacist had become aware of MedsST data and used online resources to educate themselves about how to use MedsST data, so that they could work closely with the multidisciplinary team to improve patient safety. This included attending routine patient safety meetings from summer 2014 to report medication safety incidents and interpret MedsST data. The pharmacist also contributed to nurse teaching sessions and had directed the focus of these to the biggest medication safety issues, such as omissions:
"Lactulose is usually used for constipation; however, in liver disease it is also used for patients with encephalopathy … Many of the refused omissions were due to patients refusing lactulose and saying they did not have constipation and didn't like the taste. And the nurses would think that's fine, even though it could potentially cause harm to the patient. However, now after the extra teaching sessions they know that the patient may need lactulose to reverse encephalopathy and have the knowledge to help educate patients."
(Participant 8, Pharmacist)

Study Three Figures

Figure C.1 – Run Chart 1: Proportion of patients with medicines reconciliation started within 24 hours on Ward A6 (General Surgery) of Hospital A

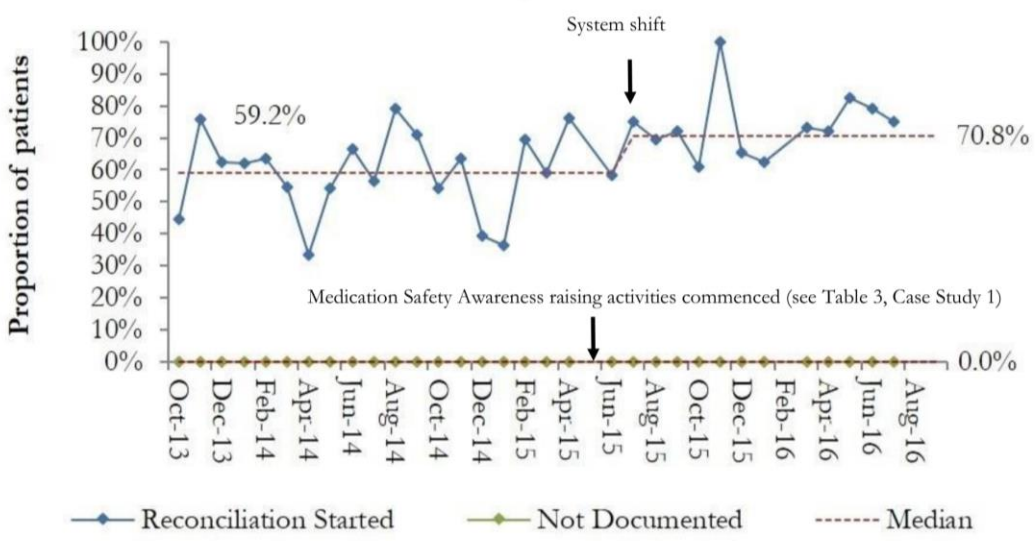
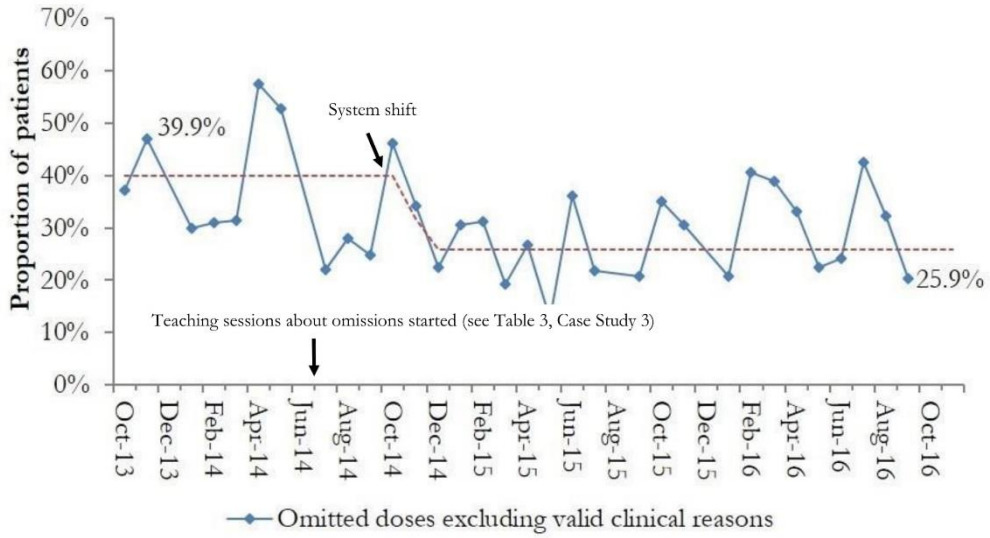
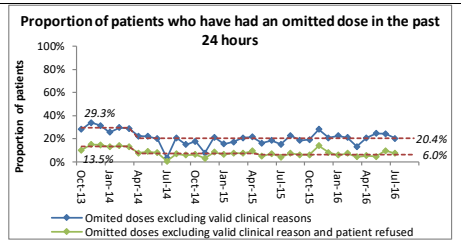
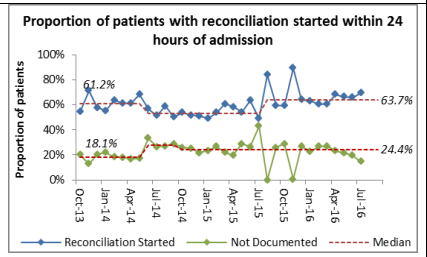
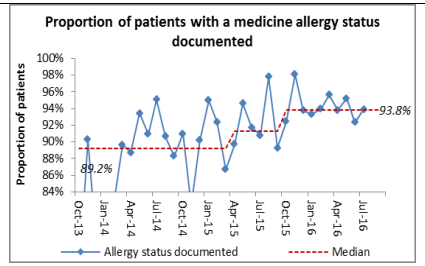
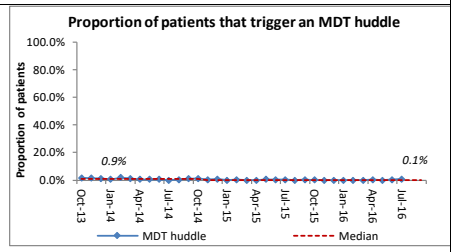
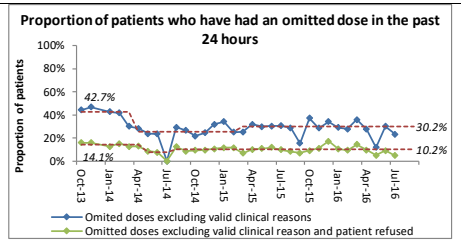
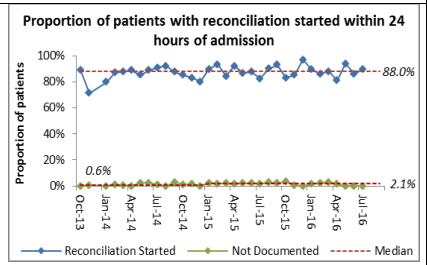
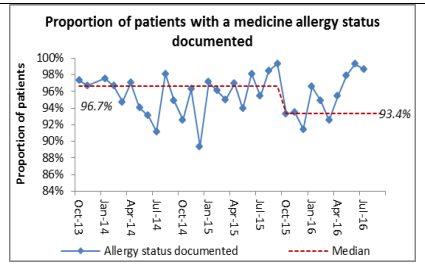
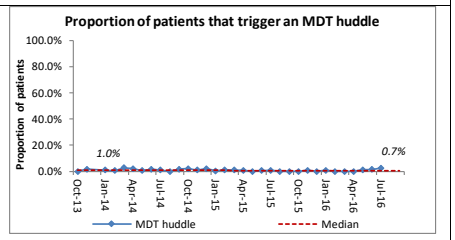
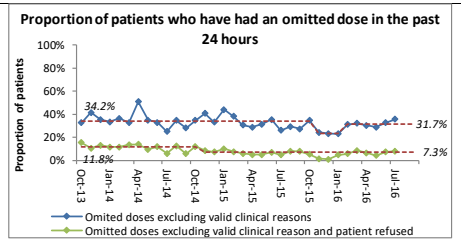
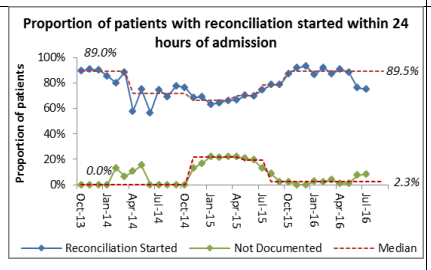
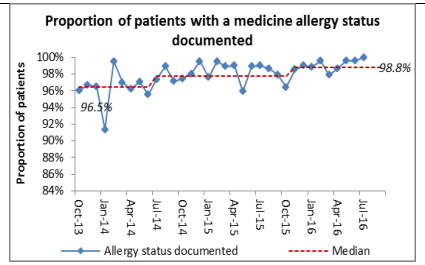
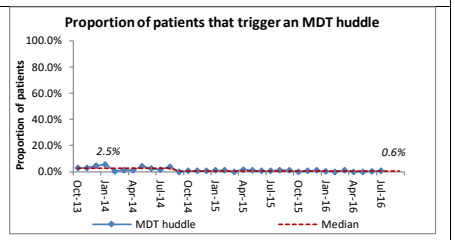


Figure C.2 - Run Chart 2: Proportion of patients with omissions excluding valid clinical reasons on Wards C1 & C2 (Hepatology and Gastroenterology) at Hospital C

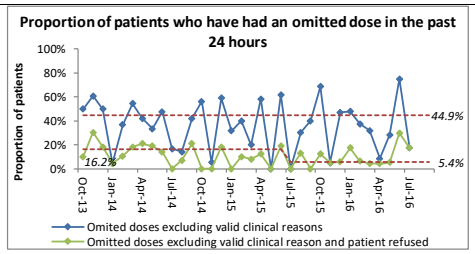
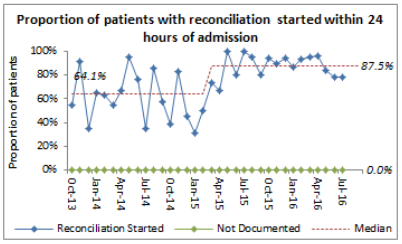
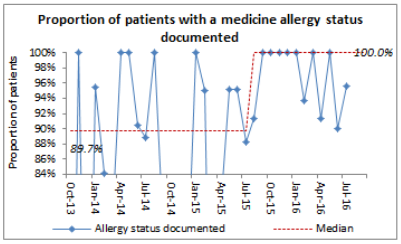
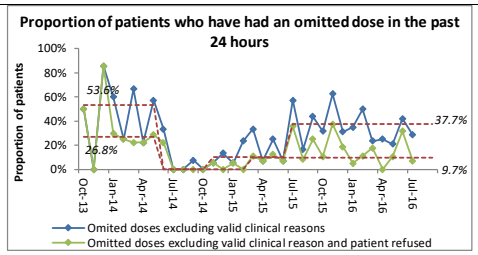
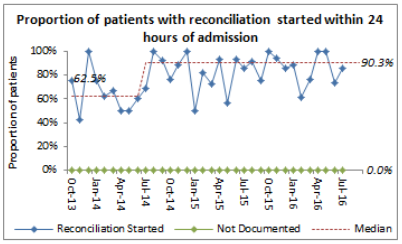
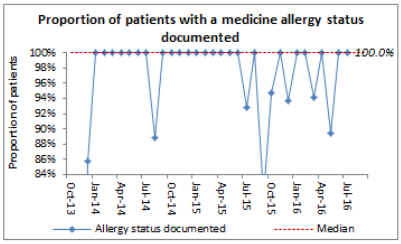
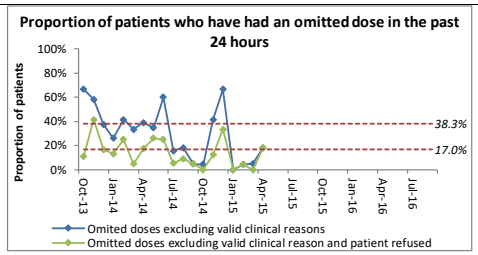
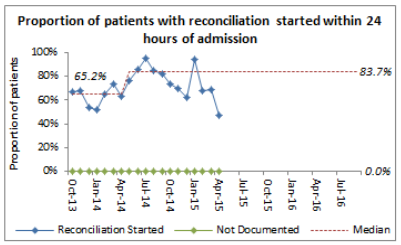
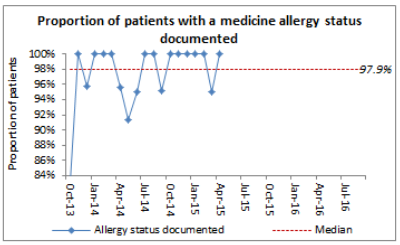
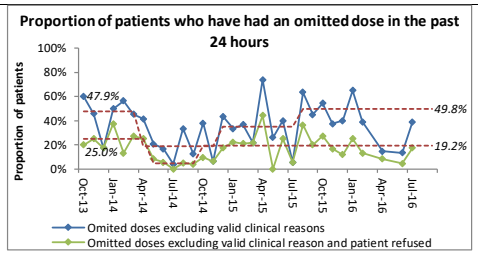
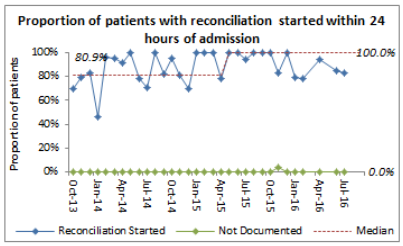
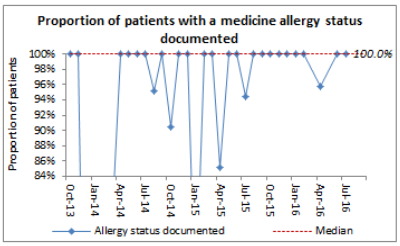
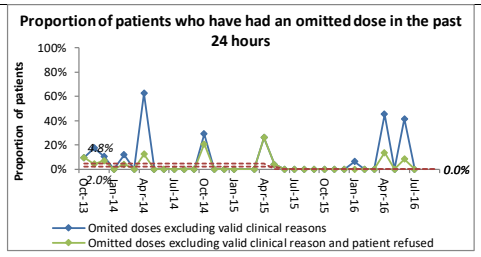
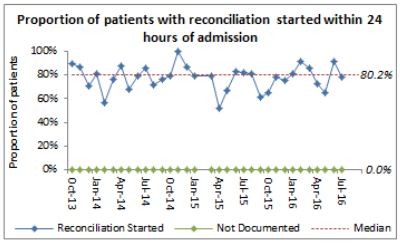
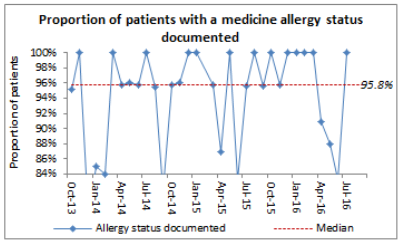


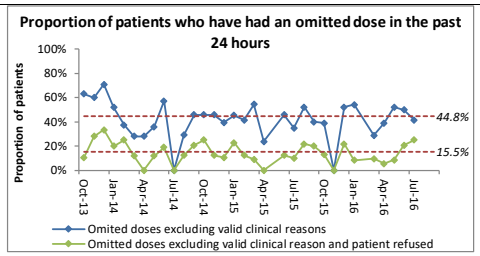
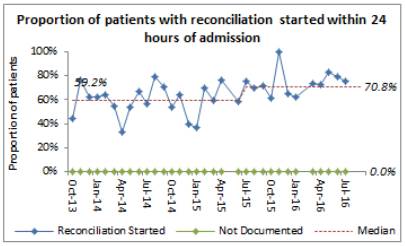
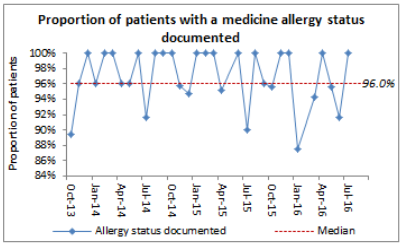
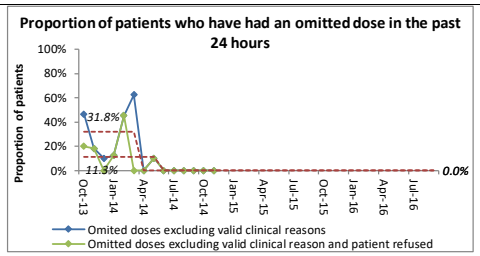
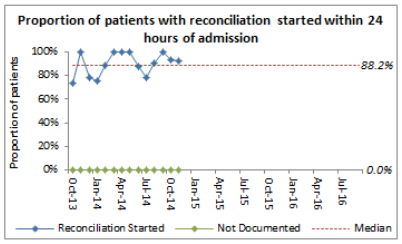
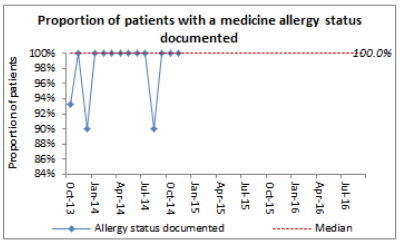
Study Three Appendices

Appendix C.1 - Small multiples table of hospitals' organizational level omissions data

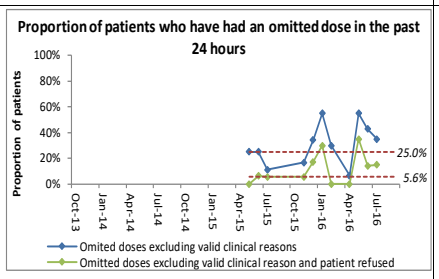
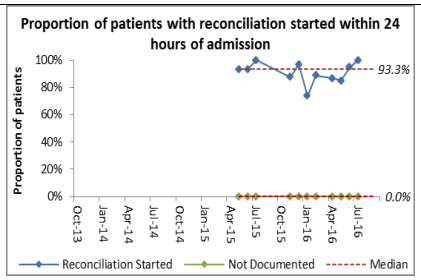
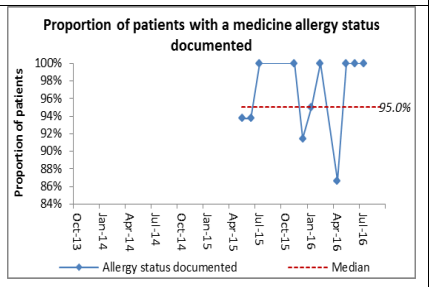
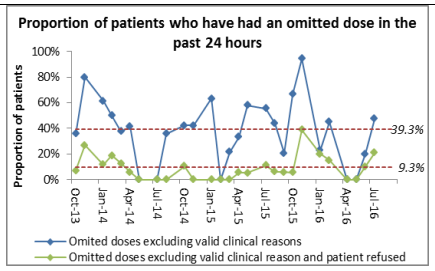
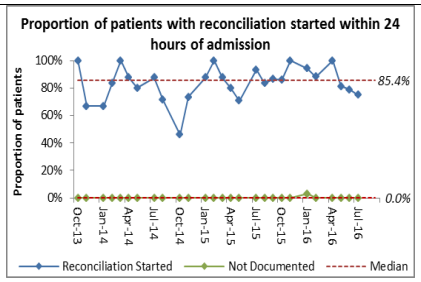
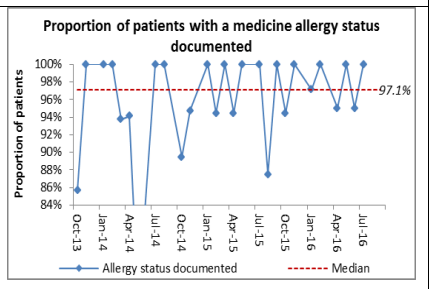
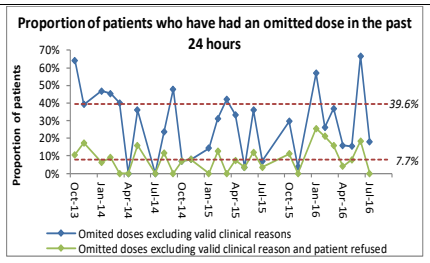
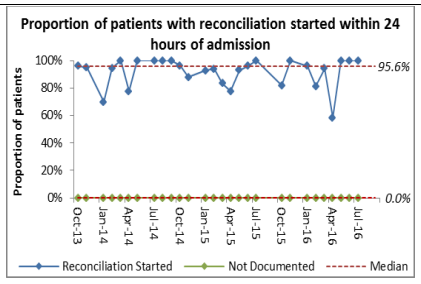
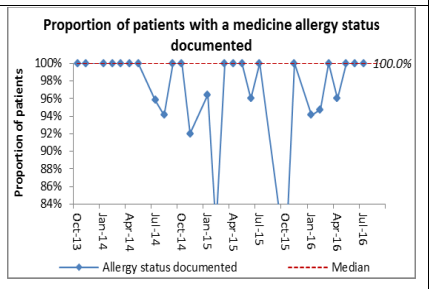
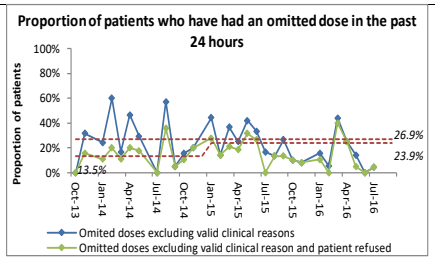
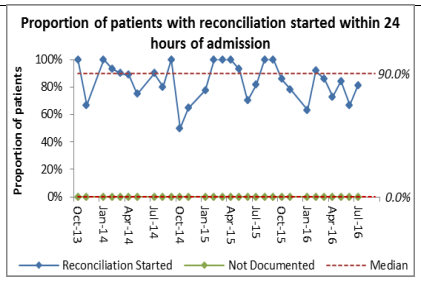
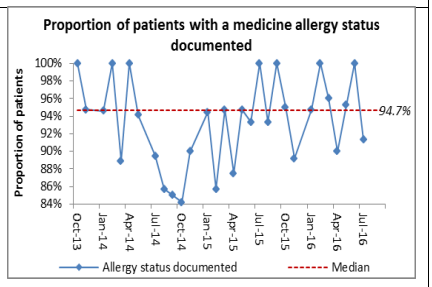
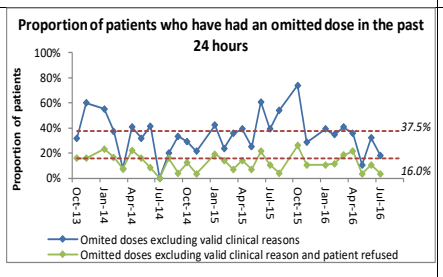
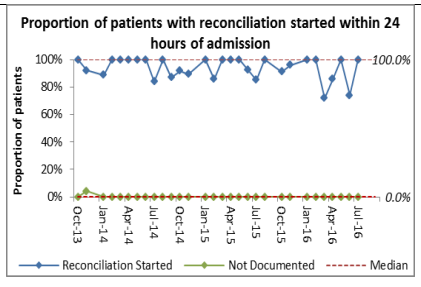
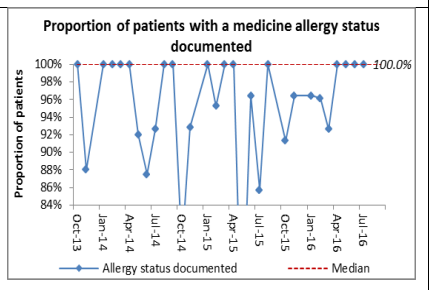
Hospital	Omissions over time	Medicines reconciliation within 24 hours	Allergy status completion	Triggers of harm
A				
B				
C				

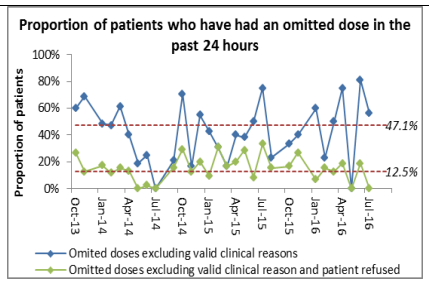
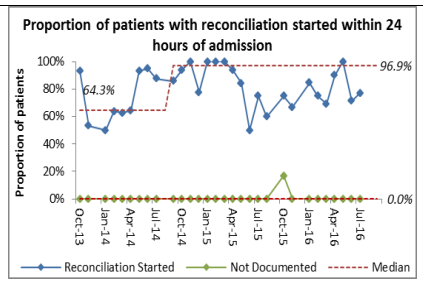
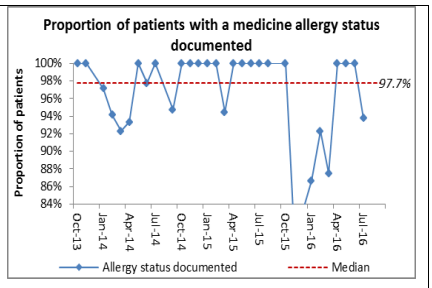
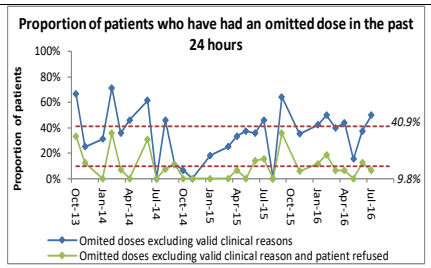
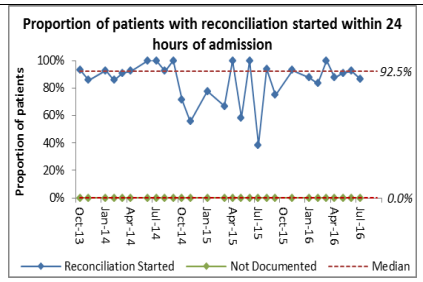
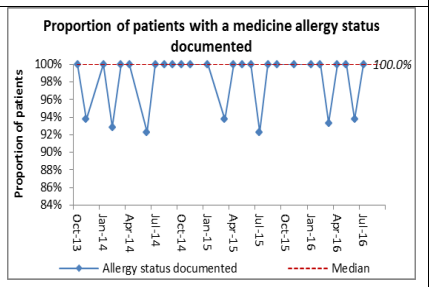
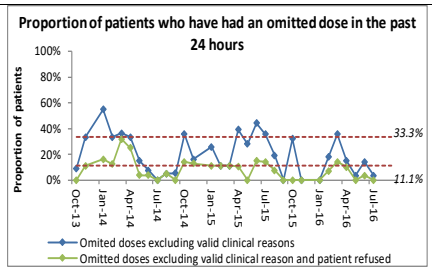
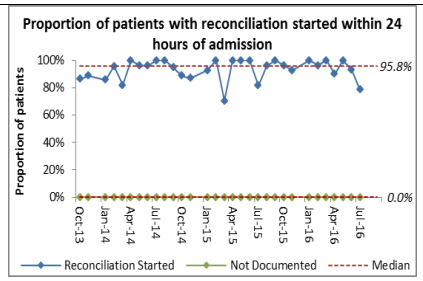
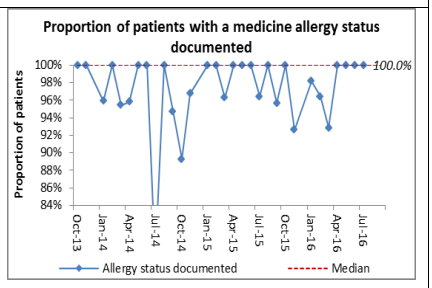
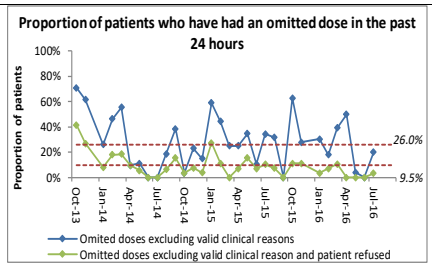
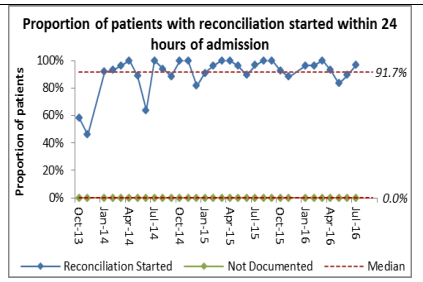
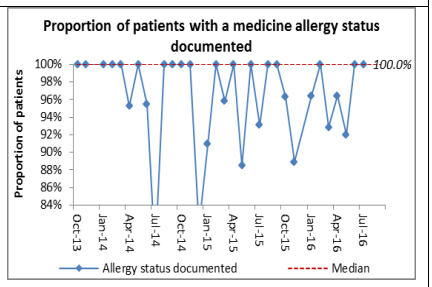
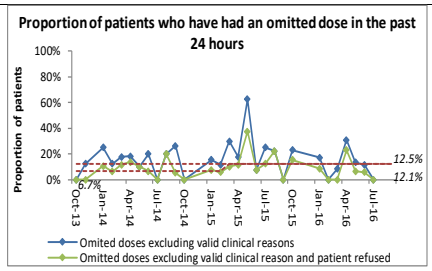
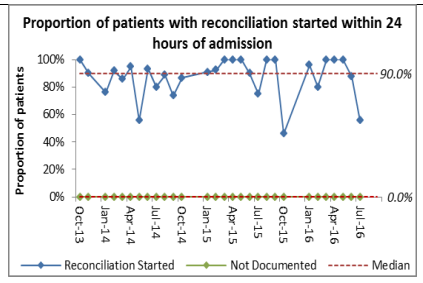
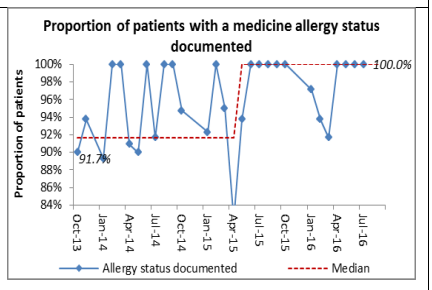
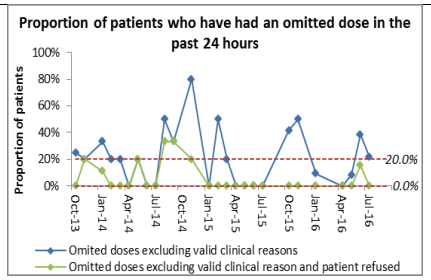
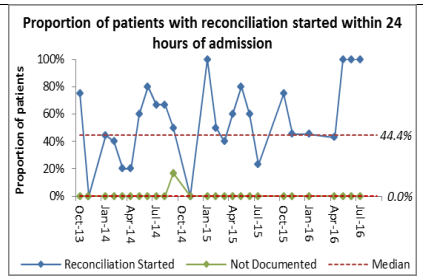
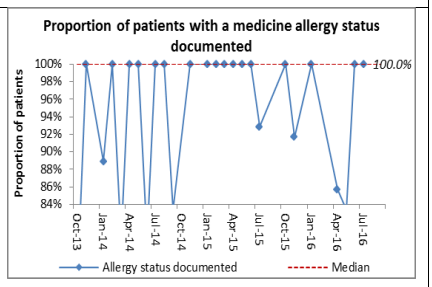
Appendix C.2: Small multiples table of Hospital A's ward- level Medication Safety Thermometer data

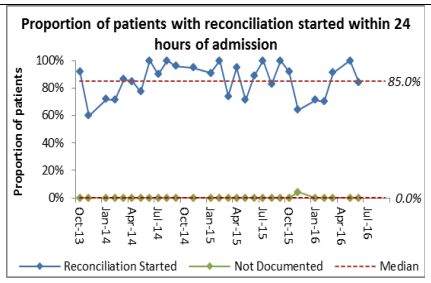
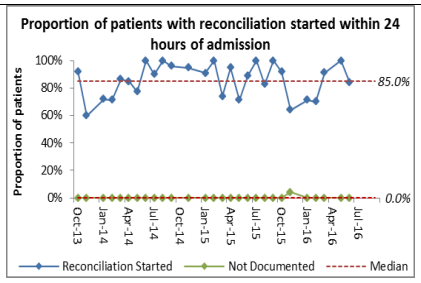
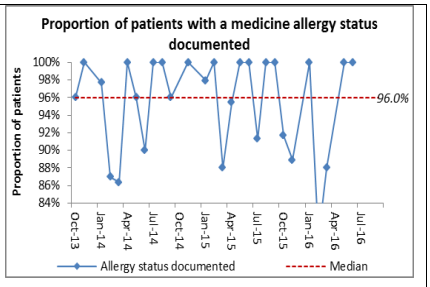
Ward	Omissions over time	Medicines reconciliation within 24 hours	Allergy status completion
A1			
A2			
A3			
A4			
A5			

A6	 Proportion of patients who have had an omitted dose in the past 24 hours Proportion of patients 100% 80% 60% 40% 20% 0% 44.8% 15.5% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Omited doses excluding valid clinical reasons Omitted doses excluding valid clinical reason and patient refused	 Proportion of patients with reconciliation started within 24 hours of admission Proportion of patients 100% 80% 60% 40% 20% 0% 59.2% 70.8% 0.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Reconciliation Started Not Documented Median	 Proportion of patients with a medicine allergy status documented Proportion of patients 100% 98% 96% 94% 92% 90% 88% 86% 84% 96.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Allergy status documented Median
A7	 Proportion of patients who have had an omitted dose in the past 24 hours Proportion of patients 100% 80% 60% 40% 20% 0% 31.8% 11.3% 0.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Omited doses excluding valid clinical reasons Omitted doses excluding valid clinical reason and patient refused	 Proportion of patients with reconciliation started within 24 hours of admission Proportion of patients 100% 80% 60% 40% 20% 0% 88.2% 0.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Reconciliation Started Not Documented Median	 Proportion of patients with a medicine allergy status documented Proportion of patients 100% 98% 96% 94% 92% 90% 88% 86% 84% 100.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Allergy status documented Median

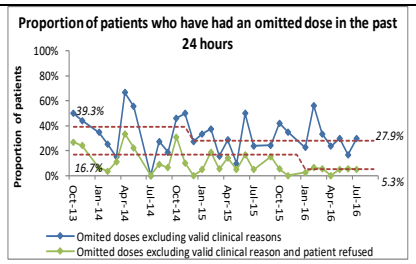
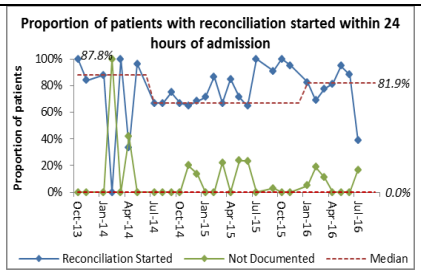
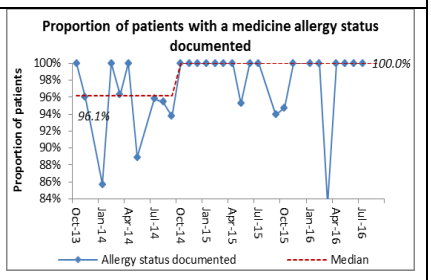
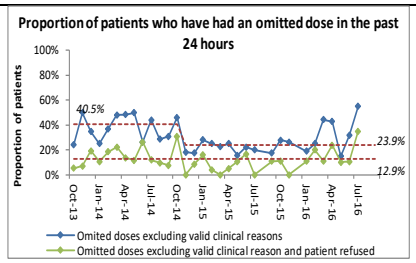
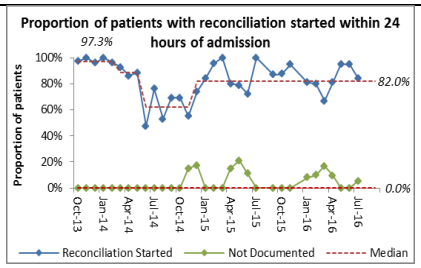
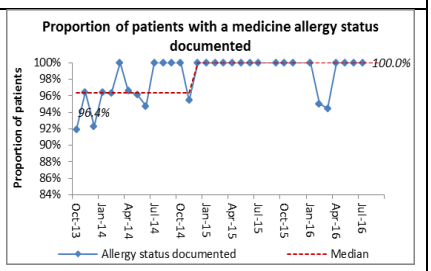
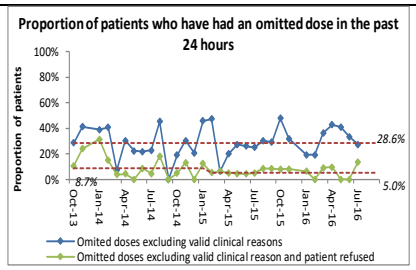
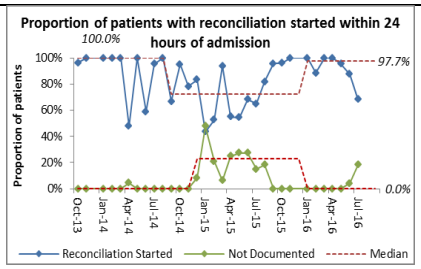
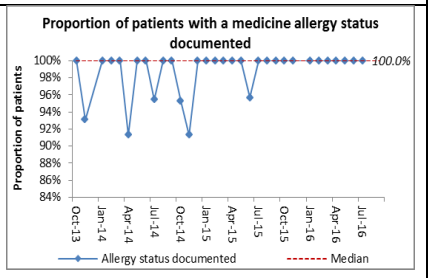
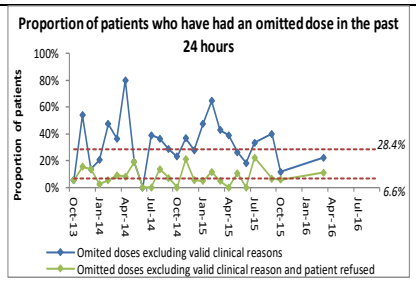
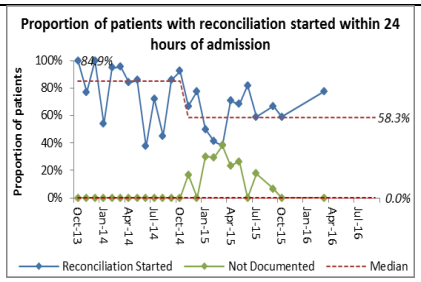
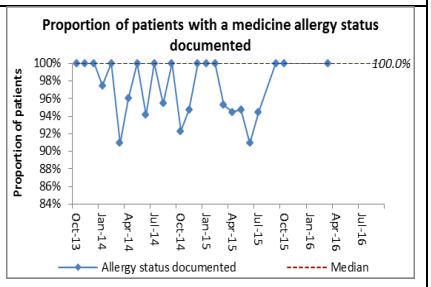
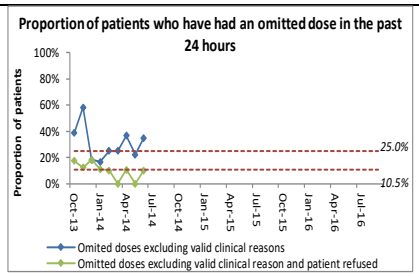
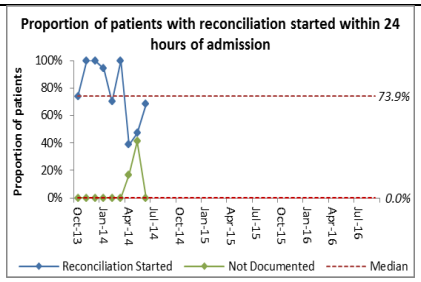
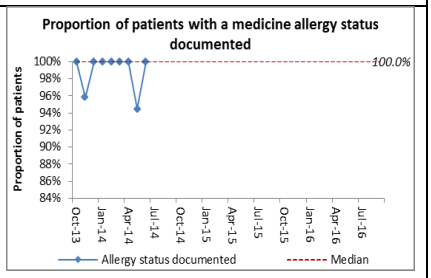
Appendix C.3: Small multiples table of Hospital B's ward-level Medication Safety Thermometer data

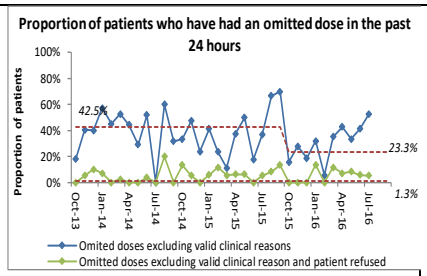
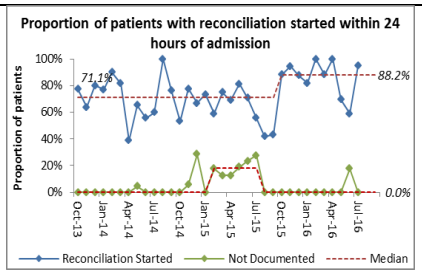
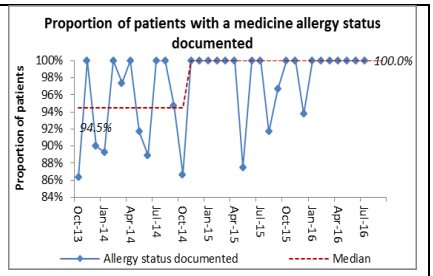
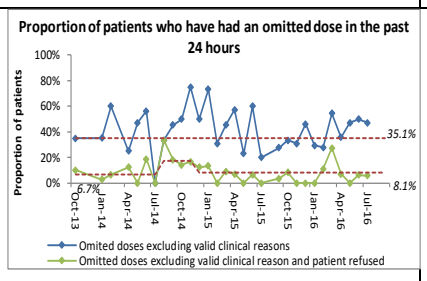
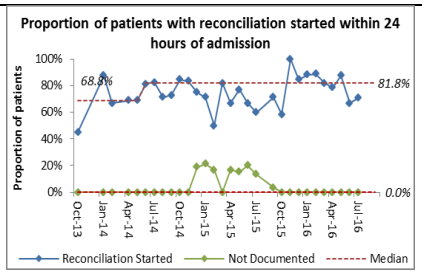
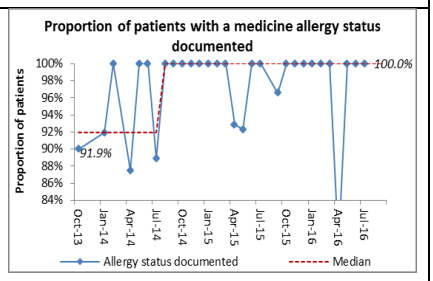
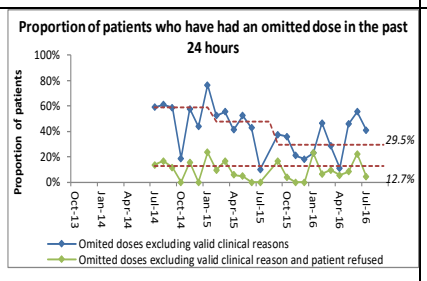
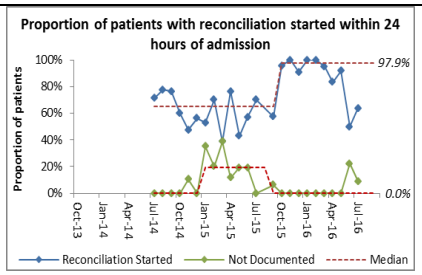
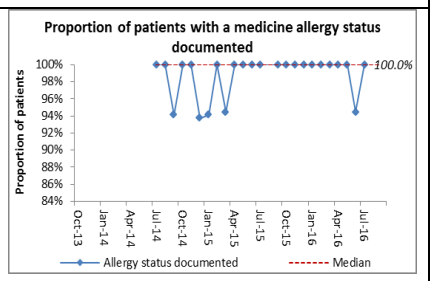
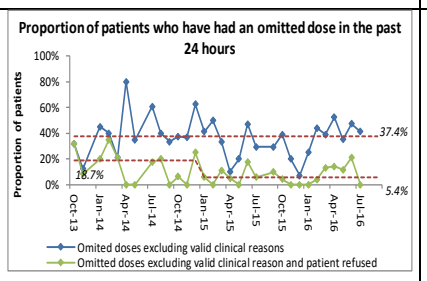
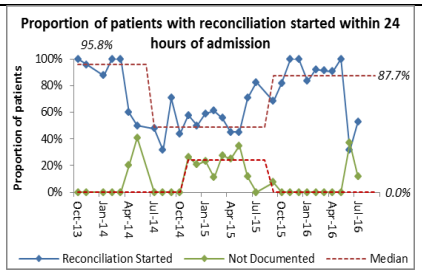
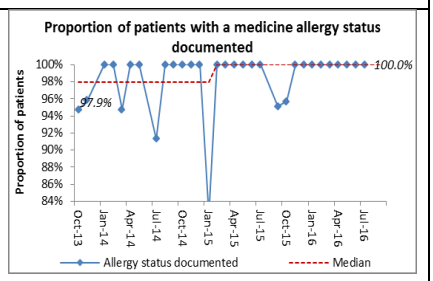
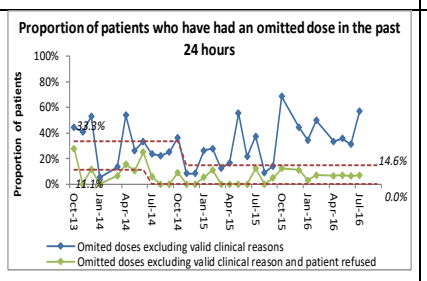
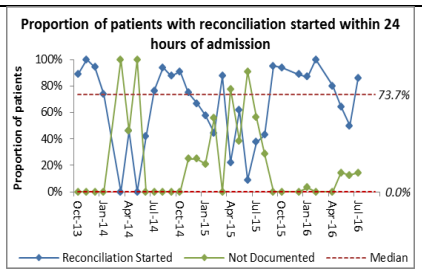
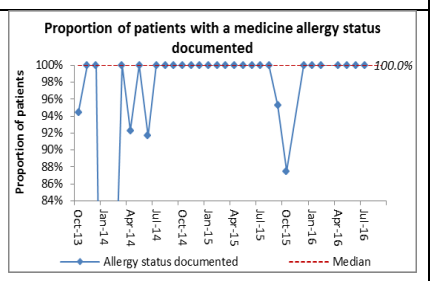
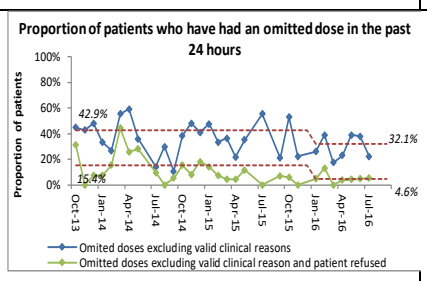
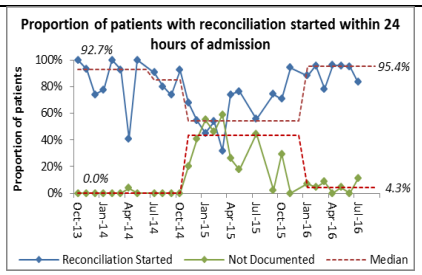
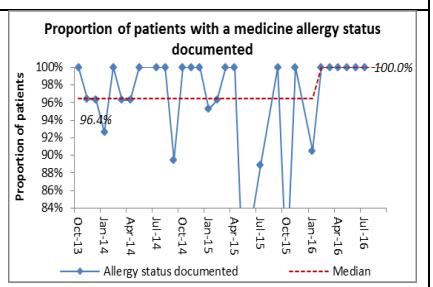
Ward	Omissions over time	Medicines reconciliation within 24 hours	Allergy status completion
B1			
B2			
B3			
B4			
B5			

B6			
B7			
B8			
B9			
B10			
B11			

B12	 Proportion of patients with reconciliation started within 24 hours of admission Proportion of patients 100% 80% 60% 40% 20% 0% 85.0% 0.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Reconciliation Started Not Documented Median	 Proportion of patients with reconciliation started within 24 hours of admission Proportion of patients 100% 80% 60% 40% 20% 0% 85.0% 0.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Reconciliation Started Not Documented Median	 Proportion of patients with a medicine allergy status documented Proportion of patients 100% 98% 96% 94% 92% 90% 88% 86% 84% 96.0% Oct-13 Jan-14 Apr-14 Jul-14 Oct-14 Jan-15 Apr-15 Jul-15 Oct-15 Jan-16 Apr-16 Jul-16 Allergy status documented Median

Appendix C.4: Small multiples table for Hospital C's ward-level Medication Safety Thermometer data

Ward	Omissions over time	Medicines reconciliation within 24 hours	Allergy status completion
C1			
C2			
C3			
C4			
C5			

C6			
C7			
C8			
C9			
C10			
C11			

Appendix C.5 - SQUIRE checklist

Title and abstract		Section OR Page(s) [Line(s)]
1. **Title**		
Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centredness, timeliness, cost, efficiency and equity of healthcare).	The title mentions the use of medication "safety" data for Quality Improvement.	1 [1-4]
2. **Abstract**		
a. Provide adequate information to aid in searching and indexing.	Key words such as "Medication Safety" and "Quality Improvement" have been listed during submission and are included in the title and abstract.	N/A
b. Summarise all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions.	The format of abstracts of BMJ Open has been followed and a structured summary has been provided in the strengths and limitations.	N/A
Introduction: Why did you start?		
3. **Problem description** - Nature and significance of the local problem.	It is stated that 'measurement of medication safety has been identified as a priority area for improvement'.	4 [83-84]
	It has been stated that many staff are unsure about how to use the Medication Safety Thermometer (MedsST) MedsST for improvement in hospitals.	4[111-113]
4. **Available knowledge** - Summary of what is currently known about the problem, including relevant previous studies.	Previous studies relating to the MedsST have been mentioned and cited. This includes a study reporting the design, development and implementation of the tool nationally and a qualitative study evaluating the implementation nationally. The gap concerning whether MedsST data are actually being used in practice has been made clear in the background and methods sections.	4-5 [107-129]

5. **Rationale** - Informal or formal frameworks, models, concepts and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s) and reasons why the intervention(s) was expected to work	The rationale for how the MedsST was designed and developed has been reported in a previous study which has been cited.	4 [107-108]
6. **Specific aims** - Purpose of the project and of this report.	The purpose of this study is stated – to show how routine medication safety can be collected & used for improvement purposes at local levels.	5[111-115]
Methods: What did you do?		
7. **Context** - Contextual elements considered important at the outset of introducing the intervention(s).	As mentioned previously the MedsST has been introduced in a previous study that has been cited, however, the context of the hospitals this study looks at and why they were chosen for this study is considered.	5[138-143]
8. **Intervention(s)**		
a. Description of the intervention(s) in sufficient detail that others could reproduce it.	The MedsST form is available freely online and anyone can use it. Collected data can be analysed in a similar way to this study (which describes how to analyse run charts (Table C.1). Although the individual improvements can be learnt, they are context dependent.	See Methods
b. Specifics of the team involved in the work.	Some details about the participants interviewed have been given for context. However, to keep participants anonymised specifics have been limited.	See Results
9. **Study of the intervention(s)**		
a. Approach chosen for assessing the impact of the intervention(s).	It has been detailed in the methods section that this was a mixed-methods assessment consisting of both qualitative and quantitative methodology.	See Methods
b. Approach used to establish whether the observed outcomes were due to the intervention(s).	The in-depth qualitative data provides information about where outcomes were related to MedsST data collection and use.	See Results & discussion
10. **Measures**		
a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their	N/A.	

operational definitions and their validity and reliability.		
b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency and cost.	N/A	
c. Methods employed for assessing completeness and accuracy of data.	Data analysts checked the accuracy of data and worked with hospital staff if issues had arisen, this is stated.	6[159-162]
	Notes including quotes from qualitative data were collected by two interviewers and compared for accuracy after interviews. Finalised notes and the overall report were sent to participants to clarify and check accuracy – changes were made if necessary.	7[184-192]
11. **Analysis**		
a. Qualitative and quantitative methods used to draw inferences from the data.	Yes, this is described in the methods.	See Methods
b. Methods for understanding variation within the data, including the effects of time as a variable.	N/A as the focus was how to use the tool and the data.	N/A
12. **Ethical considerations** - Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest.	This work was identified as Service evaluation and this is stated. The main researcher (PR) is a PhD student funded by Haelo, who originally facilitated the development of the MedsST. AH is also an employee of Haelo, however, they are no longer facilitating use of the MedsST and did not influence the results of this study.	8 [210-213]
Results: What did you find?		
13. **Results**		
a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart or table), including modifications made to the intervention during the project.	This has been reported in previous study.	N/A
b. Details of the process measures and outcomes.	This has been reported in previous study.	N/A
c. Contextual elements that interacted with the intervention(s).	Contextual factors were explored during interviews and have been reported, e.g. availability of funding for using the intervention.	e.g. 11[303-310]

d. Observed associations between outcomes, interventions and relevant contextual elements.	Examples of these associations have been given, for example, in the context of a hepatology ward with funding for patient safety, improvements were reported in specific types of medication omissions (e.g. lactulose).	e.g. Table 3 [Case Study 3]
e. Unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s).	This study focuses on whether data have been used for improvement, unexpected positive uses, such as use to updating of guidelines have been reported. A previous paper discussed the associated challenges with unexpected uses such as benchmarking.	e.g. Table 3 [Case Study 2]
f. Details about missing data.	N/A	
Discussion: What does it mean?		
14. **Summary**		
a. Key findings, including relevance to the rationale and specific aims.	Key findings are presented in the results, with examples in the three case studies (Table 3), all ward SPC charts are provided in appendices to be used as supplementary material (and 2 specific SPC charts are also provided for use within the paper). Interview results are related to the thematic framework provided in the methods. The findings regarding how data are collected and used (the aim of the study) have clearly been discussed with the paper.	Results, Table 3 and SPC charts, discussion
b. Particular strengths of the project.	Strengths and Limitations have been provided in the article summary.	See strengths and limitations.
15. **Interpretation**		
a. Nature of the association between the intervention(s) and the outcomes.	The in-depth qualitative data provides good association between the use of the data collected and outcomes	e.g. Table 3 [Case Study 3] and SPC charts 1&2
b. Comparison of results with findings from other publications.	The discussion draws comparison of findings to a range of other studies.	See Discussion
c. Impact of the project on people and systems.	The paper discusses the impact of the data collected and how "systems" can be improved using the data, and the impact of staff "championing" the MedsST.	See Discussion
d. Reasons for any differences between observed and anticipated	N/A – exploratory study with no expected outcomes.	N/A

outcomes, including the influence of context.		
e. Costs and strategic trade-offs, including opportunity costs.	N/A	
16. **Limitations**		
a. Limits to the generalisability of the work.	Discussed in strengths and limitations	
b. Factors that might have limited internal validity such as confounding, bias or imprecision in the design, methods, measurement or analysis.	N/A	
c. Efforts made to minimise and adjust for limitations.	N/A	
Conclusions		
a. Usefulness of the work.	The conclusion states improvement of medication safety using routinely collected data is possible, however, collecting MedsST data and not reviewing and using it is an inefficient use of resources.	17[516-526]
b. Sustainability.	The sustainability of "system changes" versus "individual behaviour change" is discussed.	17[525-526]
c. Potential for spread to other contexts.	The lessons that can be learnt, regarding implementation, for other organisations using the MedsST or similar tools has been discussed.	15 [447-454] and 16[472-478]
d. Implications for practice and for further study in the field.	This study shows concrete examples of how routine medication safety data can be used for improvement. This will help more organisations to understand how and why medication safety data should be collected and used.	See Discussion & Conclusion
e. Suggested next steps.	The next steps include raising awareness of the MedsST, increase support of clinical champions and increasing collaboration between hospitals and universities to implement the system of data collection, review and uses. Furthermore, new organisations implementing the MedsST should focus more of data review and use, in addition to data collection. These next steps have been stated in the discussion.	17 [519-526]
Other information		

18. **Funding** - Sources of funding that supported this work. Role, if any, of the funding organisation in the design, implementation, interpretation and reporting.	Funding information has been declared under Funding	See Funding.

Progression from Study Three to Study Four

Study Three explored how MedsST data had been used by the three organisations that had used the tool for the longest period of time. Therefore, Study Three helped to address Objectives Three and Four of this programme of work: to identify whether MedsST data have been used to influence and measure improvements in medication safety, and if so, how and to identify positive practice associated with use of the MedsST to aid medication safety improvement.

The final study sought to address Objective Five: to explore how nationally aggregated MedsST data can be used to learn more about medication safety at scale within the NHS. Thus, an overarching aim of Study Four was to explore how such nationally aggregated MedsST data could be used learn about medication safety by selecting one area of medication safety measured by the MedsST to focus on as an exemplar.

Findings from Studies Two and Three were used to select medication administration omissions as an area to focus on for Study Four. Studies Two and Three highlighted that that medication administration omissions were problematic and was a priority area for improvement for participants' hospitals. Therefore, Study Four focussed on medication omissions and was a quantitative study that presented an exemplar of how nationally aggregated MedsST data could be used to learn about medication safety.

Studies Two and Three highlighted that staff trusted omissions data, and used it for improvement purposes successfully, but only in hospitals not in community settings. Therefore, data from community settings were excluded in this study.

Chapter Nine:

Study Four

Chapter type:	Journal article
Article title:	Prevalence, nature and risk factors for medication administration omissions in UK NHS hospital inpatients: a retrospective multi-centre study using Medication Safety Thermometer data
Authors:	Paryaneh Rostami, Calvin Heal, Abigail Harrison, Gareth Parry, Darren M Ashcroft, Mary P Tully
Article Type:	Original Research
Status:	Under review

Note. As this paper is ready for submission, the formatting, referencing and layout are consistent with the requirements for the target journal. The abbreviations used may also differ. For this chapter, references, tables, figures and appendices will be placed at the end of the chapter rather than at the end of the thesis.

Prevalence, nature and risk factors for medication administration omissions in UK NHS hospital inpatients: a retrospective multi-centre study using Medication Safety Thermometer data

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Abstract:
Objective: To determine the prevalence, nature and predictors of patients experiencing medication administration omissions in hospitals.

Methods: All omissions data collected using the standardised methodology of the Medication Safety Thermometer (MedsST) in January 2015 were examined. Hospital in-patients prescribed at least one medication were included in the analysis. Multi-level logistic regression models ascertained the effects of patients' gender, age, number of prescribed medicines, ward speciality and medicines reconciliation initiation status on the likelihood of experiencing omissions. Valid clinical reasons (VCRs) were excluded from regression models. A sensitivity analysis, excluding patient refusal omissions, was also conducted.

Results: The final study sample included 5708 patients from 320 wards in 37 hospitals. Excluding VCRs, 30% of patients experienced omissions (95% confidence interval [CI] 29-30) or 40% including VCRs (95% CI 38-41). Approximately half of patients with omissions had refused medicines (51%, 95% CI 49-53). Univariable analysis suggested that all variables were significantly associated with omissions. However, in the multivariable model significant differences were only observed regarding the numbers of medicines patients were prescribed and their ward speciality. Patients prescribed more than 20 medications were approximately 5 times more likely to experience omissions than patients prescribed 1-4 medications (Odds Ratio [OR] 4.99; 95% CI 3.22-7.73). Patients on surgical wards were also more likely to experience omissions than those on medical wards (OR 1.58; 95% CI 1.14-2.18, p=0.006), but there was no significant difference when patient refusals were excluded (OR 0.57; 95% CI 0.27-1.22, p=0.473).

Conclusion: Medication administration omissions are a substantial problem that affect many hospital patients and certain patient groups are at higher risk. Specific interventions are required targeting different medication omission reasons for different patient sub-groups.

Background:

Several studies and reports have highlighted that 10% of patients are harmed by healthcare [1-3]; in particular, adverse events associated with medication appear to be a primary cause of this harm [2 4 5]. These adverse drug events caused by medication errors are associated with additional healthcare costs and increased lengths of stay in hospitals [6].

One of the most common types of medication error appears to be medication administration errors [7-9]. A medication administration error is the administration of a dose, or lack of administration (omission) of a dose, of medication that deviates from the prescription, as written on the patient chart, or from hospital policy and procedures [10 11]. A systematic review of medication administration error prevalence found that they were common and affected approximately 19.1% of doses due to be administered in hospitals [4]. Furthermore, the review found that medication administration omissions were the biggest cause of medication administration errors [4]. This study focuses on medication administration omissions, which will hereafter be referred to as omissions.

A report published in 2007 from the Patient Safety Observatory [9] highlighted that an important step for improving medication safety is to:

"Ensure medicines are not omitted: Identify current levels of omitted medicines and target areas for action (for instance, anticoagulation or other high-risk medication)."

Within healthcare settings, omissions are a well-known issue amongst healthcare staff who have often reported anecdotal evidence of prescribed medicines not reaching patients [12]. A number of studies have quantified the issue of omissions within hospitals [12], but these have often been either small studies[13-16], focussed on one type of medication group[17], or have been conducted in one organisation [14 18 19 5 20] or specific speciality area only [5 15 20 21]. The rates of omissions reported by these previous studies have been highly variable, partly due to the varying definitions and classification systems used in studies[14]. Furthermore, most of the aforementioned studies have investigated the rate of omissions as the number of doses that have not been administered

[17 18 21 22], rather than the number of patients that have not received their medicines. Whilst it is useful to know about the former, it is also useful to know about the latter so that specific patient groups can be prioritised for improvement of omissions.

Focussing on patients with omissions, rather than omitted doses, is in line with the NHS 'Harm Free Care' programme. This programme was initiated by a large group of NHS healthcare professionals and aims to encourage those involved with healthcare improvement to "*stop dealing with safety issues in silos, (and) think about complications from the patient's perspective and aim for the absence of all harm to each and every patient*" [23]. In terms of medication safety, this means that healthcare organisations should aim to measure and improve the proportion of patients who are free from harm from medication related adverse events, including omissions.

One tool that is part of the Harm Free Care programme, focussing on improving medication safety for patients, is the NHS Medication Safety Thermometer (MedsST). The MedsST has been used to collect medication safety data by over 100 UK hospitals since 2013 [23]. It was developed to help healthcare organisations monitor harm due to medication errors and was designed to measure improvement over time [23]. It consists of three steps, which focus on potential and actual harm [24]. The potential harm is measured using process measures, such as the frequency of omissions, specifically whether any of a patient's prescribed medications have not been given in the 24 hours prior to the point of survey. Actual harm is also measured by reviewing whether harm has occurred from four classes of drugs that can cause patient harm if not administered appropriately: anticoagulants, injectable sedatives, insulin and opiates. These four medication classes were identified as the most likely to cause death and severe harm by the UK National Reporting and Learning System (NRLS), 2005-2010 [22 23].

It is recommended that the MedsST tool is used on one day per month to survey all patients on wards using the MedsST [24]. The data collected from the MedsST tool can be reviewed and used by organisations to measure associated

improvement at local levels, but the data can also be aggregated for use nationally [23].

After collecting and inputting MedsST data online, organisations can review and use their collected data immediately. Whilst the data has been used within certain organisations to aid improvement[23], nationally aggregated MedsST data has not yet been used to learn about the magnitude of medication safety issues, such as omissions.

Aims:

The aims of this study were to use MedsST data collected by hospitals to identify the prevalence of patients experiencing medication omissions in secondary care, describe the nature of omissions and to investigate predictors of patients experiencing omissions.

Methods:

Data Source:

This study involved a secondary analysis of data that had already been collected and compiled. The data had been collected by various healthcare staff in various hospitals using the MedsST and compiled by Haelo. Data collected from community settings were excluded. The REporting of studies Conducted using Observational Routinely-collected Data (RECORD) statement[25] was used to guide the reporting of this manuscript (Appendix D.1). The RECORD statement is an extension of the more commonly used Strengthening the reporting of observational studies in epidemiology (STROBE) checklist[26], developed specifically for routinely collected healthcare data.

There is open-access to data provided in statistical process control charts in a dedicated dashboard, which can be accessed at www.SafetyThermometer.nhs.uk[24]. For the purpose of this study, raw data were obtained from Haelo who managed the data collection between 2013-2017.

The data collected included demographic information on gender (male/female), age band (<18 years, 19-24 years, 25-44 years, 45-69 years, >70 years), clinical specialty of ward a patient was on (e.g. medical, surgical or

other), medication safety process measures (allergy status completion, medicines reconciliation initiation and medicine administration omissions) and triggers of actual harms (e.g. low glucose levels in patients on insulin). No patient identifiable data were collected. Data collection had been completed by a range of healthcare staff including pharmacists, nurses and pharmacy technicians. Information was sourced from examination of the patient, patient report and clinical records.

For the omissions data, data collectors reviewed medical records and spoke to other healthcare professionals or patients to determine whether an omission had occurred within the last 24 hours from the time of data collection. If a patient was included as having experienced an omission, staff recorded the reason for the omission (e.g., medicine not available).

Definitions

Figure D.1 shows the precise operational definitions that were provided with the tool regarding omissions. Data were collected on all regularly prescribed medicines and not 'as required' drugs as the tool specifies that data collectors should *"Exclude PRN medicines (refers to medicines taken only when required), Stat doses (doses taken immediately and not routinely), IV (Intra-venous) fluids, O2 (Oxygen), food supplements or devices. Different doses of the same medicine count as one medicine"*[24].

Study Design and Population:

Data collected voluntarily from 38 UK NHS hospitals across England during January 2015 were examined, as the highest number of patients had been surveyed in this month. All surveyed patients who were prescribed one or more medication(s) were included in this study. Patients who had not been prescribed any medicines were excluded from analysis as they were not able to have an omission. One hospital that had collected data in January 2015, was excluded as it had submitted data for one patient only.

1.6a Please tick below which medicines the patient has been prescribed. 1.6b If any have been omitted in the last 24 hours please tick all reasons that apply for each ✔		Reasons for Omission								
		Valid Clinical Reason (eg low BP)[1]	Patient Refused	Outstanding Reconciliation	Medicine not available	Route not available	Patient absent at med round	Not Documented	Other	*Excluding food supplements & O2*
	Anticoagulant									
	Opioid									
	Insulin									
	Anti-infectives[2]									
	Any other prescribed medicines									

Figure D.1 - Medication Safety Thermometer Question 1.6 (from version 16) regarding medication administration omissions

Statistical Analysis:

The primary outcome measure was the point prevalence of all patients who had experienced one or more omissions, excluding valid clinical reasons (VCRs), and the secondary outcome measure was the point prevalence of all patients who had experienced one or more omissions, excluding both VCRs and patient refusals (PRs). Variations between demographic subgroups were examined formally using a two-stepped approach. Chi-square tests and univariable logistic regression were applied to assess homogeneity of the prevalence of omissions between patient sub-groups, and a multilevel logistic regression was performed to assess the impact of adjusting for hospitals and wards. Significance was assessed at an α level of 0.05 (two-sided). Analyses were conducted using IBM SPSS Statistics (v. 23) and Microsoft Excel 2016.

In the second analytical phase, multilevel binary logistic regression was performed to ascertain the effects of patient characteristics on the odds that patients experience one or more omissions. The following patient variables, available from MedsST data, were included: age group, number of medications prescribed, ward speciality, and medicines reconciliation initiation status at the time of data collection. Multilevel modelling allowed us to account for the hierarchical nature of the data (hospital-ward-patient) in estimating our results. This included using fixed effects for each of the variables (predictors) of interest and random effects to account for hospital and ward-level clustering.

Separate regressions were performed for omissions excluding VCRs, and omissions excluding both VCRs and PRs.

Research Governance and Ethics:

This study is a secondary analysis of publicly available anonymous data, as the MedsST tool does not collect any identifiable patient information. No ethical approval was required as identified using the NHS research ethics decision tool[27] and the University's Ethics Decision Tool[28]. Nonetheless, high ethical standards were adhered to and, although publicly available, the names of the hospitals who collected MedsST data in January 2015 have not been published in this study.

Results

A total of 7425 patients were surveyed in January 2015. However, 1717 patients in primary care settings and 140 hospital patients who were not on any medication were excluded from this study. Furthermore, patient submissions with incomplete data were excluded, as the number of missing values was very small (55 cases out of 5763; less than 1%). The remaining 5708 patients included in this study were based across 320 wards in 37 hospitals.

Overall Omissions

The mean rate of inpatients with omissions across all hospitals was 30% excluding VCRs (n=1717, 95% CI 29-31), or 40% including VCRs (n=2256, 95% CI 38-41). However, this varied greatly between hospitals with hospitals ranging from 0-64% excluding VCRs and 0-41% excluding both VCRs and PRs.

Drug Groups Omitted and Reasons for Omissions

Omissions were not limited to any specific drug group or patient characteristic. Of the patients prescribed high-risk medicines, patients prescribed insulin (n=270) had the highest proportion of omissions (n=40, 15%, 95% CI 11-19). Of the patients who had experienced omissions of all medicines (n=2256), the most common reason for omissions were PRs, which were reported for over half of all patients with omissions (n=1150, 51%, 95% CI 49-53).

Table D.1 shows how different high-risk drug groups have different causes of omissions. For example, PRs were the main cause of omissions for patients prescribed insulin (n=8, 20%, 95% CI 7-33), opioids (n=46, 54%, 95% CI 43-65) and anticoagulants (n=48, 24%, 95% CI 18-30), but not for anti-infectives. Within the group of patients who experienced omissions of anti-infectives (n=149), over a quarter did so due to the unavailability of their prescribed anti-infective medications (n= 42, 28%, 95% CI 20-35). Unavailability of medicines was rarely an omission reason for patients on other high-risk medicines, for example, of patients who had experienced omissions of anti-coagulants (n=200), only 2% had omissions due to anti-coagulant unavailability (n=4, 95% CI 0-4).

Table D.2 shows how the omission reasons varied for patients on surgical and medical wards who were prescribed high-risk drugs. For example, omissions due to outstanding medicines reconciliations were experienced by patients on surgical wards, albeit very rarely, but these were not reported at all for patients on medical wards.

Univariable Regression Model with Chi-Square Tests

A univariable model with separate logistic regressions and Chi-square tests for each patient variable found statistically significant differences for all patient characteristics on the likelihood of having omissions, (see Table D.3).

Multivariable Model for Predicating Patients with Medication Omissions

The multivariable logistic regression model, which was adjusted for variables at patient, ward and hospital levels, revealed that patients' age group and their medicines reconciliation initiation status were not associated with omissions (Table D.4). Conversely, the following characteristics were found to be significantly associated with the likelihood of a patient experiencing one or more omissions: gender, the number of medications prescribed, and the specialty of the ward they were on.

As expected, an increase in the number of medicines a patient was prescribed was significantly associated with an increase in omissions; patients prescribed 20 or more medicines were around 5 times more likely to experience omissions

than patients prescribed 1-4 medicines (OR 4.99; 95% CI 3.22-7.73, p<0.001). Patients on 15-19 medicines also had a three-fold higher likelihood of experiencing an omission compared to those on 1-4 medicines (OR 3.61; 95% CI 2.86-4.56, p<0.001). Additionally, patients on 5-9 medicines were twice as likely to experience omission compared to those on 1-4 medicines (OR 2.02; 95% CI 1.61-2.53, p<0.001).

Patients on surgical wards were approximately 1.6 times more likely to experience omissions than those on medical wards (OR 1.58; 95% CI 1.14-2.18, p<0.001). 'Other' wards were also included in the analysis, these included mental health, critical care, emergency department, paediatrics and obstetrics wards grouped together due to the relatively low numbers of these compared to medical and surgical wards. No significant differences were found in the likelihood of patients experiencing omissions on medical wards compared to other wards, possibly because less data were collected on other wards or due to the mixed nature of this group.

Multivariable Model for Predicating Patients with Medication Omissions (excluding Valid Clinical Reasons and Patient Refusals)

The tests were repeated excluding PRs, which halved the proportions of omissions (n=852, 15%, 95% CI 14-16). However, excluding PRs did not alter the significance of the number of medicines prescribed as predictors; patients on >20 medicines were over 4 times more likely to have an omission than those prescribed 1-4 medicines (OR 4.18, 95% CI 2.59-6.74, p<0.001). However, the differences between medical and surgical wards, and gender became insignificant (OR 0.57; 95% CI 0.27-1.22, p=0.473 and OR 1.07; 95% CI 0.95-1.20, p<0.284 respectively), suggesting that PRs may drive the differences between omissions of medical and surgical wards. Table D.2 shows that on both wards, 55% of patients who were prescribed opioids had refused them (medical wards: n=16/29, 95% CI 36-74 and surgical wards: n=30/55, 95% CI 41-68). The proportion of patients who were prescribed and refused anti-infectives, insulin and anticoagulants were all higher on medical wards, suggesting that other drugs (not classified as high-risk) were driving the higher rate of all PRs on surgical wards compared to medical wards.

Discussion

This study found that omissions in hospital remain a substantial problem and are more prevalent in certain patient sub-groups. The results indicated that 30% of patients experience medication omissions (excluding VCRs) and that half of these omissions are due to PRs, which were more likely for patients on surgical wards. The most strongly associated predictor of omissions in this study was found to be the number of medicines a patient was prescribed, with patients on 20 or more medicines five times more likely to experience an omission then a patient on 1-4 medicines.

It is difficult to compare our findings to previous research about omissions rates as many studies have looked at 'doses' rather than 'patients'. However, the studies that have included data about the rates of hospital inpatients who experience at least one omission have reported rates between 17-80%[12 13 19] and our result for patients experiencing omissions (40%) is close to the median of this range. Furthermore, a recent study conducted specifically within a UK NHS hospital reported a rate of 12.4%[14] of patients experiencing omissions, excluding PRs and VCRs (before any interventions to improve omissions) and our result is similar to this rate (15%).

The main reasons for omissions found in this study were PRs, followed by VCRs and then medicines not being available. Another study looking specifically at medical and surgical wards across four hospital sites also found these to be the leading causes of omissions[13]. Omissions due to PRs can be grouped with omissions due to 'patients absent from ward round' to form a sub-group of reasons due to 'patient reasons'. This study confirmed the findings of previous research, which has highlighted that patient reasons account for more omissions that 'process reasons', such as 'medicine not available'. There is literature to suggest that involving patients with their medication use and decisions can improve PRs, and strategies to improve medication adherence, including educating patients about their medicines and the importance of taking them, should be encouraged[29].

Although many previous studies evaluate proportions of dose omissions rather than proportions of patients experiencing omissions they have also highlighted

that PRs are one of the largest reasons for omissions, reporting that 41-46% of dose omissions being reported are due to PRs[13 18 22]. On the other hand, some studies haves have reported different reasons as the most prevalent explanation for omissions. For example, Green et al. in 2010 found that the most prevalent reasons for dose omissions were that the medicines were not available or that the patient was 'nil by mouth'. The latter definition may come under 'VCRs' or 'route not available' according to the MedsST definitions this study has used. The variations in definitions between hospitals highlight the need for standardised definitions and methodology if hospitals are to collect data to be aggregated nationally.

There have been various efforts made to improve omissions[14 15 30 31], and whilst results have been promising, it has been found to be a complicated and large task. Different actions are required for individual patient sub-groups. For example, whilst over a quarter of patients who experienced omissions of anti-infectives medicines did so due to the unavailability of their prescribed anti-infectives, only 2% of patients prescribed anti-coagulants had omissions due to unavailability of their prescribed anti-coagulants. Therefore, efforts to reduce unavailability of medicines for patient groups prescribed anti-infectives will have a larger impact than efforts to reduce omissions due to unavailability of medicines for patients prescribed anticoagulants. These issues require specific actions to help tackle a larger proportion of omissions with less resources[23]. For example, to reduce the number of omissions of anti-infectives, senior members of the organisation must examine associated supply and administration systems to see where they can be further improved to optimise patient care. Any such improvement strategies implemented by one hospital, may be easier to understand, replicate and monitor across wards and hospitals due to the use of the standardised MedsST data collection methodology, as progress can be more easily compared.

Some hospitals such as NHS University College London hospitals have already used MedsST omission data, alongside other omission audit data, for further improvement initiatives[31]. At this hospital, omission data have been fed back to frontline staff by the Medication Safety Officer alongside suggested omission improvement strategies though guidance on behalf of their medication safety

committee[31]. This shows that some use of MedsST omission data, for monitoring and aiding improvement, is occurring at hospital-level and further research is required to explore how the data are being used, and by whom.

This study has also confirmed that patients with polypharmacy are one of the main priority areas for medication safety improvement. Polypharmacy is a growing global problem due to an ageing population and increasing prevalence of multi-morbidity[32]. Therefore, focus is required on methods of identifying and improving unnecessary polypharmacy. Particularly in older patients who tend to be prescribed more medicines, such as the Screening Tool of Older Person's potentially inappropriate Prescriptions (STOPP) and Screening Tool of Alert doctors to the Right Treatment (START) criteria that has been used by a number of organisations internationally[33].

Previous studies have also found that omissions are more common on surgical wards than medical wards[19], and these results suggest that PRs drive these differences. One could assume that omissions of opioids would be higher on the surgical wards, as they are commonly prescribed after surgery for pain relief. However, Table D.2 showed that an equal proportion of patients are experiencing omissions of opioids on medical and surgical wards (55%). Regardless of wards, a high number of patients refuse opioid medicines, which has also been found in previous research that demonstrated analgesia and anti-inflammatory medicines, such as opioids, to be associated with high rates of omissions, often due to PRs[13]. Healthcare staff may need to ensure regular review of medication so that it can be stepped down from regular to as required or discontinued if and when appropriate.

The results of this study indicated that medicines reconciliation initiation did not impact the likelihood of a patient experiencing an omission. It could be argued that medicines reconciliation is more likely to cause issues with medicines not being prescribed when patients transition from other care settings into hospitals[34], rather than not administered whilst in hospital. However, the data about medicines reconciliation initiation could be a proxy measure for the patient's drug chart having been seen by a pharmacist and any unavailable medication ordered. This would potentially reduce omissions of

medicines, particularly if bundled with interventions aimed at improving patients' transitions between care settings[35]. Furthermore, medicines reconciliation could provide a potential opportunity for pharmacy staff to discuss medicines with patients and why they are refusing medications. For example, reviewing whether surgical ward patients should have their regular prescribed opioids discontinued or stepped down. Previous research has highlighted that many of the benefits of resolving unintended discrepancies during the medicines reconciliation process may not become apparent for months after discharge[35].

The current WHO global patient safety challenge, 'Medication without harm', has identified three early priority action areas: high-risk situations, polypharmacy and transitions of care. Although we focussed on omissions, a very specific area of medication safety, our findings support the need for improvement of these areas. Patients with polypharmacy were significantly more likely to have omissions, patients on particular high-risk medicines are at higher risk of missing medicines and, in terms of improving transitions of care, patients who do not have medicines reconciliation started within 24 hours were more likely to experience omissions. Improvement of omissions in all of these areas is required.

Strengths and Limitations

This study adds to knowledge about patients with omissions and potential predictors of patients experiencing omissions using a large data set, from a variety of wards with different specialties across 37 hospitals. The data used in this study have also been collected using a universally available tool and standardised methodology. As this study focuses on the proportion of patients with omissions, rather than the number of missed medicines, it could aid healthcare professionals to identify or confirm which patient groups are at higher risk of omissions and adapt omissions improvement strategies accordingly.

This study, and data collected by the MedsST, were not without limitations. Although the data collection method was standardised, multiple healthcare staff were involved, leading to potential variations in data collection practice,

even with the guidance provided. For example, although the MedsST guidance states that only data regarding regular medicines (rather than 'as required' medicines) should be collected, it is not clear whether this guidance has been adhered to. Furthermore, data collected relied on complete medical records and drug charts. If these patient documents were incomplete, or the data collected failed to identify or to record omissions, this would result in our data underestimating the actual omission rate. However, the median number of patients data were collected on calculated to be 19 (interquartile range [IQR] 12 – 24) per ward, and 129 patients per hospital (IQR 47-207). As these ranges were not wide it suggests that the data are being collected somewhat consistently across hospitals and wards. Furthermore, the staff within hospitals trust the omissions data[36], and have reported that they have successfully used MedsST omissions data to conduct and monitor further improvement work successfully[34].

While this was a large study that used multilevel regression modelling to account for variance between the wards and hospitals, its findings may not be generalisable to other hospitals, particularly those in other countries. Furthermore, all hospitals included collected data voluntarily in January 2015, which may mean they are more pro-active about improving patient safety, further underestimating the prevalence across England.

Conclusion

This study found that a large proportion of patients are affected by medication omissions; however, many of these are due to VCRs, or possibly appropriate PRs. Overall, the main predictor for a patient experiencing medication omissions is the number of medicines that they have been prescribed.

Funding Statement

This work was supported by Haelo, an independent innovation and evaluation organisation hosted by Salford Royal Foundation Trust.

Data Sharing Statement

The Medication Safety Thermometer data for all organisations collecting data, which have been referred to in this study, are available via

https://www.safetythermometer.nhs.uk. To access a dedicated dashboard presenting the data in graphical format, the *"Medication"* tab must be selected, followed by the *"analyse data"* button [10]. Since this study was conducted, management of the MedsST data has been transferred from Haelo to the Quality Observatory team at South, Central and West Commissioning Support Unit on behalf of NHS Improvement[24], who can be contacted for more recent raw data.

Competing Interests

The first author (PR) of this manuscript has the following competing interests: PR is a PhD student funded by Haelo who facilitated the initial development of the tool being evaluated in the study. However, PR is based at the University of Manchester and Haelo had no role in the study design. The other authors declare that they have no competing interests.

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Study Four Tables

Table D.1 - Reasons for Omissions Overall and Within each High-Risk Drug Group.

		Anticoagulants		Anti-infectives		Opioids		Insulin		All medicines	
Total patients prescribed		**1589**		**1318**		**764**		**270**		**5708**	
Total patients with omission (PO)		**200**		**149**		**85**		**40**		**2256**	
Total pts with omission/pts prescribed		13%		12%		11%		15%		40%	
Reasons group	**Reasons for omission**	**n**	**n/PO [%(95% CI)]**	**n**	**n/PO [%(95% CI)]**	**n**	**n/PO [%(95% CI)]**	**n**	**n/PO [%(95% CI)]**	**n**	**n/PO [%(95% CI)]**
Process reasons	**Valid Clinical Reasons**	114	57 (0.50-0.64)	39	26 (0.19-0.33)	21	25 (0.15-0.34)	16	40 (0.24-0.56)	579	31 (0.29-0.33)
	Outstanding Reconciliation	5	3 (0.00-0.05)	1	1 (-0.01-0.2)	0	0 (constant)	0	0% (constant)	16	1 (0.00-0.01)
	Medicine Not Available	4	2 (0.00-0.04)	42	28 (0.20-0.35)	8	9 (0.03-0.16)	3	8 (-0.01-0.16)	435	19(0.18-0.21)
	Route Not available	1	0 (0.00-0.01)	15	10 (0.05-0.15)	5	6 (0.01-0.11)	2	5 (0.02-0.12)	82	4 (0.03-0.04)
	Undocumented reasons	33	16 (0.11-0.22)	23	15 (0.09-0.21)	5	6 (0.01-0.11)	5	13 (0.02-0.23	186	8 (0.07-0.09)
Patient reasons	**Patient refusals**	48	24 (0.18-0.30)	29	19 (0.13-0.25)	46	54 (0.43-0.65)	8	20 (0.07-0.33)	1150	51 (0.49-0.53)
	Absent patient at ward round	5	2 (0.00-0.05)	10	7 (0.03-0.11)	2	2 (0.01-0.06)	1	3 (-0.03-0.08)	24	1 (0.1-0.1)
Other	**Other reasons**	9	4 (0.02-0.07)	20	13 (0.08-0.19)	5	6 (0.01-0.11)	9	23 (0.09-0.36)	174	8 (0.07-0.09)

N.B. It is possible for patients to experience omissions due to different reasons, for medicines from the same drug group, therefore the sum of each column will exceed 100%.

Table D.2 – Reasons for Omissions of High-Risk Medicines on Medical and Surgical Wards.

		Patient's Ward speciality															
		Medical								Surgical							
		Anti-infectives		Insulin		Opioids		Anticoagulants		Anti-infectives		Insulin		Opioids		Anticoagulants	
		n	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]	*n*	*n*/PO [%(95% CI)]
Patients' omission reasons	**Valid Clinical Reasons**	25	25 (16-33)	13	52 (0.31-0.73)	5	17 (0.03-0.32)	74	56 (0.48-0.65)	11	25 (12-38)	3	23 (0-50)	15	27 (15-39)	40	58 (46-70)
	Outstanding reconciliation	0	-	0	-	0	-	0	-	1	2 (2-7)	0	-	0	-	5	7 (1-14)
	Medicine not available	32	32 (22-41)	1	4 (0-12)	4	14 (0-27)	2	2 (0-4)	10	23 (10-36)	1	8 (9-24)	4	7 (0-14)	2	3 (0-7)
	Route not available	11	11 (22-41)	0	-	1	3 (0-11)	1	1 (0-2)	4	9 (0-18)	2	15 (0-38)	4	7 (0-14)	0	-
	Undocumented reasons	14	14 (7-21)	3	12 (0-26)	4	14 (0-27)	19	15 (8-21)	9	20 (8-33)	2	15 (0-38)	1	2 (0-5)	13	19 (9-28)
	Patient refusals	21	21 (13-29)	5	20 (3-37)	16	55 (36-74)	34	26 (18-34)	8	18 (6-30)	2	15 (0-38)	30	55 (41-68)	14	20 (11-30)
	Absent patient at ward round	7	7 (02-12)	0	-	0	-	2	2 (0-4)	2	5 (0-11)	1	8 (0-24)	2	4 (0-9)	3	4 (0-9)
	Other	12	12 (5-18)	6	24 (6-42)	1	3 (0-11)	7	1 (1-9)	5	11 (2-21)	2	15 (0-38)	3	5 (0-12)	2	3 (0-7)
Total patients with omissions (PO)		**101**		**25**		**29**		**131**		**44**		**13**		**55**		**69**	

n=number of patients with omissions reason, PO = Total patients with omissions, N.B., It is possible for patients to experience omissions due to different reasons, for medicines from the same drug group, therefore the sum of each column will exceed 100%.

Table D.3 – Univariable Logistic Regression Model: Prevalence of Patients with Omissions and Chi-Square Tests

		Omissions (excluding VCR)				Omissions excluding (VCR and PR)			
Variable		Observed prevalence (%)	Odds Ratio (CI 95%)	Sig.	Chi^2 Test	Observed prevalence (%)	Odds Ratio (CI 95%)	Sig.	Chi^2 Test
Gender	Male	791/2766 (29)	1.00 (reference)	-	x2 (1) =5.619, p=0.018	404/2766 (15)	1.00 (reference)	-	x2 (1) =0.139, p=0.709
	Female	926/2942 (32)	1.15	0.018		448/2942 (15)	1.02 (0.92-1.14)	0.709	
Patient age group	<18*	10/84 (12)	1.00 (reference)	-	x2 (5) =18.581, p=0.002	7/84 (8)	1.00 (reference)	-	x2 (5) =18.581, p=0.002
	18-24	27/109 (25)	2.44	0.027		10/109 (9)	2.76 (1.30-5.88)	0.009	
	25-44	140/453 (31)	3.31(1.66-6.60)	0.001		61/453 (14)	4.54 (2.34-8.79)	0.000	
	45-59	219/692 (32)	3.43(1.74-6.76)	0.000		108/692 (16)	3.92 (2.04-7.53)	0.000	
	60-74	406/1373 (30)	3.11 (1.59-6.07)	0.001		178/1373 (13)	3.54 (1.86-6.75)	0.000	
	>75	915/2997 (31)	3.25 (1.63-6.32)	0.001		488/2997 (16)	3.83 (2.02-7.25)	0.000	
Patients' number of medicines group	1-4*	185/984 (19)	1.00 (reference)	-	x2 (4) =115.877, p<0.001	76/984 (8)	1.00 (reference)	-	x2 (4) =30.383, p<0.001
	5-9	669/2352 (28)	1.72 (1.43-2.06)	0.000		326/2352 (14)	1.77 (1.50-2.10)	0.000	
	10-14	616/1753 (35)	2.34 (1.94-2.82)	0.000		331/1753 (19)	2.13 (1.79-2.54)	0.000	
	15-19	206/519 (40)	2.84 (2.24-3.61)	0.000		100/519 (19)	2.23 (1.78-2.81)	0.000	
	>20	41/100 (41)	3.001 (1.95-4.61)	0.000		19/100 (19)	2.67 (1.76-4.06)	0.000	
Ward speciality	Medical	929/3434 (27)	1.00 (reference)	-	x2 (2) =48.269, p<0.001	512/3434 (15)	1.00 (reference)	-	x2 (2) =34.091, p<0.001
	Surgical	743/2086 (36)	1.49 (1.33-1.68)	0.000		326/2086 (16)	1.32 (1.18-1.48)	0.000	
	Other	45/188 (24)	0.85 (0.60-1.20)	0.348		14/188 (7)	0.65 (0.46-0.91)	0.011	
Medicines reconciliation	initiated	1169/4053 (29)	1.00 (reference)	-	x2 (1) =10.176, p=0.001	580/4053 (14)	1.00 (reference)	-	x2 (1) =16.427, p<0.001
	not initiated	548/1655 (33)	1.22 (1.09-1.38)	0.000		272/1655 (16)	1.28 (1.14-1.44)	0.000	
Total prevalence		1717/5708 (30)				852/5708 (15)			

*=Reference group for each predictor, VCR=Valid Clinical reasons, PR= Patient Refusals, **Medicines reconciliation initiation= medicines reconciliation has been initiated since admission to the ward at the time of survey

Table D.4 – Multivariable Model: Prevalence of Patients with Omissions, Surveyed by the MedsST in January 2015 with Adjusted Odds Ratios from a Three-level Logistic Regression Model with Random Effects at Hospital and Ward levels

		Omissions (excluding VCR)				Omissions excluding (VCR and PR)			
Variable		Observed prevalence (%)	Adjusted Odds Ratio (CI 95%)	t	Sig.	Observed prevalence (%)	Adjusted Odds Ratio (CI 95%)	t	Sig.
Gender	Male	791/2766 (29)	1.00 (reference)			404/2766 (15)	1.00 (reference)		
	Female	926/2942 (32)	1.21 (1.02-1.43)	2.34	0.019	448/2942 (15)	1.07 (0.95-1.20)	1.07	0.284
Patient age group	<18*	10/84 (12)	1.00 (reference)			7/84 (8)	1.00 (reference)		
	18-24	27/109 (25)	1.03 (0.37-2.86)	1.64	0.101	10/109 (9)	0.56 (0.14-2.27)	-0.82	0.414
	25-44	140/453 (31)	1.37 (0.58-3.28)	2.39	0.017	61/453 (14)	0.73 (0.14-3.83)	-0.37	0.710
	45-59	219/692 (32)	1.23 (0.51-2.95)	2.34	0.019	108/692 (16)	0.78 (0.18-3.27)	-0.35	0.730
	60-74	406/1373 (30)	1.23 (0.53-2.87)	2.05	0.041	178/1373 (13)	0.65 (0.14-3.08)	-0.54	0.590
	>75	915/2997 (31)	1.20 (0.51-2.80)	2.26	0.024	488/2997 (16)	0.77 (0.16-3.71)	-0.33	0.743
Patients' number of medicines group	1-4*	185/984 (19)	1.00 (reference)			76/984 (8)	1.00 (reference)		
	5-9	669/2352 (28)	2.02 (1.61-2.53)	5.78	0.000	326/2352 (14)	2.22 (1.67-2.96)	5.46	0.000
	10-14	616/1753 (35)	2.99 (2.46-3.62)	8.91	0.000	331/1753 (19)	3.52 (2.73-4.53)	9.75	0.000
	15-19	206/519 (40)	3.61(2.86-4.56)	8.76	0.000	100/519 (19)	3.28 (2.38-4.52)	7.27	0.000
	>20	41/100 (41)	4.99 (3.22-7.73)	5.17	0.000	19/100 (19)	4.18 (2.59-6.74)	5.85	0.000
Ward Speciality	Medical	929/3434 (27)	1.00 (reference)			512/3434 (15)	1.00 (reference)		
	Surgical	743/2086 (36)	1.58 (1.14-2.18)	7.14	0.000	326/2086 (16)	0.57 (0.27-1.22)	0.47	0.473
	Other	45/188 (24)	1.02 (0.46-2.26)	1.57	0.117	14/188 (7)	1.12 (0.82-1.52)	0.15	0.150
Medicines reconciliation Initiation**	yes	1169/4053 (29)	1.00 (reference)			580/4053 (14)	1.00 (reference)		
	no	548/1655 (33)	1.06 (0.89-1.27)	3.53	0	272/1655 (16)	1.03 (0.87-1.22)	0.330	0.742
Total prevalence		1717/5708 (30)				852/5708 (15)			

*=Reference group for each predictor, VCR=Valid Clinical reasons, PR= Patient Refusals, **Medicines reconciliation initiation= medicines reconciliation has been initiated since admission to the ward at the time of survey

Appendix D.1 - RECORD Checklist (Extended from the STROBE Statement)

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	The title states that the study is looking at the "prevalence, nature and risk factors of medication administration omissions" and that the design is "a retrospective multi-centre" (page 1, Lines 1-2).	RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly	The title states that "Medication Safety Thermometer data" has been used. (Page 1, Lines 1-2) Data were from hospitals in England and this is stated in the title (Page 1, Line 2) N/A

				stated in the title or abstract.	
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	The background highlights the issue of medication administration omissions, and the variation in rates and collection methods reported by previous studies (pages 3-4, lines 54-89). The background also briefly explains the standardised methodology by which the Medication Safety Thermometer data is collected and how it can be used to learn about the rate of patients with medication administration omissions (page 4, lines 90-110).		
Objectives	3	State specific objectives, including any prespecified hypotheses	Aim of study stated (page 4, lines 11-114). Exploratory study with no hypothesis.		
Methods					
Study Design	4	Present key elements of study design early in the paper	The study design is described in the methods section, after context about the data used, and related definitions have been described (page 6, lines 149-155).		

Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	The study involved secondary analysis of previously collected data and this is stated in the methods (page 5, line 117). However, information about the data collection is provided (page 4, lines 125-139).		
Participants	6	*(a) Cohort study* - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study* - Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* - Give the eligibility criteria, and the sources and methods of selection of participants *(b) Cohort study* - For matched studies, give matching criteria and number of exposed and unexposed	N/A as this study involves secondary analysis of data already collected. However, inclusion criteria are described in study design and population (page 6, lines 149-155).	RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided. RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed	6.1. Data from all patients in hospital settings who have been prescribed one or more medicines included (page 6, lines 151-152). 6.2 N/A 6.3 N/A

		Case-control study - For matched studies, give matching criteria and the number of controls per case		methods and results should be provided. RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.	Predictors were the patient variables available from Medication Safety Thermometer data e.g. age groups (page 7, lines 168-169). Potential confounders were the hospital and ward, accounted for in multi-level modelling (page 7, lines 170-173).	RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement).	N/A		

		Describe comparability of assessment methods if there is more than one group			
Bias	9	Describe any efforts to address potential sources of bias	Multi-level modelling was used to account for the hierarchical nature of the data, this is stated (pg 7, lines 170-173).		
Study size	10	Explain how the study size was arrived at	Data from the month where the most MedsST data had been collected were used (January 2015) (page 6, lines 150-151).		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	Groupings provided by the Medication Safety Thermometer were used. This is stated (page 7, lines 168-170).		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *Cohort study* - If applicable, explain how loss to follow-up was addressed	a) Statistical methods have been described (Pages 6-7, lines 156-174). b) Regression Models used to examine sub-group interactions (Page 6 161-164 and Tables 3 & 4). c) Missing data were excluded because the number of missing		

		Case-control study - If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	values was very small (55 cases out of 5763, less than 1%). d) N/A. e) Sensitivity analyses was conducted by excluding omissions due to patient refusals.		
Data access and cleaning methods		..		RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population. RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.	All data were available online; however, raw data were requested from Haelo who facilitated data management at the time. Stated (pg 5, lines 125-127 and data sharing statement). Data cleaning methods included excluding community organisations, patients prescribed 0 medicines or with incomplete data. Furthermore, one organisation with only

					1 patient surveyed. Stated (Pg 7, lines 183-187).
Linkage		..		RECORD 12.3: State whether the study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.\	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (*e.g.*, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram	N/A – secondary analysis.	RECORD 13.1: Describe in detail the selection of the persons included in the study (*i.e.,* study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text	

				and/or by means of the study flow diagram.	
Descriptive data	14	(a) Give characteristics of study participants (*e.g.*, demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study* - summarise follow-up time (*e.g.*, average and total amount)	a) Demographic information provided as patient sub-groups/variable (page 7, lines 168-170). b) Fifty-five patient submissions excluded due to incomplete data, stated (Page 7, line 187). c) N/A		
Outcome data	15	*Cohort study* - Report numbers of outcome events or summary measures over time *Case-control study* - Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study* - Report numbers of outcome events or summary measures	Outcomes events (patients with omissions) reported in results. Overall omissions reported (page 7, lines 184-188) and then omissions due to various reasons in Table 1.		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence	a) Unadjusted estimates given (Table 3). Multi-level regression model adjusted for variation,		

		interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	including these levels: hospital-ward-patient (Table 4). b) N/A no continuous variables. c) N/A.		
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses			
Discussion					
Key results	18	Summarise key results with reference to study objectives	Key results discussed with respect to aims: -Prevalence of overall omissions summarised (page 7, lines 188-192). -Nature of omissions (Table 1) -Predictors for patients having omissions (Table 4 [adjusted] and discussed pages 8-9, lines 216-250)		

Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Limitations discussed in strengths and limitations (pages 12-13, lines 347-367).	RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	This has been given in the discussion, and strengths and limitations (pages 9-12, lines 252-367).		
Generalisability	21	Discuss the generalisability (external validity) of the study results	Generalisability discussed (page 13, lines 363-367).		
Other Information					
Funding	22	Give the source of funding and the role of the funders for the	Funding information is provided (page 13, lines 373-375).		

		present study and, if applicable, for the original study on which the present article is based			
Accessibility of protocol, raw data, and programming code		..		RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	Information about how to see data online, has been provided, or the Quality Observatory team at South, Central and West Commissioning Support Unit can be contacted for more recent raw data. (pages 13-14, lines 376-383)

SECTION FIVE: GENERAL DISCUSSION

Section Five Introduction

Sections Three and Four presented the four studies conducted in this programme of research. Section Five, consisting of Chapter Ten only, summarises and combines the key findings of the four studies and outlines the contribution of this programme of research to the wider literature. Practical implications of the studies conducted and recommendations for future research are also discussed.

Chapter Ten:

Discussion

The overall aim of this programme of research was to evaluate the use of the MedsST for both learning about and improving medication safety. The individual aims of the four studies were met. The next section will present a summary of the findings from each study and how they contributed together towards addressing the overall aim of the thesis.

10.1 Summary of Findings

To achieve the overall aim of this programme of work, there were two over-arching objectives that regarded:

1) Understanding how the MedsST was designed, developed and implemented.
2) How MedsST data can be used to learn about and improve medication safety.

Section Three and Four of this thesis consisted of four separate studies that addressed these objectives, a recap of the aims of these four studies are provided in Figure 8.0.

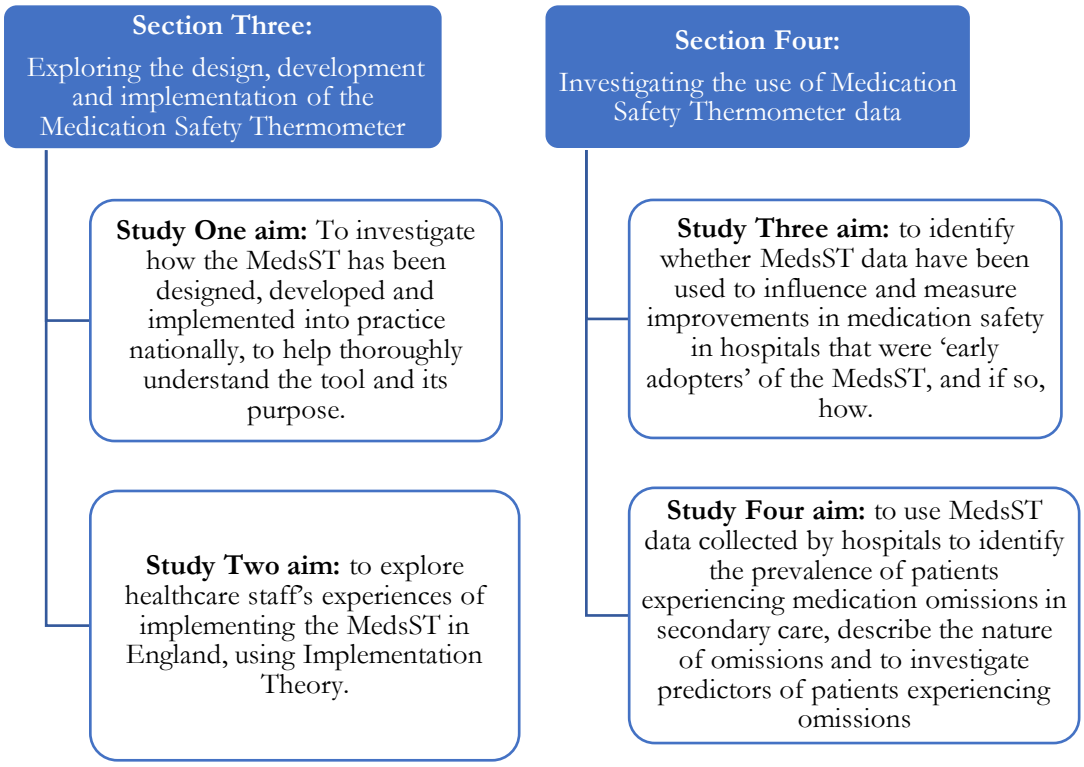

Figure 8.0 - Summary of the aims of the studies presented in this PhD

Studies One and Two focused on achieving the first objective listed above. An initial documentary analysis (Study One) was conducted exploring how the MedsST had been designed, developed and implemented nationally. This provided insight into how the steering committee developing the MedsST had achieved the end result of the current MedsST (Version 16). The steering committee that had developed the MedsST aimed to design the first tool with a national focus that enabled healthcare organisations to measure medication safety over time for improvement purposes. Whilst this aim had been achieved, the development process highlighted that measuring harm from MEs is complex and requires steps to measure individual errors, triggers of harm and actual harm. The development of the MedsST involved several repeated PDSA cycles to test and improve the various MedsST steps and measures. The PDSA tests led to several changes between versions and sub-versions. The use of these improvement science methods allowed gradual scale-up of the MedsST. The study showed how the engagement with the MedsST has increased over time, suggesting that the use of the PDSA approach and gradual scale-up of using the tool for data collection had been successful for implementing MedsST data collection within several NHS organisations. Study One also provided recommendations for implementation and use of the MedsST that had been provided for individual organisations by the steering group who had developed the MedsST.

Whilst recommendations existed for how organisations should implement and use the MedsST, there was little knowledge about how this happened within individual NHS organisations. Therefore, Study Two was conducted to explore how the MedsST had been implemented into practice within individual healthcare settings. NPT was used in Study Two. The four constructs of NPT (See Table B1, Study Two, Chapter Seven) were used to explain how use of the MedsST has been adopted and implemented into practice. It was found that staff involved with implementation, or use of the MedsST, had strong understanding of the purpose of the MedsST and why medication safety measurement was required and were therefore acting as facilitators for staff engagement with collecting data. Conversely, there was less understanding of how to monitor the use of the MedsST data and use its data for improvement, which was acting as a barrier for organisations to continue the use of the

MedsST and to scale up its use. The identification of a lack of understanding about how MedsST data can be used led to Studies Three and Four, which looked at how MedsST data has been used locally by hospitals, and how aggregated national MedsST data can be used, respectively. Primary care organisations were excluded from Studies Three and Four because Study Two identified that staff did not feel the tool was suitable for primary care and did not trust data from primary care for a number of reasons. For example, because healthcare assistants collecting data ignored errors if they felt it was not their fault.

Study Three explored if, and how, MedsST data had been used for medication safety improvement purposes within hospitals. The use of MedsST data at three hospitals that had collected MedsST data for the longest was investigated in Study Three. Study Three aimed to describe how data were used by healthcare organisations for improvement purposes; however, it was found that collected MedsST data were seldom used. A few cases of collected data being used for medication safety improvement were reported, most of which highlighted that use of data often occurs in silos, at ward-level and relied on champions to take ownership of MedsST data. A range of healthcare professionals were championing the use of the MedsST for improvement locally, including pharmacy technicians and ward managers, medication safety pharmacists and pharmacists with specialist interests other than medication safety (e.g. hepatology). Champions were fundamental to scaling-up the use of the MedsST and used a variety of methods to engage colleagues. Champions included those involved with MedsST data collection and those who had come across the data through team meetings and pharmacy department communications. In the context of using the MedsST, it was very important that champions felt supported. If they were not, this caused a barrier to using the MedsST and improving medication safety overall. Support for champions included acknowledgement and encouragement from colleagues, as well as financial support. Unfortunately, there was often a lack of support or acknowledgement from those who were perceived by healthcare staff as having a duty to assist with medication safety improvement, for example whilst most MSOs were engaged with use of the MedsST and its data, other MSOs were described as uninterested. Champions were fundamental for scaling-up use of

the MedsST and they improved medication safety both through actions that encouraged behaviour change in staff (such as raising awareness of omissions) and specific system changes (such as introducing new guidelines to ensure appropriate insulin adjustments were made for diabetic patients with reduced nutritional intake). When champions left organisations, the momentum for improving medication safety would stop, however, system changes would remain, highlighting the importance of improving systems rather than relying on individual behaviour change.

The final study (Study Four) explored how aggregated MedsST data could be used to learn about medication safety issues. Study Four highlighted that national data can be used to learn more about specific medication issues, in this case, medication omissions. The study found similar rates of omissions to that of previous research regarding medication omissions, validating the omissions data collected by the MedsST. Differences in the rates of omissions between wards, and specialities that appeared significant in a univariable logistic regression model were found to be insignificant when the variance between wards and hospitals were accounted for in a multivariable model. This study also pointed out great variation between organisations, further strengthening the argument that all organisations have different contexts and caution is required when comparing data between organisations. Omissions of medications are a substantial problem that affect many hospital patients and certain patient groups are at higher risk. Specific interventions are required to target the causes of different types of medication omissions. Other MedsST data collected about issues other than omissions, such as allergy status completion, could also be aggregated nationally for learning purposes.

10.2 Key Strengths and Limitations of the Studies

The mixed-methods approach to the research allowed the exploration and description of complex phenomena in which the implementation and use of the MedsST occurred. Use of the pragmatist paradigm allowed an in-depth evaluation of the use of the MedsST by enabling a descriptive and flexible approach of data collection and extraction throughout the four studies. The key strengths and limitations of each of the four studies are discussed below.

A strength of Study One was that it was the first documentary analysis to describe the design, development and implementation of a routine medication safety data collection tool used monthly to collect data and developed with a national focus. It described some of the major lessons learnt about developing medication safety measurement tools, which may be generalisable to other health systems globally. A limitation of this programme of work was that other tools measuring medication safety were not reviewed. However, a literature search conducted at the beginning of this programme of work revealed that no tools similar to the MedsST existed that allowed monthly medication safety data collection with a national focus. Nonetheless, a review of ME measurement tools in general would have helped understand the context to medication safety measurement. However, due to the time constraints of this programme of work, an investigation of how the MedsST was designed, developed and implemented was thought to be more useful as a preliminary step to evaluating the MedsST. Furthermore, the large-scale study by Elliott et al. mentioned in Chapter Two identified the definitions and categorisations used when measuring MEs in NHS organisations (38). The study by Elliott et al. highlighted that there is great variation in systems used and the need for standardised measurement systems such as the MedsST (38).

Studies Two and Three were the first studies to explore views and experiences of staff using a medication safety measurement tool with a national focus. The use of implementation theory, specifically NPT, greatly strengthened these studies and facilitated the finding that one of the causes for data being unused was that more focus had been given to implementing MedsST data collection within the NHS, rather than the holistic system of collection, reviewing and use of data. The relatively small sample sizes of the interview studies (Studies Two and Three) may be perceived as a limitation, however, a range of healthcare professionals holding a range of roles and levels of experience from a variety of healthcare settings and specialties participated in both studies, and each of these contributed to a rich data set resulting in data saturation. The variety of participants included in interviews, resulted in theoretical generalisability as findings may be transferable to other organisations that are using the MedsST, regardless of which staff may be involved with MedsST collection. Overall, in Studies Two and Three, the majority of participants were

pharmacy staff (n=16), compared to nursing staff (n=4) and clinical audit staff (n=1). However, this was representative of staff using the MedsST, who have predominantly been pharmacists and pharmacy technicians.

Audio recording of interviews did occur in Study Two; however, some of the MedsST users displayed more comfort with not being audio-recorded, therefore in Study Three audio-recording of conducted interviews did not occur. Nonetheless, notes from the two interviewers who collected data in Study Three were merged, and meanings of notes and quotes from participants were clarified with participants after interviews, addressing potential inaccuracies.

Study Four was the first study that used national aggregated MedsST data to learn about an area of medication safety. One of the main strengths of Study Four is that it has specifically added to the knowledge about patients with omissions and potential predictors of patients experiencing omissions using a large data set, from a variety of wards with different specialties. The data used in this study was collected using a universally available tool and standardised methodology. As this study focuses on the proportion of patients with omissions, rather than the number of missed medicines, it could aid healthcare professionals to identify or confirm which patient groups are at higher risk of omissions and adapt omissions improvement strategies accordingly.

However, Study Four is not without its limitations and although the MedsST data collection method was standardised, multiple healthcare staff were involved, leading to potential variations in data collection practice, even with the guidance provided. For example, although the MedsST guidance states that only data regarding regular medicines (rather than 'as required' medicines) should be collected, it is not clear whether this guidance has been adhered to. Furthermore, data collected relied on complete records of medicines administration on patients' medical records and drug charts. If these patient documents were incomplete, or the data collected failed to identify or to record omissions, this would result in our data underestimating the actual omission rate.

10.3 Contribution of Thesis Studies to the Literature

It has been highlighted by researchers as a common issue that measurement tools introduced into healthcare, such as the MedsST, that seek to reduce distinct quality measures are presented with limited or no information about the derivation and interpretation of constituent measures (175). The technical information required to understand how composite indicators were designed is sometimes not published (175). This programme of work has helped to address this issue specifically for the MedsST.

Taken together, the results of this programme of research suggest that we are closer to the aim of improving medication safety within the NHS, due to the implementation of routine medication safety data collection in many organisations. However, collecting data alone does not lead to improvements in medication safety. At the time of its publication (2000), the DoH's report 'an Organisation with a Memory', that was mentioned in the initial chapters of this thesis, highlighted that although there is a wealth of experience on analysing and learning from adverse events at an organisation level in industries, such as aviation and nuclear power, there was very little experience of this in healthcare. The report concluded that within in the NHS there was *"no reliable way of identifying lapses in standards of care, analysing them in a meaningful way, learning from them and introducing changes to prevent similar events from recurring"* (10, 92). Since the publication of the aforementioned report, there has been an increased interest in the measurement of healthcare quality and safety. A number of systems to help identify lapses in standards of care have been introduced within the NHS, including the MedsST and other STs. Measurement systems like the STs are particularly beneficial because in order to improve something, measurement is required to enable organisations to understand when improvement has been made. However, many problems with safety measurement systems have been highlighted, and there have been calls for clear and transparent reporting of the design of these indicators used (175). This programme of work has provided clear and transparent reporting of how the MedsST has been developed from an independent perspective.

Previously there was a lack of routine medication safety measurement data collected in organisations, making it difficult for them to know if any

improvements in medication safety were being made. The findings of this programme of work have contributed to the literature regarding routine measurement of medication safety for improvement purposes. In particular, the MedsST has allowed many organisations to collect routine medication safety for the first time; however, whilst data collection is occurring, improvements are not, highlighting that data collection alone does not lead to improvements, and data must be used to drive further improvement work.. This research has identified the facilitators and barriers of implementing medication safety measurement tools, such as the MedsST, and using them for improvement purposes.

As mentioned above "An Organisation with a Memory" concluded that as well as introducing ways to identify serious lapses, organisations must *"analyse (data from) them in a meaningful way, learning from them and introducing changes to prevent similar events from recurring"* (10, 92). The findings of this programme of work show that whilst the MedsST provides a way for organisations to collect data about medication safety issues, the majority of data are not yet being analysed in a meaningful way. Underuse of data is unacceptable from a quality assurance perspective, as the requirement to perform analyses without proper resources risks key details being missed and resources are being invested with little return of insights to improve care (176). Previous research has identified other patient safety data that are collected but not used, with one of the causes for data remaining unused being staff unable to make sense of the data or not fully understanding how it was collected, and this issue applies to the collection of MedsST data also. This programme of work has helped those using the MedsST to understand how the data are collected and how the measures data are collected on have been chosen. It has also provided some examples of how data can be used, but more needs to be done to enable NHS staff to interpret and use the data that have been collected. In summary, most organisations using the MedsST (hospital organisations) have implemented MedsST data collection successfully; however, the holistic system of data collection, review and use has not occurred, and this has been discussed further in Section 10.3.3.

10.3.1 Normalising Use of the Medication Safety Thermometer.

As mentioned previously, Studies Two and Three involved interviews using NPT as an underlying theory to help evaluate whether use of the MedsST had normalised into routine practice within NHS organisations. The themes based on the four constructs of NPT were first presented in Table B1 (Study Two, Chapter Seven). In terms of the first construct, coherence, it was found that all staff involved with use of the MedsST had a strong understanding of why medication safety measurement is vital for improving medication safety. Investigating the second construct, cognitive participation, showed that all staff are somewhat engaged with the MedsST in terms of data collection, and this engagement increased depending on the staff seniority and ownership of patients' medication use process. For example, ward managers would show greater engagement than pre-registration pharmacists, as they were involved with a patient's medication administration and more accountable for medication safety due to their senior role. Investigating the first two constructs of NPT, coherence and cognitive participation, showed strong evidence that the act of data collection using the MedsST has been implemented well into practice in most NHS healthcare organisations. An exception to this was in non-hospital primary care settings where there was a lack of understanding of what the tool was measuring, and also a lack of engagement as the questions were not suitable for community settings.

Investigation of the latter two constructs of NPT, collective action and reflexive monitoring, revealed the more problematic areas of the implementation of the MedsST; collective action and scaling-up. In order for the MedsST to be used as part of routine practice, as recommended by MedsST guidance, it needs to be scaled-up to all wards of an organisation. Many organisations have not managed to scale-up the use of the MedsST past the initial testing wards as part of the PDSA methodology recommended in MedsST guidance (23). The PDSA methodology allowed participating hospitals to implement the MedsST to all wards, however this seems to have contributed to hospitals not scaling-up use of the MedsST to all wards, acting as a barrier to normalising the MedsST within organisations, as it contributes to staff seeing the MedsST as an extra project that only some wards are involved with, rather than an activity that is part of routine practice. This was further

highlighted by participants from organisations where all wards collect MedsST data, stating that the MedsST was seen as routine practice.

The use of PDSA has been beneficial for allowing hospitals to help develop the tool and highlights that the shift from an initially 'top-down' implementation model within the NHS (177-179) to a model that allows more local input in decision making among implementing hospitals, has been beneficial. The fact that many settings have volunteered to test and use the MedsST has been valuable as hospital staff are more likely to reject a system that they feel has been forced upon them (180).

10.3.2 Use of Data Collected for Medication Safety Research Purposes

There is opportunity to use collected MedsST data for further research purposes. AHSCs are ideal settings for the development and testing of such strategies for many reasons including that they represent a bridge between policy-making and front-line delivery of services; their focus on research and teaching fosters an innovative institutional culture that facilitates the development and testing of new, creative solutions (181, 182). The AHSCs that have been formed in a number of areas of England (183) provide an opportunity for researchers and healthcare professionals to work together to learn about medication safety from the data that healthcare professionals have collected themselves, for example to use quantitative data within their organisations to learn about prevalence of different areas of medication safety such as omissions.

Quantitative data provides a good basis for where to start, but should trigger qualitative investigation for in-depth understanding. Each area and patient group has to be targeted differently. For example, patient refusals of a particular type of drug may have a particular reason in the way that patients with hepatic failure rejected lactulose because they thought it was for treating constipation rather than hepatic encephalopathy in Study Three. As highlighted previously, collecting data and not using it is a problem that applies to the MedsST, and the implications for policy and practice have been highlighted in Section 10.4, and further research and quality improvement work (discussed in section 10.5).

10.3.3 The System of Data Collection, Review and Use for Improvement

It is not possible to know for certain whether improvements are occurring without the collection of data over time. However, collection of data alone does not result in improvements. Reviewing of data requires understanding and effort from staff. Organisations must focus on strategies to encourage their staff to review and use data rather than to continue using resources to collect data that is not used. In particular, staff must be trained to understand how MedsST data can be used over time to see the impact of any medication-safety related improvements they make. When incorporating MedsST data training into staff inductions, it is not just how to use the data that needs to be included, but how the collected data can be used for improvement. Organisations must ensure that staff understand what the MedsST is and that they understand the MedsST data collected.

In order to use the collected data, it is vital that there are procedures in place for staff to access the MedsST feedback. This work highlighted that in some cases where feedback was provided to ward staff, it was often via e-mail, which is problematic because not all frontline staff are able to access emails easily. The importance of feedback, particularly when combined with educational support, to improve practice was highlighted in Study Three (Table C.3, Case Study Three) where two wards of Hospital C had introduced teaching sessions based on common mistakes that were being made as identified from investigating MedsST data. This approach of combining feedback with outreach and educational support has been proven to have greater impact than providing feedback alone by previous research studies, for example. The Pharmacist-led information technology intervention (PINCER) trial conducted in primary care settings highlighted that a system of feedback, outreach and educational support was more effective than simple feedback (184). Greater work must be done to provide similar interventions related to MedsST data.

10.4 Implications for Policy and Practice

The NHS has stated that one of their aims is to support their patients to live longer and healthier lives, and have highlighted that high quality information regarding care being provided to patients is required to ensure they are

achieving this aim, leading to increased healthcare data collection (185). Whilst the increase in healthcare data collection is beneficial if it is used, it can be counter-productive if it is not helping improvement and is adding to burdens and leads to various potentially adverse effects on workflows and collaborative working (177-179). Previous research has found that in some instances, data collection systems can reduce face-to-face contact within teams and between healthcare professionals and patients, and shifts the focus of healthcare professional work to increased data entry activities (177-179). However, the fact that MedsST data is only collected one day per month has somewhat alleviated this issue from occurring. Nonetheless, data collection is still a waste of resources if data are not used as mentioned in Section 10.3.3.

In order to ensure data are used, staff ownership of medication safety is important. Studies Two and Three of this programme of research found that involving ward-level staff to collect and review their own MedsST data has many benefits as, although data were anonymised, it allowed staff to know exactly which patients had experienced lapses in care, rendering the lapses more personal. Furthermore, Study Two highlighted that normalising the use of the MedsST was viewed as beneficial by the majority of staff. Most hospital NHS staff trusted MedsST data and some staff demonstrated it was possible to use MedsST data successfully for improvement purposes. Therefore, this programme of research recommends that the government should encourage use of the MedsST to be incorporated into existing clinical audits that routinely take place within secondary care hospitals across England. However, the data collected in primary care settings was not trusted and normalising it into primary care is not recommended (see section 10.5.2 for research recommendations in primary care). It is also recommended that it should be encouraged for MSOs at each hospital to lead the use of the MedsST at their organisation and be responsible for reviewing MedsST data. This recommendation is based on the findings from Study Three that highlighted MSOs are not necessarily aware of the medication safety issues and improvements that can be be identified and investigated using MedsST data.

One of the concerns with mandating the MedsST would be its use as a blame allocation device, in the way that the original ST had been used (128) and that

healthcare organisations having access to others' data could lead to competition and gaming the system to be the "better hospital" (128). However, the evaluation of the MedsST found little evidence of its data being used in this way. Only one participant interviewed had used the MedsST data to allocate blame nor was there any evidence of MedsST users gaming the system. However, this was likely to be because the data was not being reviewed. If organisations do start reviewing their own data, and data from other hospitals, there is a risk that staff at organisations may become competitive and manipulate MedsST data. This is something that must be monitored and reviewed in the future.

This programme of work has reiterated previous research about composite measures, that highlighted that periodic reviews of all measures must be undertaken by stakeholders, so that those measures that were found to be no longer relevant or useful are either withdrawn or appropriately revised (175). For example, this programme of work highlighted that MedsST users in primary care do not feel the MedsST is appropriate for non-hospital settings calling for an immediate review of the tool in primary care.

Whilst the MedsST and other STs have been designed to allow measurement of individual areas of safety, they have also been designed to be used to measure "harm-free" care as a composite measure (129). One of the issues with composite indicators is that when rates are reported, their accuracy are not reported (175) and this is true for the measures of the MedsST and other STS (132). Composite indicators are not immune to chance variation: tiny differences in individual measures can translate into differences in the final rating, but will often be due to chance (175, 186). The rates reported in Study Four demonstrated the chance variation for the omissions rates. Similar statistical analyses to those used in Study Four could be used more routinely to analyse collected data, in line with expert recommendation and established practice for individual performance measures (175, 187, 188) This would require increased statistical support, that could be provided by research partners in the AHSCs (see section 10.3.2). Whilst calculating and reporting confidence intervals could improve the accuracy of MedsST, this may make the data even more confusing for frontline staff to understand and less accessible

(175). Therefore, analysed data must be interpreted, and use to build a narrative about medication safety improvement, for frontline staff. This must be done by the relevant hospital departments, for example Quality Improvement departments, and associated university researchers to ensure maximum learning from MedsST data is gained. Information provided to frontline staff must be concise as indicated by frontline staff in Studies One and Two, stating they would prefer online summaries of how their wards are progressing in terms of medication safety improvement, rather than accessing data online.

Whilst improvement science allows healthcare organisations to implement quality improvement tools, such as the MedsST at a small scale and gradually scale-up over time, it is important to deliver the full scale-up plan. Organisations often implemented the tool on a few wards, without scaling up to more wards as initially planned. However, Studies Two and Three found that it was necessary to fully implement it to all wards to normalise use of the tool into practice. The widespread use of the MedsST across all wards of a hospital, also provided wards more opportunities to learn about positive medication-safety practice from each other, and to find wards that were positive deviants (see section 10.5.4).

The implementation of the MedsST was more successful in organisations with a stronger understanding of quality improvement, where staff understood the PDSA methodology and how to review run charts. Therefore, it is recommended that the NHS focuses on improving the understanding of Quality Improvement among healthcare staff.

Previous literature has highlighted the importance of including Quality Improvement in undergraduate healthcare education (189). This is important because students and trainees are the "front-line" providers in many healthcare institutions where their awareness and positive involvement in quality improvement is crucial to the success of robust quality initiatives (189). It is also important because the future healthcare practitioners will face issues of quality and safety in daily practice (189). Quality Improvement is an area of healthcare that all healthcare professionals should be aware of and therefore

"interprofessional education" programs provide an ideal opportunity to teach healthcare students from different professions about Quality Improvement. Interprofessional education is defined as an intervention where the members of more than one health or social care profession, learn interactively together, with the aim of improving interprofessional collaboration or the health/wellbeing of patients/clients, or improvements in both (190). Quality Improvement aligns well with the aforementioned aim of interprofessional education, highlighting it as an ideal subject to be taught in this way.

10.5 Future Research and Quality Improvement

This programme of research was conducted as part of a PhD. It was therefore limited by time and resource constraints. Below is a description of further research that could be conducted.

10.5.1 Improving the Quality of Medication Safety Data Collected

As highlighted previously, there is great variation in the definitions and systems used to identify MEs (38). Introducing standardised systems such as the MedsST is the first step towards monitoring and measuring medication safety (191). However, to increase the usefulness of the data, there must also be focus on the quality of data. For example, by statistically analysing the collected data as mentioned in section 10.4, but also by ensuring that data collected are collected consistently.

Study one highlighted how extra training sessions conducted via WebEx in Summer 2014 helped to rectify issues with data consistency issues, after the introduction of Version 16 of the MedsST. However, considering that there is often a high turnover of NHS staff in some organisations(192), more routine standardised training must be implemented within hospitals. Studies Two and Three highlighted that MedsST data collection training is including in staff inductions, but more work must be done to investigate how the MedsST training is occurring in individual organisations and if necessary to ensure regular and standardised training for using the MedsST across all organisations.

10.5.2 Future Research for Primary Care Settings

As mentioned above, there is a strong body of evidence to suggest that the current MedsST is not suitable for primary care settings, except community hospitals. Although the aims of the developers were to use a tool suitable for all settings, it has greatly been developed using incident reports to the NPSA and approximately 75% of medication-related reports to the NPSA were from acute general hospitals (n=394,951), whereas only 8.5% of reports were from primary care settings (n=44,592) (18). Through testing, the steering committee of the MedsST have realised that it is not feasible to have exactly the same tool in both primary and secondary care settings, as highlighted by the introduction of a community sub-version in 2014 (Appendix 2.0). However, Study Two found that the community sub-version was still difficult to use in primary care. The findings suggested that a different tool may be necessary for community settings, for example focussing on the medicines more likely to cause harm in various community settings. The measures chosen for the MedsST were based on areas of medication safety highlighted as particularly problematic in the UK by the NRLS. However, approximately 75% of the reports received by the NRLS were from hospital settings, and only 8.5% in primary care settings, despite most medication use occurring in primary care (18). Previous research studies have investigated and highlighted the errors and drugs most commonly associated with medication-related harm in primary care (193, 194), and these should be used to develop routine medication safety measures for primary care settings.

Whilst the MedsST was not suitable for use in primary care, the routine measurement of medication safety in primary care settings, albeit a complex process, may be of great benefit as the reporting culture in primary care is not as robust as hospital settings as mentioned above (18), this is particularly true for the reporting of omissions (195). Tools used to measure medication safety in primary care settings should be based on robust research evidence from primary care, as was done in the data used by the pincer trial, rather than relying on NRLS reports alone due to the underreporting of MEs in primary care settings (184). Research studies often use observational techniques that allow us to learn about incidents that may not be reported.

10.5.3 Use of Implementation Theory for Implementing Initiatives.

As mentioned in section 9.3.2, this study strengthens the argument of researchers who have highlighted that the large-scale implementation of tools, such as the MedsST should consider implementation theory in the very initial stages (160). The use of implementation theory is not just important for tools that are evaluated through research studies, but to help organisations evaluate the initiatives they are using in everyday practice. (160). If newer versions of the MedsST are implemented, or other similar tools for medication safety measurement, it is vital that guidance and support for the on-going evaluation of the tools must also be developed and implemented, not just guidance and for data collection.

10.5.4 Further Research using Medication Safety Thermometer Data

As mentioned previously, the newly formed AHSCs provide a good opportunity for hospitals and universities to work together to use routinely collected data. Further multi-disciplinary work is required between research departments and organisations, to support the "champions" who have been using MedsST data to aid improvement of medication safety and to share and disseminate their work. Changes made to systems, rather than just individual behaviour must be encouraged, to make improvements more sustainable. For example, conducting a review of the changes in hospital guidance based of MedsST data would be useful for sharing system changes that improve medication safety, between different hospitals.

10.5.5 Further Research of Positive Deviance

There was also evidence of Safety II approaches to use of data, where participants spoke about exploring "what is going right" with medication safety (196) and which wards had shown improvement. Previous research has shown how Safety Thermometer data (for other areas of patient safety) can be used to identify positive deviants within organisations (197). For example, Baxter et al. conducted a cross-sectional and temporal analyses of original ST data from 34 elderly medical wards in North England to identify a discrete group of positively deviant wards that consistently demonstrated exceptional levels of safety (197). Baxter et al. then explored how staff and patient perceptions were

different on positively deviant wards compared to a group of matched comparison wards (197).

The AHSCs mentioned above provide an opportunity for hospital staff to work with researchers to use MedsST data that are trusted by hospital staff to identify positive deviant wards. The differences in the behaviours and systems of the wards with exceptional medication safety practice, compared to standard wards, may be used to help identify actions or system components that could be scaled up.

10.6 Final Conclusions

This programme of research has provided insight into how the MedsST has been designed developed and implemented, including implementation nationally, as well as locally within organisations. This research has identified the MedsST as a useful tool in hospital healthcare settings, but not primary care settings. It has also provided insights into how the MedsST can be used for learning about medication safety and improving it. Furthermore, this programme of research has identified the factors that influence how the MedsST is implemented and used for improvement purposes within individual organisations. This area has been, until now, under-researched in use of the MedsST, as well as routine medication safety measurement in general. Using NPT, this work identified that there is understanding and engagement with using the MedsST to collect medication safety data; however, the data is not being reviewed or necessarily being used for improvement. Therefore, the main recommendation made as a result of this research is that more focus is needed on implementation of the holistic system of data collection, review and use, rather than data collection alone. This research has also enabled further recommendations to be made about the implementation of patient safety initiatives in general. It has also made a contribution to how aggregated MedsST data can be used to enable learning about medication safety.

This research is timely with the increased recognition and focus on improving medication safety and the current WHO Global Patient Safety Challenge (17, 39). As more organisations, both within the NHS and globally, implement the MedsST and similar tools, it is vital that they develop as a result of the lessons

learnt from this evaluation of the MedsST. Furthermore, organisations already using the MedsST must recognise and share the improvements being made internally within organisations and externally. An example of how improvement could be shared is through the newly formed MSO network within the NHS. The unused MedsST data also provides further opportunities for learning and improvement, for example, for measuring the prevalence of other areas of medication safety or similar omissions. Further improvement to medication safety within the NHS using MedsST data will help to improve each patient's healthcare journey, and further strengthen the world-leading UK NHS.

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Thesis Appendices

Appendix 1.0 – The Medication Safety Thermometer Version 16a (Acute) Steps 1 and 2

Medications Safety Thermometer - Acute Collection Form V16 'Harmfree'care

Number: **Setting:** **Specialty:**

SECTION 1 This section should be completed by the nurse or primary carer using the medication administration or prescription chart, information from clinical records and dialogue with the patient / carer. The focus of this section is on the fundamentals of safe medication use. It should be completed for ALL patients surveyed. Each question should be answered by circling the response or the box completed as requested.

Please circle answers

1.1 Gender:		M / F
1.2 Age:		Under 18 / 18- 24 / 25-44 / 45-59 / 60-74 / 75 or Over
1.3 Is the medicine allergy status documented in your clinical record in this care setting?	*(including no known drug allergies) e.g on prescription or MAR sheet*	Yes / No
1.4 Was medicines reconciliation for all medicines undertaken (started) by the pharmacy team within 24 hours of admission to this care setting?	*Pharmacist or medicine management technician has been involved*	Yes / No / **No** Patient still within 24 hour period at point of survey
1.5 How many regular medicines is the patient prescribed?	*Exluding PRN, Stat doses, IV fluids, O2, food supplements or devices. Different doses of the same medicine count as one medicine*	0 / 1 - 4 / 5 - 9 / 10 - 14 / 15 - 19 / More than 20

1.6a Please tick below which medicines the patient has been prescribed.

1.6b If any have been omitted in the last 24 hours please tick all reasons that apply for each ✓

	Reasons for Omission								
	Valid Clinical Reason (eg low BP)[1]	Patient Refused	Outstanding Reconciliation	Medicine not available	Route not available	Patient absent at med round	Not Documented	Other	*Excluding food supplements & O2*
Anticoagulant									
Opioid									
Insulin									
Anti-infectives[2]									
Any other prescribed medicines									

1.7 Has the patient received any of the following medicines in the last 24hrs? (If yes circle medicines that apply)	*Anticoagulants (Heparin, LMWH , Warfarin and NOACs[3]){Excluding VTE Prophylaxis), Opioid (excluding oral codeine, dihydrocodeine and Tramadol), IV or SC Sedatives[4], Insulin*	Anticoagulant / IV/SC Sedatives / Opioids / Insulin

If YES to Q1.7 proceed to Section 2 (If NO then form is complete)

SECTION 2 Only complete section 2 if a patient has received an **Anticoagulant, Opioid, IV/SC Sedatives** or **Insulin** in the past 24 hours as answered in question 1.7. Only answer the corresponding questions to the medication that the patient has received. **Data can be collected by nursing staff, medicines management technician and pharmacist.**

Please circle the relevant answers only

2.1 Anticoagulants (Heparin, LMWH, Warfarin & NOACs)	
Has the patient had a bleed of any kind or a VTE? / Has the patient had an administration of Vitamin K, Protamine or clotting factors e.g. Octaplex?	**If Yes which Trigger of Harm?** Bleed / VTE / VIT K or other / INR > 6
Does the patient have an INR greater than 6 or APTT ration greater than 4?	None of these
2.2 Opioids	
Has the patient had an administration of naloxone? / Is the patient's respiratory rate below 8 breaths per minute (bpm)?	**If Yes which Trigger of Harm ?** Naloxone / bpm less than 8
	None of these
2.3 Injectable Sedatives (Midazolam, Lorazepam, diazepam, clonazepam)	
Has the patient had a common complication of over sedation which includes hypotension, delirium, respiratory depression, reduced GCS? / Has the patient had an administration of reversal agent Flumazenil?	**If Yes which Trigger of Harm?** Common complications / Flumazenil
	None of these
2.4 Insulin	
Does the patient show signs of common complications (capillary blood sugar <4mmol/L) or symptoms of hypoglycaemia? / Has the patient had an administration of a reversal agent for hypoglycaemia (10-50% IV Dextrose, Glucagon)?	**If Yes which Trigger of Harm?** Complications / Reversal agent given / DKA or HHS
Is the patient in Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycaemic State (HHS)?	None of these
Symptoms of hypoglycaemia include: anxiety confusion, extreme hunger, fatigue, irrability, sweating or clammy skin, trembling hands	

Auditor (print name): **Date:**

[1] According to local guidance.
[2] Anti-infectives (antibiotics, antifungals, antivirals & antimalarials).
[3] (Warfarin, Acenocoumarol (SINTHROMEO), Phenindione, Novel Oral Anticoagulants (NOACs), Dabigatran (PRADAXA) Apixaban (ELIQUIS), Rivaroxaban (XARELTO) LMWH: Dalteparin (FRAGMIN), Tinzaparin (INNOHEP), Enoxaparin (CLEXANE).
[4] IV or SC Sedatives Midazolam, Lorazepam, Diazepam, Clonazepam.

Appendix 2.0 – The Medication Safety Thermometer Version 16b (Community) Steps 1 and 2

Medications Safety Thermometer - Community Collection Form (including district nursing) V16 'Harmfree' care

Only complete for patients that you are responsible for administering medication to on day of survey

SECTION 1 This section should be completed by the nurse or primary carer using the patient's medicine administration sheet, Medicines prescribing sheet, Medicines administration records (MARS) or other locally used record that records the patient's medication you are responsible for administering on the day of survey. The focus of this section is on the fundamentals of safe medication use. It should be completed for ALL patients surveyed. Each question should be answered by circling the response or the box completed as requested.

Number: **Setting:** **Specialty:**

1.1 Gender:								M	F
1.2 Age:								Under 18	18 - 24	25 - 44	45 - 59	60 - 74	75 or over
1.3 Is the allergy status recorded on your patient's documentation? e.g. Administration/ Meds sheet	*Including no known drug allergies if applicable*							Yes	No
1.4 Was medicine reconciliation for all medicines started within 24 hrs of admission to the care setting?	*Pharmacist has been involved or known GP involvement*							Yes	**No** Patient still within 24 hour period at point of survey	No	N/A (District Nurse)
1.5 How many regular medicines are you responsible for administering to this patient? Refer to administration sheet	*Not including PRN, Stat doses, IV fluids, O2, food supplements or devices. Different doses of the same medicine count as one medicine*							0	1 - 4	5 - 9	10 -14	15 - 19	More than 20

1.6a Please tick below which medicines the patient has been prescibed which are administered by a District or Community Nurse.

1.6b If any have been omitted in the last 24 hours please tick all reasons that apply to each.

✓

		Reasons for Omission								*Excluding food supplements & O2*
		Valid Clinical Reasons (e.g. low B.P.)[1]	Patient Refused	Outstanding Reconcilliation	Medicine not available	Route not available	Patient absent at med. round	Not Documented	Other	
	Anticoagulant									
	Opiod									
	Insulin									
	Anti-Infectives[2]									
	Any other prescribed medicines									

1.7 Has the patient received any of the following medicines in the last 24hrs from a District or Community Nurse? (If 'yes' circle all that apply)

Anticoagulants (Heparin, LMWH, Warfarin and NOACs3), { Excluding VTE Prophylaxis}, Opioid (excluding oral codeine, dihydrocodeine and Tramadol), IV or SC Sedatives4,Insulin

Anticoagulant	IV/SC Sedatives
Opioids	Insulin

If YES to Q1.7 proceed to Section 2 (If NO then form is complete)

Please circle answers

SECTION 2 Only complete section 2 if a patient has received an **Anticoagulant, Opioid, IV/SC Sedatives** or **Insulin** in the past 24 hours as answered in question 1.7. Only answer the corresponding questions to the medication that the patient has received. i.e. If a patient has been administered Insulin then Q 2.4 **must** be completed.

2.1 Anticoagulants (Heparin, LMWH, Warfarin & NOACs)	
Has the patient had a bleed of any kind or a VTE?	**If Yes which Trigger of Harm?**
Has the patient had an administration of Vitamin K, Protamine or clotting factors e.g. Octaplex?	Bleed or VTE / VIT K or other / INR > 6
Does the patient have an INR greater than 6 or APTT ration greater than 4?	None of these
2.2 Opioids	
Has the patient had an administration of naloxone?	**If Yes which Trigger of Harm ?** Naloxone / bpm less than 8
Is the patient's respiratory rate below 8 breaths per minute (bpm)?	None of these
2.3 Injectable Sedatives (Midazolam, Lorazepam,, diazepam, clonazepam)	
Has the patient had a common complication of over sedation which includes hypotension, delirium, respiratory depression, reduced GCS?	**If Yes which Trigger of Harm?** Common complications / Flumazenil
Has the patient had an administration of reversal agent Flumazenil?	None of these
2.4 Insulin	
Does the patient show signs of common complications (capillary blood sugar <4mmol/L) or symptoms of hypoglycaemia? Has the patient had an administration of a reversal agent for hypoglycaemia (10-50% IV Dextrose, Glucagon)?	**If Yes which Trigger of Harm?** Complications / Reversal agent given / DKA or HHS
Is the patient in Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycaemic State (HHS)?	None of these
Symptoms of hypoglycaemia include: anxiety confusion, extreme hunger, fatigue, irrability, sweating or clammy skin, trembling hands	

Please circle the relevent answers only

Auditor (print name): **Date:**

[1] According to local guidance.
[2] Anti-infectives (antibiotics, antifungals, antivirals & antimalarials).
[3] (Warfarin, Acenocoumarol (SINTHROMEO), Phenindione, Novel Oral Anticoagulants (NOACs), Dabigatran (PRADAXA) Apixaban (ELIQUIS), Rivaroxaban (XARELTO) LMWH: Dalteparin (FRAGMIN), Tinzaparin (INNOHEP), Enoxaparin (CLEXANE).
[4] IV or SC Sedatives Midazolam, Lorazepam, Diazepam, Clonazepam.

Appendix 3.0 – Step 3 (Acute and Community)

Medication Safety Thermometer	'Harmfree'care "It's not just counting, it's caring"

Step 3 Multidisciplinary Huddle

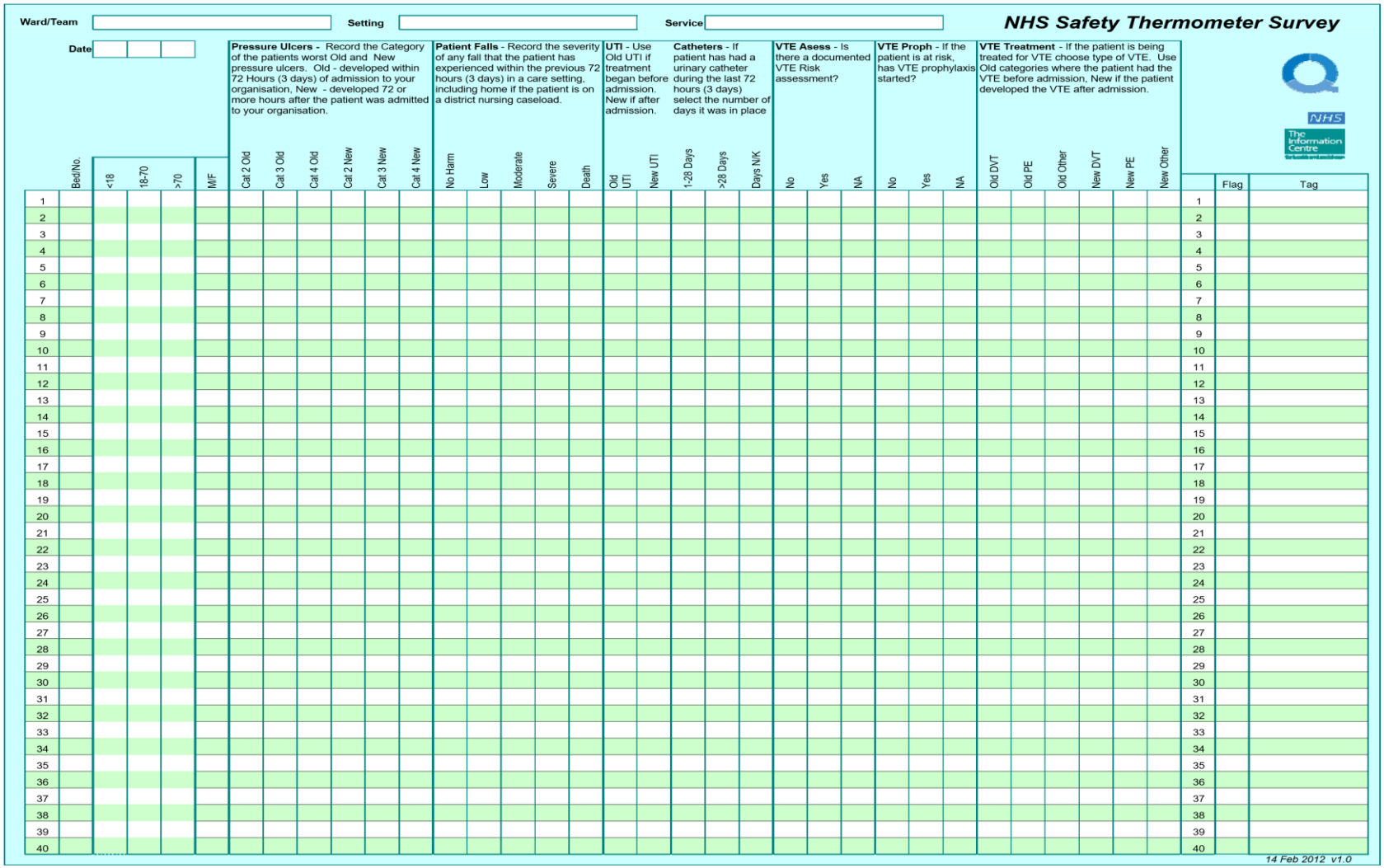
If a patient has received a trigger of harm as indicated by Step 2 please discuss this in an multidisciplinary huddle/whiteboard round and agree a level of harm based on the NPSA harm scale rating. An multidisciplinary huddle should involve (minimum) a Nurse, Pharmacist and Doctor. In the community this may involve a conversation between the District Nurse and patient's GP.

NPSA Harm Definitions	
No Harm	Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.
Low Harm	Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.
Moderate Harm	Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
Severe Harm	Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

Multidisciplinary Huddle - Staff involved

1. Name: ..... Job Title: ..... Involved in the Patients care Y / N
2. Name: ..... Job Title: ..... Involved in the Patients care Y / N
3. Name: ..... Job Title: ..... Involved in the Patients care Y / N
4. Name: ..... Job Title: ..... Involved in the Patients care Y / N
5. Name: ..... Job Title: ..... Involved in the Patients care Y / N

Appendix 4.0 – The original Safety Thermometer paper form



Ward/Team | Setting | Service | **NHS Safety Thermometer Survey**

Date

Pressure Ulcers - Record the Category of the patients worst Old and New pressure ulcers. Old - developed within 72 Hours (3 days) of admission to your organisation, New - developed 72 or more hours after the patient was admitted to your organisation.

Patient Falls - Record the severity of any fall that the patient has experienced within the previous 72 hours (3 days) in a care setting, including home if the patient is on a district nursing caseload.

UTI - Use Old UTI if treatment began before admission. New if after admission.

Catheters - If patient has had a urinary catheter during the last 72 hours (3 days) select the number of days it was in place

VTE Asess - Is there a documented VTE Risk assessment?

VTE Proph - If the patient is at risk, has VTE prophylaxis started?

VTE Treatment - If the patient is being treated for VTE choose type of VTE. Use Old categories where the patient had the VTE before admission, New if the patient developed the VTE after admission.

	Bed/No.	<18	18-70	>70	M/F	Cat 2 Old	Cat 3 Old	Cat 4 Old	Cat 2 New	Cat 3 New	Cat 4 New	No Harm	Low	Moderate	Severe	Death	Old UTI	New UTI	1-28 Days	>28 Days	Days N/K	No	Yes	NA	No	Yes	NA	Old DVT	Old PE	Old Other	New DVT	New PE	New Other		Flag	Tag
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Appendix 5.0 - University Ethics Approval letter

MANCHESTER 1824

The University of Manchester

Ref: ethics/111115

Ms. Paryaneh Rostami
Manchester Pharmacy School

Date 25/11/15

Research Governance, Ethics and Integrity
2nd Floor Christie Building

The University of Manchester
Oxford Road
Manchester
M13 9PL
Tel: 0161 275 2206/2674
Email: research.ethics@manchester.ac.uk

Dear Ms. Rostami

Study title: Rostami: The Medication Safety Thermometer (MST): An exploratory study of NHS staff's experiences and perceptions of using the MST in secondary care (ref 15479)

Research Ethics Committee [3]

I write to thank you for coming to meet the Committee on the 11th November 2015. I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation as submitted and approved by the Committee.

This approval is effective for a period of five years. If the project continues beyond that period an application for amendment must be submitted for review. Likewise, any proposed changes to the way the research is conducted must be approved via the amendment process (see below). Failure to do so could invalidate the insurance and constitute research misconduct.

You are reminded that, in accordance with University policy, any data carrying personal identifiers must be encrypted when not held on a secure university computer or kept securely as a hard copy in a location which is accessible only to those involved with the research.

Reporting Requirements:

You are required to report to us the following:

1. Amendments
2. Breaches and adverse events
3. Notification of Progress/End of the Study

Feedback

It is our aim to provide a timely and efficient service that ensures transparent, professional and proportionate ethical review of research with consistent outcomes, which is supported by clear, accessible guidance and training for applicants and committees. In order to assist us with our aim, we would be grateful if you would give your view of the service that you have received from us by completing a feedback sheet https://survey.manchester.ac.uk/psswcb/index.php/153715/lang-en

We hope the research goes well.

Yours sincerely,

Adrian Jarvis.

Mr. Adrian Jarvis
Secretary to University Research Ethics Committee

Appendix 6.0 - Email of Invitation

Dear (name of Medication Safety Thermometer user),

We would like to invite you and your colleagues to take part in a research study to help us to understand how the Medication Safety Thermometer (MST) is being used and to explore the views and experiences associated with its use. The study is being conducted by Paryaneh Rostami, a PhD student at the University of Manchester.

We are investigating the perceptions and experiences of NHS staff using the MST with regard to its use in primary and secondary care. We are contacting MST leads from the Haelo database of appointed representatives from organisations who have been the point of contact between Haelo and their respective organisations, such as yourself, to take part. We would also like to invite MST users (i.e. the frontline staff collecting data for the MST) and would be grateful if you could forward this e-mail to MST users within your organisation. We are particularly interested in primary or secondary care organisations that have used the MST for at least 3 months. During the study, we would like to:

(a) Explore how the MST is used in primary and secondary care.
(b) Gather information regarding how NHS staff who are using the MST feel about the efficacy of the tool and its impact on quality of care.
(c) Explore participants' views regarding the practicality of using the MST, including both facilitative factors and challenges.

We aim to use the findings from this study to highlight areas requiring further research regarding the use of the MST for subsequent studies that will contribute to my PhD project. The overall results of the PhD project will be used by Haelo to facilitate the development and implementation of the MST in the NHS.

Participants will be involved in a single interview lasting approximately 1 hour. Depending on your location and preference, the interviews may be conducted face-to-face or by telephone. The interview involves a number of open-ended questions and aims to get an idea of your experiences and perceptions of using the MST in your organisation, such as how it is used in your organisations and how you, as an MST lead or user, feel about its use. **This study is not a test of your knowledge and there are no right or wrong answers** as it is your views and experiences that we want to know about. All information obtained will remain strictly confidential.

Please read the attached participant information leaflet, which describes the study in more detail and tells you what you will be asked to do if you choose to participate in our study. If you have any questions or if you want to take part, please do not hesitate to contact Paryaneh Rostami by replying to this email or calling 0161 275 8363. If you have any complaints about the study, please contact Dr Mary Tully via e-mail at Mary.P.Tully@manchester.ac.uk. Thank you very much for your time.

Kind Regards,
Paryaneh Rostami
PhD student, on behalf of the research team – Dr Mary Tully and Professor Darren Ashcroft

Appendix 7.0 - Information Sheet for staff implementing the MedsST

The University of Manchester

Information Sheet for MST leads (version 1 22/10/2015)
Title of Project: Views and experiences towards the use of the Medication Safety Thermometer: an interview study (v1)

You are being invited to take part in a study about the use of the Medication Safety Thermometer (MST). Before you decide to take part, it is important for you to understand the purpose of the study and what it involves for you. Please read the following information sheet carefully.

Introduction

The NHS MST tool has been in development since 2011 and its use is continuously increasing. Little is known about the views that health professionals have towards the MST and their experiences of implementing it. This study asks MST leads and users for their views and perceptions about the use of the MST. The study is part of a PhD project and will be used to inform further research and development of the MST.

Why are you being contacted?

You have been contacted because you are on the Haelo database of MST. This is an interview-based study that will inform areas of further research and development of the MST. The study requires a sample of approximately 20 MST leads and users. We would also like to include a range of MST leads and users with different professional backgrounds (i.e. nurses, doctors and pharmacists) to ensure a range of views and experiences regarding the use of the MST are represented in the interviews and from a range of NHS organisations.

What does the study involve?

The study interviews, lasting roughly 1 hour. Depending on your location and preference, the interviews may be conducted face-to-face or by telephone. The interview will be digitally recorded to ensure your views are accurately represented.

About the interview

The interview involves a number of open ended questions and aims to get an idea of your experiences and perceptions of using the MST in your organisation. There are no right and wrong answers to the questions that will be asked. It is your opinions and experiences that are important. The interview will involve a number of open ended questions about the MST, how it is used in your organisations and how you, as an MST lead, feel about its use.

What happens to the interview data?

Interview recordings will be transcribed after each interview. The resulting transcript is anonymised, (your name will be replaced by a study identification number). The anonymised paper and electronic versions of these transcripts will be used when analysing their content, alongside those from other participants. Recurring themes and patterns will be used to inform areas of

further research. Anonymised quotes from these combined analyses will be used in the study results and disseminated via thesis, publication and conference presentations.
Upon completion of this study, raw data from this research will be stored for a minimum period of five years and subsequently safely destroyed. Anonymised interview data may be kept for a further 5 years, with consent, for future research use, for example, for research questions that may require historical data. Haelo, the organisation facilitating the development of the MST, may also likely to use the data for further research, improvement and development of the MST. They will only have access to anonymised versions of the transcripts.

Confidentiality and anonymity
Your identity will be anonymised so that no one can recognise you from the interview data. The data from the interviews will be stored in a locked filing cabinet at Manchester University. All electronic versions of data will be stored on a university-encrypted, password-protected, secure drive that the researcher and her supervisors have access to. If any third parties are used for transcription, the person transcribing the recordings will erase any versions of the recordings and transcripts on their computers after the interview has been transcribed. Haelo, who are funding this research, will also have access to the anonymised data, as mentioned above.
Any discussions that take place during the study are confidential. However, if you were to tell us something about unsafe practice that has not been through your trust's normal governance procedures, we may have to report this information to the relevant parties within your organisation. If so, we would discuss this with you during the interview and tell you what we intend to do.

Is participation voluntary?
Yes, it is entirely your choice whether you participate or not. If you participate in the study, you can choose not to talk about an issue raised during the interview or you can withdraw from the study at any time without giving a reason (before, during or up to one week after the interviews), and if you do, all data gathered from you will be immediately destroyed.

What if there is a problem?
If you have concerns about any aspect of this study, you should speak with the researchers who will do their best to answer your questions (see contact details). If you wish to complain formally, you can contact the University Research Practice and Governance Co-ordinator on 0161 2758093, or by e-mail to research-governance@manchester.ac.uk. This contact is independent of the research team.

Who has organised the study?
The study has been organised with The University of Manchester and is funded by Haelo, the NHS organisation who have developed the MST.

Who has reviewed the study?
This study has been granted HRA approval and has also been approved by The University of Manchester Research Ethics Committee.

Who is funding the study?

This study is funded by Haelo, an NHS innovation and improvement science organisation who are facilitating the development of the MST. As previously stated, they will only have access to anonymised versions of the transcripts.

What happens next?
If you agree to take part, please complete and return the enclosed consent form in the pre-paid envelope provided. I will contact you to arrange a time that is convenient to you for a face-to-face or telephone interview to discuss your views and experiences of using the MST.

Contact details
If you wish to ask any questions, please feel free to contact me or my supervisors:

Paryaneh Rostami-H (Researcher) Manchester Pharmacy School, University of Manchester, Oxford Road, Manchester, M13 9PT	Pharmacy Practice PhD student T: 0161 306 1738 E-mail: Paryaneh.Rostami@postgrad.manchester.ac.uk
Dr Mary Tully (Supervisor) Manchester Pharmacy School, University of Manchester, Oxford Road, Manchester, M13 9PT	Reader in Pharmacy Practice Tel: 0161 275 4242 E-mail: Mary.P.Tully@manchester.ac.uk
Professor Darren Ashcroft (Supervisor) Manchester Pharmacy School, University of Manchester, Oxford Road, Manchester, M13 9PT	Professor of Pharmacoepidemiology Tel: 0161 275 4299 E-mail: Darren.Ashcroft@manchester.ac.uk

Thank you for reading this information sheet.

Appendix 8.0 - Information Sheet for staff collecting MedsST data

The University of Manchester

Title of Project: Views and experiences towards the use of the Medication Safety Thermometer: an interview study (v1)

You are being invited to take part in a study about the use of the Medication Safety Thermometer (MST). Before you decide to take part, it is important for you to understand the purpose of the study and what it involves for you. Please read the following information sheet carefully.

Introduction

The NHS MST tool has been in development since 2011 and its use is continuously increasing. Little is known about the views that health professionals have towards the MST and their experiences of implementing it. This study asks MST leads and users for their views and perceptions about the use of the MST. The study is part of a PhD project and will be used to inform further research and development of the MST.

Why are you being contacted?

You have been contacted because you have been referred by someone who is on Haelo's list of MST leads or a user at a primary or secondary healthcare organisation which has used the MST for at least 3 months. This is an interview-based study that will inform areas of further research and development of the MST. The study requires a sample of approximately 20 MST leads and users. We would also like to include a range of MST leads and users with different professional backgrounds (i.e. nurses, pharmacists and doctors) to ensure a range of views and experiences regarding the use of the MST are represented in the interviews and from a range of NHS organisations.

What does the study involve?

The study interviews, lasting roughly 1 hour. Depending on your location and preference, the interviews may be conducted face-to-face or by telephone. The interview will be digitally recorded to ensure your views are accurately represented.

About the interview

The interview involves a number of open ended questions and aims to get an idea of your experiences and perceptions of using the MST in your organisation. There are no right and wrong answers to the questions that will be asked. It is your opinions and experiences that are important. The interview will involve a number of open ended questions about the MST, how it is used in your organisations and how you, as an MST user, feel about its use.

What happens to the interview data?

Interview recordings will be transcribed after each interview. The resulting transcript is anonymised, (your name will be replaced by a study identification

number). The anonymised paper and electronic versions of these transcripts will be used when analysing their content, alongside those from other participants. Recurring themes and patterns will be used to inform areas of further research. Anonymised quotes from these combined analyses will be used in the study results and disseminated via thesis, publication and conference presentations.

Upon completion of this study, raw data from this research will be stored for a minimum period of five years and subsequently safely destroyed. Anonymised interview data may be kept for a further 5 years, with consent, for future research use, for example, for research questions that may require historical data. Haelo, the organisation facilitating the development of the MST, may also likely to use the data for further research, improvement and development of the MST. They will only have access to anonymised versions of the transcripts.

Confidentiality and anonymity
Your identity will be anonymised so that no one can recognise you from the interview data. The data from the interviews will be stored in a locked filing cabinet at the University of Manchester. All electronic versions of data will be stored on a university-encrypted, password-protected, secure drive that the researcher and her supervisors have access to. If any third parties are used for transcription, the person transcribing the recordings will erase any versions of the recordings and transcripts on their computers after the interview has been transcribed. Haelo, who are funding this research, will also have access to the anonymised data, as mentioned above. Any discussions that take place during the study are confidential. However, if you were to tell us something about unsafe practice that has not been through your trust's normal governance procedures, we may have to report this information to the relevant parties within your organisation. If so, we would discuss this with you during the interview and tell you what we intend to do.

Is participation voluntary?
Yes, it is entirely your choice whether you participate or not. If you participate in the study, you can choose not to talk about an issue raised during the interview or you can withdraw from the study at any time without giving a reason (before, during or up to one week after the interviews), and if you do, all data gathered from you will be immediately destroyed.

What if there is a problem?
If you have concerns about any aspect of this study, you should speak with the researchers who will do their best to answer your questions (see contact details). If you wish to complain formally, you can contact the University Research Practice and Governance Co-ordinator on 0161 2758093, or by e-mail to research-governance@manchester.ac.uk. This contact is independent of the research team.

Who has organised the study?
The study has been organised with The University of Manchester and is funded by Haelo, the NHS organisation who have developed the MST.

Who has reviewed the study?

This study has been granted HRA approved and has also been approved by The University of Manchester Research Ethics Committee.

Who is funding the study?
This study is funded by Haelo, an NHS innovation and improvement science organisation who are facilitating the development of the MST. As previously stated, they will only have access to anonymised versions of the transcripts.

What happens next?
If you agree to take part, please complete and return the enclosed consent form in the pre-paid envelope provided. I will contact you to arrange a time that is convenient to you for a face-to-face or telephone interview to discuss your views and experiences of using the MST.

Contact details
If you wish to ask any questions, please feel free to contact me or my supervisors:

Paryaneh Rostami-H (Researcher) Manchester Pharmacy School, University of Manchester, Oxford Road, Manchester, M13 9PT	Pharmacy Practice PhD student T: 0161 306 1738 E-mail: Paryaneh.Rostami@postgrad.manchester.ac.uk
Dr Mary Tully (Supervisor) Manchester Pharmacy School, University of Manchester,Oxford Road, Manchester, M13 9PT	Reader in Pharmacy Practice Tel: 0161 275 4242 E-mail: Mary.P.Tully@manchester.ac.uk
Professor Darren Ashcroft (Supervisor) Manchester Pharmacy School, University of Manchester, Oxford Road, Manchester, M13 9PT	Professor of Pharmacoepidemiology Tel: 0161 275 4299 E-mail: Darren.Ashcroft@manchester.ac.uk

Thank you for reading this information sheet.

Appendix 9.0 – Interview Consent Form

The University of Manchester

Consent Form

Name of Researcher: Paryaneh Rostami

Please initial box

1. I confirm that I have read and understoond the information sheet dated 06/10/2015 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and I can terminate the interview and withdraw from the study before, during or up to one week after my interview without giving a reason, without my work or legal rights being affected. ☐

3. I permit the researcher to audio-record the interview and use anonymised extracts of data when reporting the study. ☐

4. I agree to take part in the above study. ☐

5. I permit the researchers to store the anonymised data for the future development and research into the Medication Safety Thermometer and share the anonymised transcripts with Haelo for this purpose ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 10.0 – Certificate of Participation

MANCHESTER 1824
The University of Manchester

THIS CERTIFIES THAT

.....

was a research participant in the following study exploring the use of the Medication Safety Thermometer:

'Exploring the use of the Medication Safety Thermometer: views and experiences of users.'

December 2015 – April 2016

Dr Mary Tully
Reader in Pharmacy Practice

P. Rostami

Paryaneh Rostami-H, Principal Investigator
PhD Student