A model for managing the variability of care processes – A quality improvement method for introducing Enhanced Recovery after Surgery (ERAS) within an orthopaedic elective care clinical microsystem

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Copyright Statement

Abstract

A model for managing the variability of care processes – A quality improvement method for introducing Enhanced Recovery after Surgery (ERAS) within an orthopaedic elective care clinical microsystem

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Background and purpose – The National Health Service (NHS) continues to face economic and capacity challenges. Quality improvement (QI) interventions such as Enhanced Recovery after Surgery (ERAS) that can improve clinical and economic outcomes are needed. However, implementation remains a challenge and the widespread adoption of ERAS across the NHS for total hip replacement and total knee replacement is not complete. A novel QI method (the model to manage variability) was developed and is evaluated when utilised to inform improvements to ERAS care processes within clinical microsystems performing hip and knee replacement.

Methods – The model to manage variability was adapted for use as a QI method and then deployed within two orthopaedic elective care clinical microsystems. An improvement replication programme was adopted. In the pilot site (Study 1) a retrospective observational study design was used. In Study 2, the validation site, a prospective observational study design, with a mixed-methods sequential explanatory design (QUAN emphasised) that consisted of two distinct phases was used.

Results – The model for managing variability was successfully deployed and evaluated as a QI method to help implement ERAS within both sites. Length of Stay was reduced by 45% in Study 1, and by 18% in Study 2. The interventions to improve care process highlighted by the QI method were implemented fully in Study 1 but were not able to be fully implemented in Study 2. In Study 2,

qualitative data revealed that staff thought the model to manage variability was simple, effective, and had highlighted the correct changes to make. However, they felt that contextual factors around leadership, staffing, and organizational issues had prevented changes being implemented.

Discussion – The model to manage variability was successfully adapted and utilised to improve ERAS care processes within two settings. Users within the validation site felt it had advantages over other QI methods but found improvement efforts were still affected by crucial contextual factors known to influence both QI efforts and ERAS implementation.

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List of Abbreviations

ACB	Adductor Canal Block
AHP	Allied Health Professional
BPR	Business Process Reengineering
CQI	Continuous Quality Improvement
DMAIC	Define Measure Analyse Improve Control
DVT	Deep Vein Thrombosis
ERAS	Enhanced Recovery After Surgery
ERPP	Enhanced Recovery Partnership Programme
FNB	Femoral Nerve Block
FNOF	Fractured Neck of Femur
GJNH	Golden Jubilee National Hospital
GRAMMS	Good Reporting of a Mixed Methods Study
HES	Hospital Episode Statistic
HQIP	Healthcare Quality Improvement Partnership
IHI	Institute for Healthcare Improvement
IHO	Institute of Healthcare Optimisation
ITO	Intrathecal opioid
LIA	Local anaesthetic wound infiltration
LCL	Lower Control Limit
LOS	Length of Stay
MUSIQ	Model for Understanding Success in Quality
MVP	Program for the Management of Variability in healthcare delivery
NHS	National Health Service

NSAID	Non-steroidal anti-inflammatory drug
OSH	Orthopaedic Speciality Hospital
PDSA	Plan-Do-Study-Act
PPE	Personal Protective Equipment
PREMS	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures
QI	Quality Improvement
QUAN	Quantitative
RCT	Randomised clinical trial
RECORD	Reporting of studies Conducted using Observational Routinely-collected health Data
SNB	Sciatic Nerve Block
SD	Standard Deviation
SPC	Statistical Process Control
SQUIRE	Standards for Quality Improvement Reporting Excellence
TAR	Total Ankle Replacement
THR	Total Hip Replacement
TiDieR	Template for intervention description and replication
TKR	Total Knee Replacement
TRC	Tertiary Referral Centre
TSR	Total Shoulder Replacement
TQM	Total Quality Management
UCL	Upper Control Limit
UK	United Kingdom
UKR	Unicompartmental Knee Replacement

USA	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation

Integrated Papers

In line with the alternate formats of thesis allowed within BU's regulations, this thesis follows an integrated format, where one or more "papers" are integrated into the thesis. The "papers" in Table 1 are integrated within this thesis. The table provides details of each paper, publication status, and where they appear within the thesis. For the jointly authored publications I am the lead author, and confirm that I contributed over 75% of the substantive content of each paper. Papers are reproduced within the thesis, but have been adapted and integrated to reduce duplication, and to ensure that it is a coherent and continuous thesis, rather than a series of disconnected publications. Sections of the thesis which are published or submitted for publication are clearly identified. Where papers are not reproduced in full, in order to avoid repetition within the thesis, this is explicitly stated, and the full papers are available in *Appendices 11-16*.

Table 1 - Table of Integrated Papers

Paper Number	Reference	Chapter and Section	Page Number
1	Wainwright, T. W., Immins, T., 2020. Orthopedic Surgery in Enhanced Recovery After Surgery. In: Ljungqvist, O., Francis, N. K. and Urman, R. D., eds. Enhanced Recovery After Surgery: A Complete Guide to Optimizing Outcomes. Cham: Springer, 477-486	3.3	53
2	Wainwright, T. W., 2021. The current status of daycase hip and knee arthroplasty within the English National Health Service – A retrospective analysis of Hospital Episode Statistic data. The Annals of the Royal College of Surgeons of England, 103:5, 324-331.	3.4	71
3	Wainwright, T. W., 2020. The quality improvement challenge – How to solve the knowing-doing gap in Enhanced Recovery after Surgery (ERAS). Medicina, 2020, 56, 652.	3.5	74
4	Wainwright, T.W., McDonald, D. A., 2021. A mixed-methods observational study to evaluate a QI method (the model to manage variability) used to inform the improvement of clinical processes within an ERAS Pathway for hip and knee replacement. The TQM Journal, 33:7, 272-294.	5.2	129
5	Wainwright, T.W., Craig, J., 2020. Wanting to improve is not always the same as knowing how to improve – An example from a total knee replacement pathway. BMJ Open Quality 2020;9:e001019.	5.3	156
6	Wainwright, T.W., 2021. Enhanced Recovery after Surgery (ERAS) – Why it should be implemented in hip and knee replacement pathways following the COVID-19 pandemic. Medicina, 57, 81.	7.3	176

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1.0 Introduction

In this chapter a general introduction to quality improvement (QI), Enhanced Recovery after Surgery (ERAS), and the need for QI within surgery is provided. This is followed by an introduction to the model to manage variability. The origins of the model are explained before an overview of the thesis is presented.

1.1 Case for research

The National Health Service (NHS) continues to face capacity pressures and healthcare providers are continually balancing the predicament of how to improve the quality of care at the same time as saving money. The ongoing strain on resources and increasing demand for services continue to provide an immense challenge to NHS organisations and staff. QI efforts may be used to improve the quality of patient care and save money, and their success is both dependent on the local context and how they are implemented (Ovretveit 2009, 2011).

ERAS (or enhanced recovery/fast-track) protocols are a QI intervention, and are a multi-modal approach to care which have been shown to reduce mortality, morbidity, and length of stay (LOS) across a range of elective surgical procedures (Ljungqvist et al. 2017). However implementation is variable and not complete across the NHS, despite the research evidence to support the approach and the associated outcomes (Albury et al. 2018). Therefore, research is needed to understand how implementation could be improved, so that ERAS is the standard of care across all hospitals, and quality of care for patients is improved.

There continues to be an ongoing focus on the quality of healthcare (King's Fund 2017), and this has led to considerable debate about how quality may be defined, and how best to improve it. This ongoing attention continues to occur because problems with the quality and safety of patient care remain common and in many cases preventable (NHS Improvement 2019). This is especially so in disciplines such as surgery, which is a high-risk specialty where complications can lead to

morbidity and mortality. QI is therefore an important focus within surgery. Post-surgical complication rates obviously vary depending on procedure, however, global estimates from the World Health Organization (WHO) range from 3% to 22% (World Health Organization 2009). In their systematic review, Anderson et al. (2013) found that 14% of patients undergoing surgery experienced an adverse event, of which 13.6% could be fatal or severe, and importantly that many of the adverse events were potentially avoidable. Avoidable adverse events are often due to sub-optimal care processes, and patients frequently do not receive treatments as intended (Panagioti et al. 2019). These findings in regard to avoidable adverse events, in combination with the first ethical principle in healthcare of “first do no harm”, continue to drive the healthcare community to find ways to improve quality.

Adverse events experienced by patients in hospital are not inevitable (Weiser et al. 2010) and QI interventions can reduce their occurrence by instigating changes that remove variability from care processes (Kohn et al. 1999). Such standardised care processes lead to more consistent, appropriate, and efficient application of established clinical interventions, which in turn can lead to improvements in care and patient outcomes (Vanhaecht 2007). To spread the adoption of effective quality improvements further, not only is more robust and compelling evidence required, but also the collaboration and active participation of all health care professionals to make it happen. As stated by Batalden and Davidoff (2007): “Everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it!”.

1.2 Introduction to the model to manage variability

Historically, economic pressures have sometimes led to decisions by healthcare managers to cut costs in ways that have negatively impacted on the quality of patient care delivered. Examples of such approaches of cost reduction have included negotiating lower prices for materials, not filling staff vacancies, and cutting the budget by intuition. Whilst these approaches may have been successful at delivering savings without negatively impacting quality in the short

term, they are not long-term solutions, and they fail to recognise other significant causes of waste in healthcare systems. One such waste factor is the unnecessary and unplanned variability in the processes used to provide patient care.

More widely, the topic of variation and the need to reduce variation has attracted significant attention within healthcare, and it is acknowledged that there are wide variations in many aspects of healthcare in the NHS and other healthcare systems around the world (NHS Atlas of Variation, 2015). In the UK, the occurrence of variation is often referred to within the media as the “postcode lottery”. This relates to variation in access to care, for example, people living in some parts of the country may wait longer to receive a hip or knee replacement, compared to people living in another part of the country. The Dartmouth Institute (which has been instrumental in influencing the quality improvement agenda within healthcare) (Nelson et al. 2007) would describe this as supply-sensitive care (where variation implies the volume of care reflects capacity rather than patient need). This is one of three categories of care they identify, the others being effective care (where variation implies some underuse of valid treatment), and preference-sensitive care (where variation implies more than one option of care is available and the exercising of patient choice).

Variations in effective care (clinical variation) have been found in almost all areas of healthcare and assessed and quantified across a wide range of acute hospital settings (Sutherland and Levesque 2020). However, despite significant attention and interest in clinical variation, the literature lacks strong conceptual frameworks to guide thorough measurement and remediation efforts; and there are few typologies that systematically map the field (Corallo et al. 2014; Harrison et al 2019; Schang et al 2014). While the Dartmouth approach identifies the three categories of care outlined above, the distinction between what is warranted, and unwarranted clinical variation remains weakly defined (Mercuri and Gafni 2011; Peabody and Hauck 2017). Such distinction is necessary, because sometimes there are good reasons for variation (e.g., warranted variation that can advance practice), but in other cases the reasons for variation can be difficult to justify. It is this type of unwarranted clinical variation that offers opportunities for improvement. However, it is often not possible to be definitive about all the

reasons for unwarranted clinical variation because the delivery of healthcare is complex, and it may not always be possible to disaggregate all the variables or 'moving parts' involved. It should be remembered that delivering effective care is achieved by combining clinical decisions informed by evidence-based medicine and necessary procedural changes, that allow the right things to be delivered in the right way (Glasziou et al. 2011).

Therefore, if as previously highlighted, the current literature does not provide the conceptual frameworks to guide the remediation efforts of unwarranted variation, despite its identification and a will to improve it, improvement efforts are likely to be unsuccessful (Dixon-Woods 2019). This is where a methodological step of classifying the sources of variability once overall unwarranted variation has been identified may be useful. Litvak and Long (2000) propose that "natural" and "artificial" sources of variation in care processes may contribute to unwarranted variations in care, and the details of this approach are outlined fully later in Chapter 2. They propose that the artificial variability of care processes is the most likely barrier to providing efficient and high-quality healthcare. They state that the effective management of variability has as much potential for reducing costs and improving quality of care, as the more traditional research approaches such as the quest for new technologies, medicines and practice guidelines. This is consistent with other industry sectors, where it is widely established that the understanding and management of variability is the most important aspect of managing any system (Wheeler 1999).

There is empirical evidence to support Litvak and Long's (2000) proposals and these findings are of interest and relevance to the NHS. Sometimes, the economic pressures within the NHS may lead to decisions that negatively impact the quality of patient care. A common method, given that the NHS pay bill accounts for around 70% of provider costs (Appleby et al. 2010), is to alter the nurse-to-patient ratio by freezing posts. In an example from the United States of America (USA), Litvak et al. (2005) illustrate how managing unnecessary variability in patient demand helped to improve patient safety, citing that "for every 5% increase in census over the adequate staffing level, an additional 20% of patients will be unnecessarily exposed to a 7% risk of increased mortality". In

another study, looking at the management of variability and mortality rates, data from 210 hospitals in Pennsylvania are presented. Each additional patient per nurse was associated with a 7% increase in the likelihood of dying within 30 days of admission and a 7% increase in the odds of failure-to-rescue (Aiken et al. 2002). Further research using Litvak's model (Boston University Health Policy Institute 2006) includes work examining the link between patient flow variability and unplanned readmissions (Baker et al. 2009), and a study measuring the effect of flow variability on patient LOS in an emergency department (Rathlev et al. 2007). Both studies illustrate how variability methodology can be used to smooth patient flow and consequently improve safety and efficiency.

Such outcomes continue to be timely given the ongoing economic and capacity pressures facing the NHS, however the transferability of any QI approach must be thoroughly considered before it is adopted. Practitioners cannot be certain that an effective model elsewhere can be successfully implemented into their own setting with the same results (Ovretveit 2011). Better descriptions of implementation and context can help (Davidoff et al. 2008), but Glasby et al. (2007) suggest that there are three types of evidence that are needed to assess whether a model such as the management of variability should be implemented in other settings. The three types of evidence are theoretical, empirical, and experiential (Walshe 2007). The previously mentioned studies start to establish the empirical evidence for the model, but in general the research has predominately been completed in the USA and tended to focus on unplanned care, in areas such as emergency departments, and operating theatres (McManus et al. 2004; Boston University Health Policy Institute 2006). Adaption of the model for its use within individual elective care clinical microsystems within the NHS has not been previously examined.

This thesis will therefore provide the context and rationale for adapting and introducing the model to manage variability within elective orthopaedic clinical microsystems. The theoretical framework behind the model will then be outlined in detail, and consideration of its merits as a QI method will be explored. The adapted model will then be described, and the approach for its evaluation within the NHS outlined. The results and outcomes of utilising the model in a pilot site,

and then in a validation site will then be presented before the findings in relation to the wider QI and ERAS literature are discussed.

1.3 Research aim

The aim of this research is to evaluate the use of the model for managing variability as a QI method to help implement ERAS (a QI Intervention) within elective orthopaedic clinical microsystems.

1.4 Research objectives

The research aim described above will be achieved through the following objectives

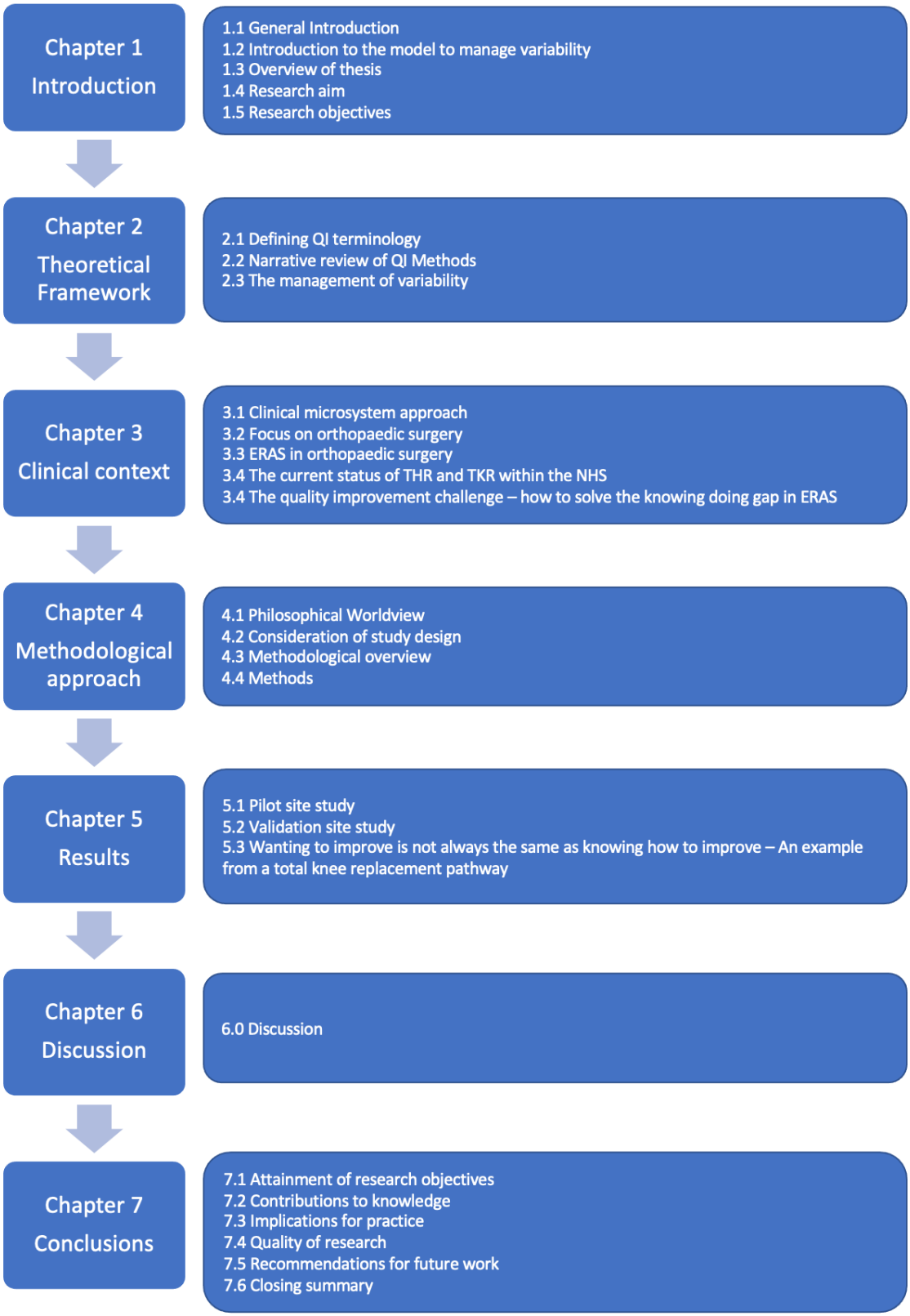
1. To establish the need for improving the implementation of ERAS pathways within elective orthopaedic clinical microsystems and the potential role of QI methods to help do this.
2. To investigate relevant QI methods and determine a theoretical framework for the model to manage variability to be adapted and used as a QI method to improve clinical care processes within clinical microsystems.
3. To use the model of variability as a QI method to inform the implementation of ERAS (a QI intervention) within two elective orthopaedic clinical microsystems (a pilot and a validation site).
4. To evaluate the success of applying the model to manage variability as a QI method, through an improvement replication programme.

1.5 Overview of thesis

This thesis is structured and reported in accordance with the SQUIRE (Standards for QUality Improvement Reporting Excellence) guidelines (Ogrinc et al. 2016)

and an overview of the thesis is provided in *Figure 1*. This format was chosen to ensure a high quality of reporting, to increase the generalisability of the findings, and in turn contribute to the wider scientific body of knowledge of QI within healthcare.

Figure 1 – Thesis overview



2.0 Theoretical framework for research

This chapter first outlines the definition of QI terms, and in particular the distinction between a QI intervention and a QI method. This is important to overcome any conceptual and terminological confusion, as terms within the QI literature are often used interchangeably without consideration of the inference. A narrative review of the literature is then presented, examining, and evaluating the evidence-base for commonly used QI methods. Conclusions are then drawn about what can be inferred from these studies of QI methods, along with consideration for the commonalities and differences, as well as the challenges associated with establishing generalisability.

The management of variability is then outlined as a QI approach and details provided of how it has been adapted to be used as QI method. The advantages it may offer when adapted as a QI Method to manage the variability of care processes within clinical microsystems over the previously analysed QI methods are suggested. It therefore provides a theoretical framework to underpin the model to manage variability that will be evaluated within the thesis.

2.1 Defining QI terminology

It is important to define terms that are often used interchangeably in both a practice setting and within the literature. QI may be broadly defined as a purposeful effort to make changes to a service that will result in improved patient outcomes and/or improved system performance (Batalden and Davidoff 2007). However, previous systematic reviews of QI and complex interventions have highlighted the poor identification of terms which have high face validity amongst health care professionals and researchers (Shepperd et al. 2009; Hoffmann et al. 2015). The term ‘intervention’ is often used interchangeably to describe both the application of a technique such as PDSA or Lean, or to describe an intervention such as a checklist or care pathway.

For the purposes of this thesis, the distinction between what constitutes and differentiates a QI intervention, and a QI method is essential. Broadly, QI interventions may be defined as specific changes to clinical care components, and QI methods as the technique used to support the necessary process improvements to enact the change, which characteristically involves a pre-defined set of steps. More explicitly, a QI intervention is defined as a "specific activity, action, or instrument targeting a defined area of practice" (Shojania and Grimshaw 2005). For example, ERAS pathways can be considered a QI intervention. This is because they combine existing knowledge (such as multi-modal opioid sparing anaesthetic/analgesic techniques, minimally invasive surgery, and early mobilisation) to improve a clinical process, to achieve an overall effect (such as reducing LOS). Other examples may include checklists and care bundles. To distinguish from a QI intervention, a QI method can be defined as a "systematic technique for identifying defects in a clinical process and making improvements, typically by involving process measurement and remeasurement" (Jones et al. 2016). Therefore, a QI Method refers to a method or technique of enacting process improvement, such as Plan-Do-Study-Act (PDSA) cycles, Lean, Six Sigma, or as in this thesis, the model to manage variability.

It is acknowledged that practical techniques (such as a QI method) for facilitating process improvement are needed to support the implementation of high quality and safe care (such as QI intervention like ERAS) (Scheer et al. 2021). Therefore, it should be noted that QI efforts will often need to involve the use of a QI intervention (e.g., an ERAS pathway), along with a QI method (e.g., the model to manage variability). In such an example, the QI Method, will inform the process changes required within the clinical microsystem so that the clinical components required as part of a QI Intervention can be delivered.

To elaborate further, over recent years clinical guidelines for ERAS (a QI intervention) in hip and knee have been developed (Wainwright et al. 2020), and such guidelines may be defined as "systematically developed statements

informed by a systematic review of evidence and an assessment of the benefits and harms of care options designed to optimize patient care" (Brouwers et al. 202). These guidelines form the basis of defining high quality and safe care (and are a QI intervention) and are produced using well-established methodologies that aim to synthesise current research, expert opinion, and are supported by national and international societies and/or professional associations (Kredo et al. 2016).

However, a guideline alone is not sufficient, because they are of course, not self-implementing. Transferring clinical guidance into practice is almost always complex, and the implementation of evidence-based practices (what should be done) as part of QI intervention (such as ERAS) depends crucially on process improvement – changes to how things are done (Chassin and Loed 2013; Holden et al. 2013). This has been specifically highlighted for ERAS (Ramaswamy and Barach 2020), and so therefore, the study of QI methods that can deliver process improvements (i.e., identifying and defining the changes in processes that need to be made to deliver ERAS) is a key task.

2.2 Narrative review of QI methods

The focus of this narrative review is to critically appraise the literature related to the use of QI methods within healthcare. Many of these methodologies have drawn on QI approaches that originate outside of healthcare. A narrative review was chosen over a systematic review, with the aim of describing the current state of the evidence from a theoretical and contextual perspective in relation to using the approaches as a QI method, as opposed to answering a specific research question. This is pertinent, given that recent systematic reviews in this area (Antony et al. 2018; Alzoubi et al. 2019; Knudsen et al. 2019; De Ramón Fernández et al. 2020; Tlapa et al. 2020) do not make this distinction, but have highlighted that the suboptimal quality and paucity of rigorous randomized multi-centre studies and heterogeneity of studies, make drawing conclusions from systematic reviews extremely difficult. Further systematic review, in the absence

of contextual critique in relation to the field of surgery and ERAS may therefore be of questionable value (Nicolay et al. 2012). In addition, the standard of reporting of QI interventions and QI methods within surgical settings is recognised as being suboptimal, making judgements of generalizability extremely difficult without the ability to add subjective nuance (Jones et al. 2016).

Subsequently the method adopted for identifying the relevant literature was both iterative and wide-ranging. The search had several inter-related components. A traditional search of the English language databases of Medline, Web of Science, Cochrane Library, CINAHL and The Health Management Information Consortium was completed. In addition, a search of the websites of relevant government bodies, health organisations and research centres were also made. These included (within the UK) the Nuffield Trust, the King's Fund, the Health Foundation, Quality Improvement Scotland, the NHS Institute for Innovation and Improvement, the National Institute for Health Research, and (outside the UK) the Institute for Healthcare Improvement (IHI), the World Health Organisation (WHO), and the Institute of Healthcare Optimisation (IHO). Further to this, a search of the publications of key individuals writing in the field of QI was also made, along with a review of the reference lists in the articles found in the original search.

This wide-ranging approach was necessary because the evidence base pertaining to QI is substantial and diverse and is a reflection of the very broad range of activities that can be considered as QI. Following the initial search, a process to define the type of studies to be reviewed was undertaken. Studies were chosen if they specifically examined the application of a QI Method, as defined earlier in the chapter. This approach allowed for the review and critique of the most popular QI methods, and in particular the methods or techniques that focused primarily on improving a process (Boaden et al. 2008; Powell et al. 2009; Walshe 2009).

Five QI methods were identified, namely, Total Quality management (TQM)/Continuous Quality Improvement (CQI), Business process focused

interventions, Lean, Six Sigma, and the IHI's rapid cycle change model. These were therefore considered and discussed alongside the management of variability.

The QI approaches that were not classified as a QI method for the purpose of this review, but that appear frequently within the QI literature, were clinical governance, medical and clinical audit, patient safety, and accreditation (Walshe 2009). These were not included in this review because their primary focus was not on process improvement, and approaches such as patient safety were considered very broad labels for a wide variety of improvement activities. In addition, the focus of this thesis on clinical microsystems meant that QI approaches occurring at a macro-level such as financial incentives, national system changes, or national accreditation of whole organisations were also not included.

Four of the QI methods chosen are approaches that were originally developed in industry before being applied to healthcare settings (TQM/CQI, BPR, Lean, and Six Sigma), and it is worth noting that before we examine the performance of these industrially based approaches in healthcare, their historical effectiveness within industry is not without dispute (Zbaracki 1998; Kaboolian 2000; Sorge and van Witteloostuijn 2007; Learmouth 2008; Messner et al. 2008).

Having now defined the scope of QI methods that this review will address, the next issue concerns the type and level of evidence available pertaining to these techniques, and whether it provides us with the ability to make judgements on their efficacy. The "gold standard" for reviewing literature about a specific intervention can be considered the approach recommended by Grimshaw et al. (2003) and described by the Cochrane Collaboration (Higgens and Green 2011). Systematic reviews are found at the top of various hierarchies of evidence (Centre for Evidence-Based Medicine 2009).

Systematic reviews themselves can be of varying quality (Moher et al. 2009) but work best when collectively examining the results of studies with homogenous characteristics, such as randomised controlled trials (O'Mathúna 2010). However, there are very few rigorously conducted trials examining the introduction of QI interventions or methods (Boaden et al. 2008), and the study design of QI mechanisms can vary (Grimshaw et al. 2003). This means that any approach to appraise the literature in this may conclude that there was very limited evidence to support any of the QI approaches (Health Evidence Network 2006; Lindenauer 2008).

The low number of randomised controlled trials is not surprising; the system level at which QI methods are aimed would make randomization of individual patients being treated within the same clinical microsystem extremely difficult. It would also by design, remove many of the context-dependent variables that are argued by some to determine the success or failure of QI efforts (Pawson et al. 2005). When individual patients are unable to be randomised, a cluster trial design may sometimes be appropriate, which randomizes interventions to groups of patients (e.g. patients being treated in different settings). However, even a pragmatic approach such as this will have limitations in regard to evaluating the success of a QI method, given the previously identified importance of context on influencing the success of introduction and implementation (Ovretveit 2004; Walshe 2007).

Therefore, traditional experimental research methods such as randomised controlled trials may actually be unlikely to illuminate the critical nuances of QI because of their design for a different purpose (Berwick 2008). Ovretveit (2011) proposes that the way to increase the external validity (or generalisability) of a QI effort is to conduct a purposeful and prospectively studied replication programme using an approach such as a mixed-methods research design. In this case, the term meaningful requires careful description of the context as well as the QI intervention and/or QI method, with clear explanations of the adaptations to the approach as it unfolds, and as repeated tests of the same approach are carried out in different contexts.

A wide and more pragmatic perspective of what counts as knowledge and evidence is therefore required, and many of the most helpful studies examining QI interventions and QI methods have adopted quantitative approaches in combination with action research, observation, and qualitative approaches (Powell et al. 2009). This review therefore draws on a range of studies with varying methodological approaches and study designs. Across the different approaches, the principles of the SQUIRE guidelines (Davidoff et al. 2008), the internationally recognised standards for QI report publication are used as a basis for appraising the rigour and generalisability of the findings reported, and the suitability of the research designs chosen.

2.2.1 TQM and CQI

TQM and CQI are considered together in this review because throughout the literature they are often used interchangeably (Gustafson and Hundt 1995). Exact and comprehensive definitions of the TQM/CQI approach are both hard to find and wide ranging in the literature detailing their use in healthcare. This may be because TQM and CQI are not so much specific QI methods, but rather general approaches to improving quality (Shojania and Grimshaw 2005). One definition, which is provided in a study examining TQM within the NHS defines the approach as “An integrated, corporately-led programme of organisational change designed to engender and sustain a culture of continuous improvement based on customer-oriented definitions of quality” (Joss and Kogan 1995, p.37).

After reviewing the published research and findings of a recent systematic review (Alzoubi et al. 2019) it can be concluded that there is very limited evidence to verify that TQM/CQI actually works, and whether it is more or less successful than other QI methods. This assertion is consistent with the findings of two previously published review articles (Shortell et al. 1998; Ovretveit 2000).

Much of the recent research on TQM has been undertaken in the Middle East and Asia (Alzoubi et al. 2019), however one historical major study undertaken in

the NHS involved the evaluation of TQM across 38 NHS units in 8 health authorities between 1990-1993. The amount of data and sample size were strengths of the study, with over 750 interviews of staff across the 38 sites (Joss and Kogan 1995). However, whilst the results reported that cost savings were made, any findings must be counterbalanced by the fact that many of the hospitals had adapted TQM principles in different ways, and with different implementation processes across sites. Whilst these differences in themselves are not a problem, detailed information about the differing contexts and introductions is a requirement for judgments to be made about the generalisability of the research findings. This information was not provided. The influence of contextual factors is known to be important in the success of QI efforts (Kaplan et al. 2010), and so this omission provides limits to any conclusions we may make about the causal relationship between improvements and the QI method. Details of cost savings were also not provided in detail, a common deficiency of QI studies (Ovretveit 2009).

Whilst it is difficult to evaluate TQM/CQI as an approach given the broad range of approaches the terms encompass (and previously highlighted paucity of research), and the differences of interpretation across units (Ovretveit 2000), some conclusions about the strengths and weaknesses of the approach can be made. Above all, the technique (like other QI methods) may help to emphasise the day-to-day need to improve quality (Shortell et al. 1998) within hospitals. However, it is also argued that most models of TQM begin with the assumption that staff are naive concerning quality, when in fact many health care professionals are familiar with the concept of QI. This tension between clinical and managerial decision-making extends since much of the TQM/CQI literature is based on assumptions that may not be applicable to healthcare. The primary one being that decision-making in hospitals is always a technical and rational process, and that managers have hierarchical control over these decisions, and that there are no significant conflicts between the needs of internal and external customers (Bigelow and Arndt 1995). This is a major challenge in adopting TQM within the NHS (Morgan and Murgatroyd 1994), and is why TQM/CQI is most likely to be successful when it is integrated into an entire organisation's structure and processes (and not seen as a single clinical microsystem or departmental

project) (Shortell et al. 1998).

However, due to the relative, size, complexity, number of different departments, range of clinicians, and competing demands faced by hospitals, utilising TQM/CQI as a QI method to drive improvement across a whole organisation would be very challenging and may be considered unrealistic. Whilst it is of course possible, there are no reports in the literature of a whole hospital undertaking the approach. In addition to adopting TQM/CQI as a whole organisation approach, the successful implementation of TQM/CQI would require both senior managers and senior clinicians to be fully supportive, actively involved, and leading the programme on an ongoing basis (Gann and Restuccia 1994; Ovretveit 1997; Trisolini 2002). This aspect is not surprising, given the known association of strong clinical and managerial leadership seen across different successful QI interventions (Kaplan et al. 2010).

2.2.2 Business Process focused interventions

The heading “Business process focused interventions” describes a number of approaches used in business to describe process redesign, the earliest being Business Process Reengineering (BPR) which was first described in the early 1990s (Hammer and Champy 2008). Business Process Redesign (Malhotra 1998) and Business Process Innovation (Davenport 1992) are also considered within this section. However, whilst the approaches are well reported in the business literature (Davenport 1992; Malhotra 1998), they do not appear within the healthcare literature where BPR is the terminology favoured by authors (Patwardhan and Patwardhan 2008; De Ramón Fernández et al. 2020). What is consistent between the management and healthcare evidence-base however is the popularity of the approach within the 1990s, firstly within business (Miller et al. 2004), and then within healthcare (Walshe 2009). The approach has since been regarded as a fad within some quarters of the business literature (Miller et al. 2004), but continues to be discussed and utilised within healthcare (De Ramón Fernández et al. 2020).

Despite some common themes, such as a strong focus on the customer, BPR may be considered different to TQM/CQI because its emphasis is on radical rethinking of processes from the ground up rather than improvement to current processes. Some of the key characteristics of the approach include; change being driven from the top by a visionary leader, the re-organisation of systems around key processes and not specialist functions, and the aggregation of tasks and functions so that narrow specialists are replaced by multi-skilled staff (Hammer and Champy 2008).

In its application in health care, BPR has evolved in different ways but in practice it has mostly been applied in part rather than completely (Willcocks et al. 1997; Packwood et al. 1998). One of the more comprehensive examples of BPR in the literature is a Department of Health backed project, where BPR was introduced to two hospitals. The relative strength of appraising the findings of this project arises due to three independent evaluations of the project available in the literature (Packwood et al. 1998; Browns and McNulty 1999; McNulty and Ferlie 2002). The reports by Packwood et al. (1998) and Browns and McNulty (1999) presented both quantitative and qualitative data, which is useful because judgments about an interventions success can be based on both the empirical and experiential evidence required by Walshe (2007). The authors however, in both cases presented the findings separately, and no formal or recognised approach was taken to connect or mix their data as defined by a formal mixed-methods approach (Creswell 2009). This highlights the more recent suggestion of Kaplan et al. (2010) that future research evaluating QI success will be strengthened by social science methodologies such as mixed-methods.

A finding across the reports was that even given the inevitable differences in the details of the experience at the different sites, the vision of radical reengineering and results attached was not realised. Instead, the changes were modest, and the improvements limited, and there was no overall organisational performance transformation. In reality change was patchy, difficult, and took longer than anticipated (Leverment et al. 1998; McNulty and Ferlie 2002). The changes varied in pace and rate in different parts of the hospital and effects varied across

different clinical settings (McNulty and Ferlie 2002). A possible reason for this slow rate of adoption may be as simple as the ongoing clinical workload experienced by staff. It is very rare for a clinical microsystem to be able to stop treating the continual flow of patients requiring treatment, which means that the ability to start from a clean slate and rethink services using a reflective and analytical approach is very difficult.

Further, a crucial determining factor of success reported across the BPR literature is the level of engagement of medical staff, who can be resistant to change (De Ramón Fernández et al. 2020). They retain a high degree of control over clinical work practices and therefore can make it very difficult for the external reengineers (who lack the medical staff's detailed specialty-specific knowledge) to reshape core processes over short timescales (Buchananl 1997; Willcocks et al. 1997; McNulty and Ferlie 2002). Other interconnected barriers to implementing BPR in the NHS include the complexity of patient processes, and the challenge of trying to carry out radical redesign while continuing to provide a continuous service to patients.

These barriers reflect the notion that the nature of BPR appears to disregard the history and culture of the organisations into which its implemented. This is a reason why it may not always be successful given that much of the organisational literature looking at change in healthcare indicates that culture, and the degree of willingness for change, are an important determinant of successful change (Kaplan et al. 2010). This may be because healthcare organisations are comprised of diverse professional groups, some of which have high levels of knowledge, skills, and expertise to choose whether or not to adopt change initiatives in light of their own agendas and interests (Pollitt 1996; Leverment et al. 1998). These professional groups have also historically competed for control over work processes and so may also be resistant to the multi-skilling demanded by BPR (Pollitt 1996).

To summarise, the findings from the literature suggest that whilst BPR can be effective (De Ramón Fernández et al. 2020), BPR in its purest form is a

challenging QI method to implement in healthcare settings. Ongoing, financial pressures will mean its radical approach will remain appealing, and its role in re-designing perioperative pathways has recently been proposed (Grocott et al. 2017). However, whist the re-design principles are useful, the presence of a culture more used to evolution rather than revolution, due to the multiple stakeholders, and visible nature of healthcare to the general public, may caution against the radical change of BPR in favour of more continuous and evolving improvement approaches.

2.2.3 Lean

Lean is a QI approach developed by Toyota in the 1950s (Liker 2004) and is based largely on the work of Deming (Institute for Healthcare Improvement 2005). The core principle of “lean” or “lean thinking” is the need to provide value to the customer whilst minimising wasted time, effort, and cost. It works by devolving all processes within an organisation to the aim of creating value for the customer. Customers of a process may be internal or external and are all those who depend on the product or service resulting from that process. Within the NHS, the five key concepts in implementing lean thinking have been described as; specifying value to the customer, identifying the process, making the process and value flow continuously, introducing pull between steps where continuous flow is impossible, and managing towards perfection (Womack and Jones 1996; NHS Institute for Innovation and Improvement 2010).

Compared to industry, the application of lean thinking within healthcare is relatively new (Antony et al. 2007) and first appeared in the NHS in 2001 (Radnor et al. 2011). Its use has increased since then, and over recent years it has become one of the most frequently reported QI interventions with numerous systematic reviews (Ramori et al. 2019; Tlapa et al. 2020; Zepeda-Lugo et al. 2020). These include studies within the literature from a wide variety of settings and include examples of the intervention being used in hospital laboratories, out-patient clinics, intensive care units, and on in-patient care projects.

When assessing the findings of these particular studies using the SQUIRE (Davidoff et al. 2008) guidelines, it can be seen that often statistical analysis and reporting are poor, and through the failure to include a comparison group, and therefore eliminate potential site selection bias, external causes for change cannot be ruled out. For example, in the study conducted by Bryant and Gulling (2006) it is reported that Six Sigma (which is discussed as a separate QI method in the next section) was already being used within the unit before Lean was implemented. However, in the study by Raab et al. (2006) where lean principles were applied to a pathology laboratory, a statistically significant improvement was found. The study sought to reduce any defect defined as 'flaws, imperfections, or deficiencies in specimen processing that required work to be delayed, stopped, or returned to the sender'. Power and sample sizes estimates were provided and an appropriate statistical test for the paired nature of the pre-test post-test observations on single laboratory staff was used. Therefore, the study had many of the criteria necessary to imply strong causal inferences, such as no ambiguous temporal sequence, no participant attrition, minimal threat of selection bias, and no changes in instrumentation. However, the single group pre-test post-test design cannot rule out the threat from history. This is consistent with studies examining all the QI methods, and a comparison group or increased length of observation period may be ways of addressing this concern.

A specific issue when examining the literature on the application of Lean is the important contextual difference between industry (private sector) and the NHS setting (public sector). These differences provide difficulties for one of the key assumptions behind lean. In the private sector the customer and commissioner are the same, a critical factor when establishing the first principle of lean, which is to specify the value desired by the customer (Womack and Jones 1996). In the NHS, the taxation system theoretically means that those who receive care also fund it. However, practically there is separation between who pays, purchases, and receives care. Depending on whether “value” is defined in terms of the individuals receiving care, or the commissioners who purchase care on their behalf, or the government who decides on how much to spend on care, evaluating improved “value” is difficult within the NHS.

The evidence for lean indicates that the approach can be useful and provide improvements to NHS settings such as in-patient care, where LOS can be reduced, and patient and staff satisfaction increased. Improvements were found in elective care settings, where processes could be more easily defined. Radnor et al. (2006) supports this by saying that lean is likely to be most suited in settings with high volume, and repeatable tasks, as this will allow for the standardisation and clear definition of value required to make a lean approach work. Outside of the NHS, the lean approach has been applied to a knee replacement pathway in Italy, with a reported success and a reduction in LOS of 17% (Ricciardi et al. 2020). Unfortunately, the reporting of the exact details of the project are hard to ascertain from the article because a clear description of the QI method and intervention are not provided.

2.2.4 Six Sigma

Motorola is widely credited for creating Six Sigma (Serrano and Slunecka 2006) and the approach has some similarities with Lean (Boaden et al. 2008). The main ideas of the approach are to eliminate defects and reduce variation of processes in order to improve the output and outcomes of a system (Westwood and Silvester 2007). The approach is based on the work of Shewhart (Wheeler 2003) and is a data reliant method based on statistical tools and analysis to identify the root cause of variation in processes (Boaden et al. 2008). It has been widely used within healthcare, and a recent systematic review revealed its international use, and highlighted that in the studies included, Six Sigma applications in healthcare have focused more on the entire hospital than on departments or clinical microsystems (Antony et al. 2018).

This use of statistical process control as a tool within Six Sigma to monitor variation has overlap with other QI methods and its use is a common factor across approaches due to the rigour it can bring to evaluating changes in process. A crucial differentiator of Six Sigma from other QI methods is the intensive training and coaching that is required before delivering the approach (Proudlove et al. 2008). This training provides a methodology for practitioners to use throughout

the process, which is called DMAIC (Define Measure Analyse Improve Control) (Naslund 2008).

In order to appraise the literature regarding the effectiveness of Six Sigma as a QI method at a clinical microsystem level, the following articles are highlighted for review because in their design they described Six Sigma specifically, they provided quantitative data describing effect or statistical significance, had a department (or clinical microsystem focus) and were not a pilot or review study. The studies included projects involving operating theatre efficiency (Adams et al. 2004; Fairbanks 2007), radiology department appointment booking (Volland 2005), reducing catheter-related blood stream infections (Frankel et al. 2005), and reducing urinary tract infections (Hansen 2006). Like many QI reports all the studies used pre-test post-test designs and they all provided positive approaches, providing support for the Six Sigma intervention. Patient turnaround time was reduced (Adams et al. 2004), the variation in the number of telephone calls required to make appointments was reduced (Volland 2005), infection rate decreased (Frankel et al. 2005; Hansen 2006), and delays in operating theatre lists were reduced (Fairbanks 2007).

However, caution must be stated when considering these positive findings due a common limitation of the study design employed. The single group pre-test post-test design means that factors occurring outside of the actual intervention cannot be excluded as potential contributors to the change in performance. This was especially relevant in the studies where other improvement activities were reported as occurring at the same time within the organisation. The other important aspect is the interventions described were all specific to their respective protocols and environments, and so the generalisability to other setting cannot be confirmed. Another concern, mentioned in two of the studies was the sustainability of the results achieved. In two of the studies, data was shared that indicated performance returned to pre-intervention levels after the initial intervention phase (Frankel et al. 2005; Hansen 2006). The reasons for this return were not explicitly stated, but are not surprising given that there is evidence to suggest that up to 70% of changes achieved via QI efforts, fail to be maintained

(NHS Institute for Innovation and Improvement 2009).

Whilst some of the tools used within the Six Sigma approach are undoubtedly useful such as SPC (Statistical Process Control) (Thor et al. 2007), Six Sigma itself, although showing improvements to outcomes in the studies highlighted, does not address the interpersonal and cultural aspects of QI. It is therefore unlikely to identify the interaction between different interconnecting processes and thus take a system wide approach (Westwood and Silvester 2007). In addition, there are also difficulties associated with the emphasis on the training and accrediting of practitioners, which means that experts in the approach are often "parachuted in" to work with units rather than staff of individual units being able to lead improvement from the bottom up. This requirement for substantial investment in training is likely to be a barrier to implementation in the health service, due not only to the cost commitment but also the time away from clinical care that the courses would require. The complexity of processes and heterogeneity of individual patients will also make implementation difficult because the complex processes being monitored for variation, are highly likely to be susceptible to "noise" caused by the many intrinsic sources of variability (Sehwail and DeYong 2003; Antony et al. 2007).

2.2.5 The IHI's Rapid Cycle Change model

Two main components of the IHI's approach are Langley et al. (1996) model, for improvement, and the PDSA cycle which the IHI developed based on Shewhart's Plan-Do-Check-Act tool described in the 1970s (Kilo 1998; Ketley and Bevan 2007). The PDSA approach works by conducting short-cycle, small-scale tests of change linked to measurement and reflection and has been considered useful to healthcare due to the similarities of the approach with action research (Iles and Sutherland 2001; Walley et al. 2006; Berwick 2008). The approach is attractive in healthcare due to its accessibility as an intervention to front line staff, both in the requirements and skills to perform the intervention, but also perhaps more importantly because of the ability for them to determine their own problems and solutions. This promotes ownership of the changes, a key ingredient of successful

organisational change (Greenhalgh et al. 2004).

PDSA has been used as a QI intervention within the NHS, and in a recent systematic review, of the 120 QI projects included, 98% reported an improvement (Knudsen et al. 2019). However, of these only 27% described a specific, quantitative aim and reached it, 60% documented PDSA cycles sufficiently for inclusion in the full analysis of key features, and only 4% adhered to all four key methodological features of the QI method. Therefore, the difficulties in proving effectiveness of the intervention, in common with the other QI methods remain due to the differences between the scientific and social science research paradigms (Boaden et al. 2008). It may be argued therefore, that PDSA as an approach, due to its similarities with the Recursive Action Research Cycle (Parkin 2009), is more suited to being studied within a Social Science paradigm.

From the available literature, which mostly consists of case studies such as Walley and Gowland's (2004) evaluation of PDSA cycles in an NHS emergency care setting, we can say that the strength of using a rapid cycle change appears to be that the approach utilizes the ideas, perception, and ingenuity of the frontline staff involved in making the change, and this helps to ensure commitment to the changes being implemented (Young 2005). However, the potential problem with the smaller scale bottom up changes it promotes, is the possible impact of changes made in one area to other areas of the organisation, and also the possible conflict of changes to the organisations overall strategic objectives (Savage and Scott 2004; Walley and Gowland 2004). There is of course also the potential for teams not to complete the cycles of change and PDSA cycles are often only completed in part (Knudsen et al. 2019).

In summary, even though there are many studies reporting the use of PDSA cycles within healthcare, the evidence to support the efficacy of the approach is limited due to the variability of application and paucity of reporting (Jones et al. 2016). Therefore, the intervention can be considered useful for smaller QI projects, involving small numbers of staff and changes, where quick tests of change are required. However, it may have limitations when used to improve care

processes across a clinical microsystem.

2.2.6 Evaluation of the different QI methods

The evidence from recent systematic reviews looking at all the QI methods discussed is supportive for all of the QI methods examined. However, there are difficulties in assessing the overall impact of the specific QI methods in each setting, and also to make comparisons regarding effectiveness across both the different techniques and specific contexts in which work was undertaken. One reason for this relates to the range of different interpretations about what constitutes the specific QI methods as well as the differences in implementation. For example, what is called BPR in one hospital may have different components and emphasis from its use in another (De Ramón Fernández et al. 2020).

Another reason is that determining the generalisability of any findings is difficult. The relative heterogeneity of each study's setting and context, as well the complexity and dynamic nature of delivering healthcare, mean that QI efforts are likely to be critically influenced by the timing and contexts into which they are introduced (Ovretveit 2004; Walshe 2007). This means that the QI methods may depend for their results more on the conditions that surround and interact with them, rather than the actual specific workings of that particular technique. Therefore, it can be concluded that no decision can be made to say that one of the QI methods should be used ahead of others in every situation and in every setting. This confirms the findings of previous reviews by the WHO Europe (2003), which found that "no single quality strategy can be recommended above any other on the basis of effectiveness, ease of implementation or costs", and others (Boaden et al. 2008; Powell et al. 2009).

However, another reason for this similarity in performance of the different QI methods may be due to the high degree of commonality found across the different approaches. This is an important point to acknowledge when evaluating the relative techniques, because if the interventions are only different in terms of

presentation and terminology, then it may be argued that the findings that one single intervention is not more successful than the any other is no surprise. There are broadly four main areas in which the QI methods are similar. The first one being that they all employ the idea of a cycle of improvement, consisting of stages involving data collection, problem description, identification of changes to be made, implementation of changes, and then evaluation of the changes. Secondly, the QI methods all make use of a commonly used set of QI tools at various stages with examples being process mapping, cause, and effect diagrams, and SPC charts. Thirdly, in the literature describing all the techniques there is acknowledgement of the organizational and cultural dimension to successful QI efforts. More specifically this relates to a need for active and supportive leadership of senior management and clinicians. Lastly, all the techniques recognize the importance of engaging frontline staff in any QI effort, and the requirement for improvement processes to be grounded in their knowledge of service delivery and ideas on improvement.

Despite the commonality across the QI methods and the similar results found for each technique within the literature, when the evidence (where available) pertaining to each is reviewed, important nuances and details of using the differing QI methods in healthcare are gained. This experiential evidence is of relevance because Glasby et al. (2007) suggest that there are three types of evidence that are needed to assess whether a QI approach should be implemented in other settings, these being theoretical, empirical and experiential (Walshe 2009). Across the literature it could be seen that all the QI methods have a theoretical framework, and also some empirical evidence to support their use, but when examining the available experiential evidence, it is clear that all of the techniques, whilst having their advantages also have their own individual limitations. This experiential evidence provides details of the experience of individuals using or applying a particular intervention and indicated areas of difficulty in applying the interventions to healthcare.

The TQM/CQI approach (Section 2.2.1) was found to be both non-specific and also relied on a hierarchical decision-making structure that is not present within

the NHS. BPR was considered next (Section 2.2.2), and similarly to TQM/CQI was noted as being a poorly defined intervention. More crucially in the case of the NHS its central thrust of using a radical approach of completely changing care processes to achieve improvements, whilst ideologically appealing, is one that does not lend itself to the complex and more evolution-based culture of the NHS. Lean (Section 2.2.3) meanwhile offers a less radical approach and is centred on improving processes rather than the complete introduction of new ones. However, the approach has difficulties around the definition of the customer within the NHS setting, which is an underpinning principle of the intervention. Six Sigma (Section 2.2.4) has many similarities to Lean and utilizes good techniques for monitoring variation of care processes but lacks an understanding and appreciation for how to manage the nuances and complex nature of the variation found in healthcare. The IHI's Rapid Cycle Change (Section 2.2.5) approach was more suited to identifying the contextual causes of variability given the fact it is a technique that lends itself to being used by those on the frontline who understand where improvements to care processes are required. However, the intervention whilst useful for small scale projects, is less suited to larger and more integrated changes to care given the short timeframe of tests of change and reduced focus on overall process measurement.

In closing, whilst all the QI methods have a strong theoretical theory to support their use, and supportive empirical evidence to illustrate their effectiveness, rigour of study design and reporting is frequently lacking, and the experiential knowledge suggests that there are individual limitations associated with all of the techniques when considering their suitability for use within an NHS elective care clinical microsystem. Therefore, the consideration of a QI methods such as the management of variability is purposeful, given that its methods of working appear to overcome the potential shortfalls of the five QI methods evaluated in this chapter and summarized in *Table 2*.

Table 2 - A summary table to summarize the discussed limitations of QI methods

Quality improvement intervention	Proposed limitations of using the quality improvement intervention in a clinical microsystem
TQM/CQI	The intervention is non-specific and represents a broad range of approaches and activities. Also relies on a hierarchical management decision making structure not present in the NHS.
BPR	The activities of the intervention are poorly defined and wide ranging. It's central theme of complete and radical change is rarely possible in the NHS and challenging to evolutionary culture.
Lean	The underpinning key assumption of increasing value to the customer is difficult in the NHS. Externally, there is separation between who pays, purchases and receives care. The complexity of care pathways and organisational structures makes internal customers of a process hard to identify
Six Sigma	Measures of variation do not identify intrinsic sources of variability. There is a large emphasis on training to use the intervention, and the terminology and techniques of the approach.
The IHI Rapid Cycle Change Model	Not suitable for larger and more integrated projects and changes due to the relative simplicity, short timeframe of tests of changes and reduced focus on overall process improvement.

2.3 The management of variability approach

The management of variability approach (as introduced in Chapter 1) was originally developed by Boston University's Program for the Management of Variability in Healthcare Delivery (MVP) (Boston University Health Policy Institute 2006). It has since been recommended as an approach to improve patient flow through hospitals by the Institute of Medicine, and is the central theme of the Joint Commission Resources book, Managing Patient Flow in Hospitals: Strategies and Solutions (Litvak 2010). It is based on sound operations management theory, and there is a growing evidence base to support its use (as described in Chapter 1). A detailed account of how the approach has been described to optimise flow through hospitals is available on the Institute for Healthcare Optimisation (IHO) website and also within the literature (Boston University Health Policy Institute 2006).

A description of how the management of variability methodology was subsequently adapted in a novel way, so that it be used to improve care processes within a clinical microsystem, is summarised below.

2.3.1 Details of the approach

The effective management of variability is proposed as being the most likely solution to help deliver health care that is both efficient and of high quality (Litvak 2005), and this is identified across the QI methods previously discussed in this chapter. For instance, within the Six Sigma approach (described in Section 2.2.4), SPC is used to display measurements and identify the presence of variability. However, the limitation of using SPC to improve processes when Six Sigma is used in healthcare is that variability is calculated outside an arbitrary "acceptable" range. There is no recognition of the intrinsic sources of the variability or attempts to either eliminate or reduce these sources with management strategies. There is instead, a more general instruction to reduce variability.

This is where the IHO's model may be considered different as it introduces a methodological step of classifying the sources of variability once overall variability has been identified. This classification is to distinguish between "natural" and "artificial" sources of variation. Natural variability is explained as being the intrinsic, normal, and naturally occurring part of every system. Natural sources of variability are identified and then subdivided into "clinical, flow, and professional" categories. Natural "clinical variability" may represent the wide range of naturally occurring clinical presentations a patient may have, and the level of their symptoms, and their responses to treatment. Whereas natural "flow variability" may relate to the random arrival of patients for treatment and their consequential referral to hospital. Natural "professional variability" refers to the intrinsic differences in experience and technical skills that normally occur across healthcare professionals.

If any variability is not easily classified into any of the “natural” subcategories it is thought to be “artificial”. The rationale for identifying artificial variability is that it usually arises in processes because of the decisions made by those managing the system. It does not naturally occur and in most healthcare systems it is almost always multi-factorial and frequently hidden. It is therefore difficult to understand and identify without a systematic approach or method.

Once the sources of variability have been identified and classified, where possible they should be “measured”. Variability should be measured as deviation from an ideal, stable pattern**.** Measurement will be different for each type and unique to the system being measured. It is important to note that when measuring variability of a system, the total variability is not necessarily the sum of its parts, since they may be mutually dependent.

Once that variability has been identified, classified, and measured, the next step is to manage the variability. The first action is to eliminate “artificial variability” from the system. Once “artificial variability” is removed, it is necessary to manage the “natural variability”. It must be managed rather than reduced, because the only way to reduce it is through advances in new medical knowledge or technology. Since natural variabilities are random by nature, many well-developed operations research methodologies, and models such as queuing theory may be applied, especially in the case of “natural flow” variability.

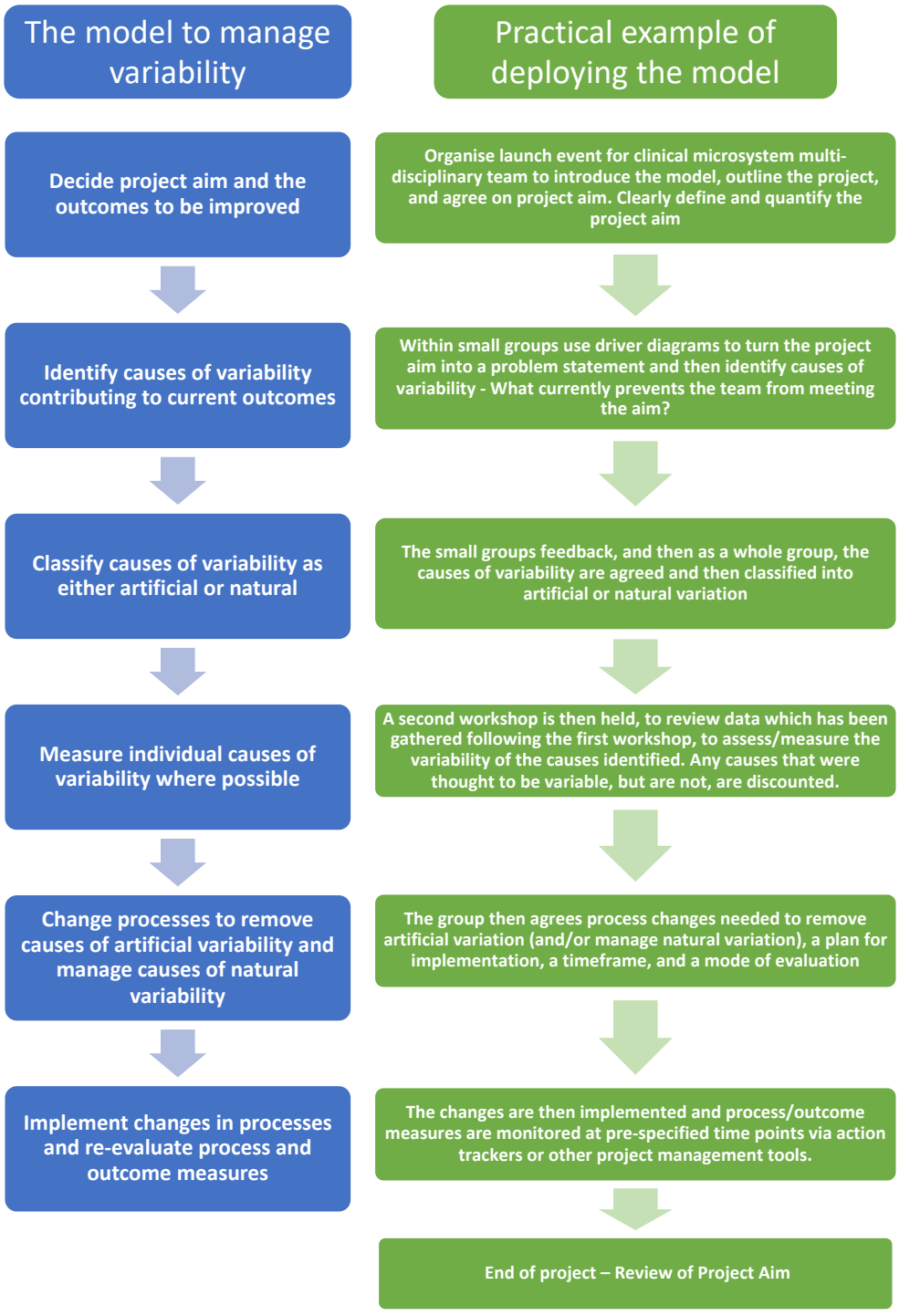
This method for managing variability, allows for the reorganisation of care process within hospitals, via a method that is based on sound operations management theory and has a solid measurement and process discipline (Boston University Health Policy Institute 2006). Crucially however, it has the sensitivity and format for clinical teams to ensure that any changes they make because of using the intervention are adapted to the unique context and setting of their improvement work. This is achieved by the identification of artificial variability and appreciation of natural variability and is a distinguishing factor from the other QI interventions described.

An outline of the approach can be seen in *Figure 2*, which illustrates how the model has been uniquely adapted for this project, so that it may be deployed within a clinical microsystem, to focus on a multi-disciplinary QI project to improve care processes.

Previously, research utilising this approach has focused on modelling improved patient flow in unplanned care areas such as critical care, emergency departments, and operating theatres (McManus et al. 2003; McManus et al. 2004; Litvak 2005). This adaption to the model, is a novel development, and utilising the model to manage variability as a QI method to improve care processes has not been previously proposed or studied. More specifically, individual elective care clinical microsystems within the NHS have not been previously examined. Clinical microsystems are the individual functional units providing care within NHS hospitals, and the term is defined in Chapter 3.

The decision to adapt Litvak's (Boston University Health Policy Institute 2006) model was underpinned by a recognition that all care processes within a clinical microsystem are subject to variability, and that an improvement to quality would occur through understanding and reducing the unintended variability within this system (Wheeler 1999). Adapting Litvak's (Boston University Health Policy Institute 2006) model for use to improve care processes was further thought to be attractive to clinical teams because whilst it acknowledges the need to remove unintended artificial variations in practice as a central objective, it also provides consideration of the natural differences between individual patients.

Figure 2 - Adapted model to manage variability for use to improve clinical care processes in a clinical microsystem (based on Litvak (Boston University Health Policy Institute 2006)



3.0 Clinical context

This chapter provides an overview of the clinical context and the relevance of the thesis to practice. To understand QI efforts, it is essential to understand what is generally known about the care problem where improvements are desired. This chapter, therefore, positions the thesis within the current context of ERAS, orthopaedic surgery, and the NHS. The aim of the chapter is to weave together the macro-level issues and rationale for the thesis, that are present both now, and at the start of project. However, before these macro-level issues are examined, the rationale for focusing on QI within a clinical microsystem is presented, and then the reasoning behind why elective orthopaedic clinical microsystems were chosen for this study.

Following this, the current state of the evidence-base for ERAS in orthopaedic surgery is summarized and reviewed within the first of the integrated papers (Section 3.3), which is a book chapter titled “Orthopaedic Surgery in Enhanced Recovery after Surgery” (Wainwright and Immins 2020). The outcomes of ERAS for hip and knee replacement are considered in detail, with the current literature examined for evidence of improved outcomes across the dimensions of quality. Issues with universal implementation are then highlighted, and it is emphasized that ERAS pathways are only successfully delivered, when evidenced-based interventions are combined with the correct implementation to do “the right things right”.

The second integrated paper is summarized in Section 3.4, and it examines the current state of ERAS implementation across the English NHS, through an observational study of English NHS providers of hip and knee replacement (Wainwright 2020a). This study of over 160,000 hip and knee replacement procedures examined LOS which is often used as a proxy for ERAS implementation. The findings show that LOS remains higher than international

comparators, and that there is significant variability in LOS across providers, suggesting that ERAS is still to be universally adopted within the NHS.

In the third integrated paper (Section 3.5) the reasons for difficulties with implementation are discussed, and a recommendation for the future use of a QI method when implementing or improving ERAS pathways is presented (Wainwright 2020b). This perspective is novel in the ERAS literature, and prepares the rationale for evaluating QI methods, such as the model for managing variability in care processes evaluated in this thesis. The paper argues that for successful implementation of ERAS, a recognised QI method (e.g., PDSA cycles, Lean, and Six Sigma) may need to be used in order to successfully implement the ERAS protocol (which is a QI intervention).

3.1 Clinical microsystem approach

Health care systems such as the NHS consist of a variety of interdependent influences, relationships, and practices. These interconnections can be distinguished by applying a micro-, meso-, and macro-level framework (Nelson et al. 2007). Whilst these levels obviously have dynamic and permeable boundaries in real life, the framework is useful and commonly used within the healthcare QI literature. The macro-level concerns national level regulatory, economic, and other policy barriers and enablers; whilst the meso-level can be thought of as the local health service and community. The micro-level relates to day-to-day practice and departments where most health professionals work.

Clinical microsystems are an appropriate organisational level at which to apply QI efforts (Donaldson and Mohr 2000; Nelson et al. 2002) and can be defined as the “small, functional, front-line units that provide most health care to most people. They are the essential building blocks of larger organisations and of the health system. They are the place where patients and providers meet, and ‘the quality and value of care produced by a large health system can be no better than

the services generated by the small systems of which it is composed" (Nelson et al. 2002, p.473).

3.2 Focus on orthopaedic surgery

A focus on orthopaedics was chosen due to my interest, clinical experience, and managerial background within orthopaedics. However, elective orthopaedics is an excellent specialty in which to study the effectiveness of QI efforts given the high volume of procedures, relative homogeneity of patients, and potential for improvement. Almost a third of all hospitals admissions are for a surgical procedure, and orthopaedic surgery is a high volume specialty, with over 1.2 million procedures performed per year in England (The Royal College of Surgeons of England). After hernia repairs (all forms of hernia), hip and knee replacement are the most common surgical procedure performed within England, and therefore the cost and capacity required to perform them is extremely significant to our health service. Large variations in outcome across providers is also recognised, suggesting significant scope for improvement (GIRFT 2020).

3.3 ERAS in orthopaedic surgery

3.4 The current status of hip and knee replacement within the English NHS

3.5 The QI challenge – How to solve the knowing-doing gap in ERAS

This section (3.5) is the third integrated paper within the thesis and has been published (Wainwright 2020b). The full paper is reproduced below. It is a viewpoint article summarizing that despite the evidence-base for ERAS protocols, universal implementation of ERAS across NHS hospitals has not occurred. It highlights that whilst previously identified local contextual factors may be barriers to implementation, there is also a need to increase the awareness of how to use QI approaches to implement ERAS protocols. In particular, the article argues that ERAS teams should be encouraged to use a QI method when seeking to implement or improve an ERAS pathway (which is a QI intervention). This is a novel perspective within the ERAS literature and has not been previously highlighted and sets the scene for why QI methods should be used to improve the implementation of ERAS.

3.5.1 Introduction

Health services around the world, including the English NHS, have faced economic and capacity challenges over the last 10 years, and these will remain and increase following the global COVID-19 pandemic. The ongoing reduction in resources and increasing demand for services, will provide an immense challenge to NHS organisations and staff. QI approaches may be used to improve the quality of patient care and save money, but their success is both dependent on the local context and how they are implemented (Øvretveit 2009, 2011). ERAS protocols are a QI intervention, and are a multi-modal approach to care which has been shown to reduce mortality, morbidity, and LOS across a range of elective surgical procedures (Ljungqvist et al. 2017).

3.5.2 The history of ERAS implementation within the NHS

ERAS protocols optimise the peri-operative pathway by minimising the surgical stress response to surgery by using and combining techniques such as minimally invasive surgery, regional anaesthetic techniques, multi-modal opioid sparing pain management, early nutrition, effective fluid management and early mobilisation. ERAS protocols have been detailed in procedure specific evidence-based guidelines for a range of surgical procedures (Ljungqvist et al. 2017), and include recommendations for THR and TKR (Wainwright et al. 2020).

In England, the spread and adoption of ERAS was initially promoted over 10 years ago via a government led programme. The Department of Health (DOH) launched the Enhanced Recovery Partnership Programme (ERPP) in April 2009, which was a 2-year national improvement programme focused on surgical procedures involving the colorectal, urology, gynaecology, and orthopaedic (focusing on THR and TKR) specialties (Department of Health 2011). The ERPP aimed to reduce and address the wide variations in LOS found across common elective surgical procedures. ERAS protocols were an attractive intervention to improve clinical outcomes, and increase the capacity required to meet the 18-week referral to treatment target. In year 1, the ERPP focused on increasing awareness of ERAS through events, conferences, and producing supportive literature and online resources. In year 2, the ERPP focused on spread, adoption, and sustainability of ERAS, and amongst other activities produced a basic national ERAS database as well as encouraging regional support through the strategic health authorities.

There is a perception that ERAS strategies have been universally adopted in England; however recently published data suggests that this is not a reality (Judge et al. 2020). For some hospitals, ERAS protocols have become so embedded into practice it is now considered the standard care, yet for others there has been a significant decline in compliance to ERAS protocols since the end of the national programme (Albury et al. 2018). Following the programme there has been no on-going formal national programme to support ERAS

adoption and so the effect of ERAS protocols on influencing outcomes at a national level is questionable. Recent research has highlighted that the programme had no discernible independent effect on decreasing LOS nationally for both THR and TKR (Judge et al. 2020).

It is important that the status of nationwide implementation is highlighted and addressed because improving surgical outcomes for THR and TKR patients is of critical importance to the NHS. Given the current economic challenges within the NHS, the relative high volume of procedures performed compared to other surgeries (THR and TKR are the most common orthopaedic procedures in the UK) (National Joint Registry 2019) means that a reduction in LOS for these patients could deliver significant capacity savings to the NHS. Given the homogeneity of the procedure, and relative fitness of patients compared to other surgical procedures, it may also be argued that THR and TKR are procedures where pathway improvements should be easier to deliver.

3.5.3 Why has ERAS not been more widely adopted within the NHS?

In the 10 years since the national ERPP was delivered, the evidence-base for ERAS in THR and TKR has continued to expand and strengthen. The literature informs us that the implementation of ERAS has resulted in reductions to LOS, morbidity, and mortality, without an increase to readmission rates or compromising patient safety (Wainwright and Kehlet 2019). It is now routine within the evidence-base for patients to be discharged within 0–2 days and the incidence and feasibility of day case THR and TKR replacement is increasing (Wainwright and Kehlet 2019). However, despite the scientific evidence for ERAS, there is still a knowing-doing gap, and widespread implementation within the English NHS has not occurred. Mean LOS remains over 4 days after THR and TKR compared with 2 days in large epidemiological studies in equivalent socialised health care systems (Petersen et al. 2019).

Therefore, the question to be addressed is why clinical practice is not reflecting evidence-based surgical care when the motives for doing so, namely improved patient outcomes and economic savings are so attractive and needed. The question of ERAS implementation has attracted previous attention (Kehlet 2018) and remains unresolved. It is not because the implementation of ERAS for THR and TKR in the NHS is not feasible. Pockets of excellence exist (Malviya et al. 2011; Jain et al. 2019) and a high-quality service should be possible within all NHS hospitals.

The failure of widespread and complete adoption is multi-faceted, and there are contextual factors, like other QI interventions, that may limit the success of implementing ERAS. Whilst some staff may feel positive about the implementation of ERAS (Cohen and Gooberman-Hill 2019), previously identified and general barriers to implementing ERAS pathways have bene reported to include; frontline clinicians being resistant to change, not having enough resources for implementation, difficulties with collaboration and communication across the multidisciplinary team, and local or contextual factors, such as patient complexity or hospital location (Stone et al. 2018; Cohen and Gooberman-Hill 2019). Conversely, facilitating factors in successful implementation sites are reported to be: 1) Adapting the programme to fit local contexts, 2) achieving and demonstrating early success, 3) gaining support from both clinicians and hospital leadership, 4) having a strong multidisciplinary ERAS team that regularly communicates and 5) recruitment of supporters and full time ERAS staff or champions (Stone et al. 2018; Cohen and Gooberman-Hill 2019).

These factors resonate with the wider QI literature where context has been found to be a crucial determinant of whether QI projects are successful. Kaplan et al. (2010) concluded that strong clinical and managerial leadership at all levels, a supportive organisational culture with high staff motivation for change, the use of process and outcome data to monitor, and the use of a recognised QI method (such as a PDSA cycle) when introducing a QI intervention were all crucial to success.

3.5.4 Recommendations for the future implementation of ERAS

We must re-focus our efforts and remember that even though ERAS has been proven to improve clinical outcomes, implementing ERAS itself is not the goal, but instead is an intervention by which patient care can be improved. Instead, it should be recognised that improving a clinical outcome is achieved by combining clinical decisions informed by evidence-based medicine (such as an ERAS protocol) with the needed process or system changes, that allow the right things to be delivered in the right way (Glasziou et al. 2011). Understanding this concept is crucial if we are to understand that “wanting to improve is not the same as knowing how to do it” (Dixon-Woods 2019).

The need for perioperative care teams to increase their knowledge of QI approaches is therefore required, and this should include the understanding that QI approaches may involve both QI methods (including techniques such as PDSA cycles, Lean, and Six Sigma) and QI interventions (such as checklists, care-bundles, and clinical pathways) (Jones et al. 2016). This nuance is important because an ERAS protocol should be classified as a QI intervention, and this has not previously been emphasized in the ERAS literature. ERAS protocols are QI interventions intended to improve a process, and the evidence for an ERAS protocol for THR and TKR is well established (Wainwright et al. 2020). In the right context and environment, there is clear evidence for successful deployment and adaption. For example, outpatient surgery for THR and TKR is now possible when implementing ERAS informed peri-operative protocols (Vehmeijer et al. 2018). However, as highlighted previously, the successful deployment of ERAS protocols across all hospitals has not been universal because of contextual factors, and the relationship between reduced compliance of ERAS components to poorer outcomes has been shown (Ripolles-Melchor et al. 2020).

This is important because one of the key contextual factors identified by Kaplan et al. (2010) to be associated with successful QI efforts, that has received minimal attention to date within the ERAS literature, is the use of a specific QI method (such as PDSA cycle, Lean, and Six Sigma) when introducing an ERAS protocol

to a specific hospital. A QI method is defined as a “systematic technique for identifying defects in clinical systems and making improvements, typically by involving process measurement and remeasurement” (Jones et al. 2016). As such, it may be considered a vital factor in the successful adaptation and implementation of ERAS protocols in varying settings and contexts. This is alongside the more widely described and acknowledged factors such as clinical and managerial leadership, the role of an ERAS champion, a supportive organisational culture, effective multidisciplinary communication and collaboration, and the use of data and ongoing audit (Herbert et al. 2017).

3.5.5 Summary

Implementing an ERAS protocol involves the introduction of a QI intervention into a dynamic environment, across multiple departments, with a varied network of multidisciplinary relationships, and it normally challenges existing working traditions. With such a complexity of factors and variables, it is extremely difficult to introduce an ERAS protocol without the use of a QI method to help understand current processes. It is therefore recommended that to improve the success of implementation, perioperative care teams must understand the role of utilising a QI method to adapt and implement ERAS protocols to their specific context. The future use and evaluation of the use of QI methods to implement ERAS should be encouraged, so that perioperative teams can transition from a will to improve, to an understanding of how to improve.

4.0 Methodological approach

In this chapter, the methodology, research design, and an outline of the research methods employed is provided. The stages of the study across the pilot and validation site are then outlined and placed within the context of an improvement replication programme (based on a model to increase the generalisability of QI research as proposed by Ovretveit et al. (2011)).

4.1 Philosophical worldview

Identifying how to best answer a research question is challenging and will be influenced by a researcher's philosophical worldview. A research philosophy determines the way in which data about a phenomenon is collected, analysed, and used, and therefore refers to the philosophical assumptions that guide the actions and define the worldview of the researcher (Lincoln et al. 2011). A worldview can be thought of as "a way of thinking about and making sense of the complexities of the real world" (Patton 2002, p. 69).

There are several worldviews that can structure and organize healthcare research (such as pragmatism, positivism, realism and interpretivism), and they all contain common elements. These elements include, ontology (assumptions about the nature of reality), epistemology (assumptions about how we know the world, how we gain knowledge, and the relationship between the knower and the known), axiology (beliefs about the role of values and morals in research), methodology (shared understanding of best means for gaining knowledge about the world) and a shared understanding of the language of research (Creswell 2009; Lincoln et al. 2011).

Therefore, a researcher's philosophical worldview will be strongly influenced by their personal understandings and beliefs (Greene and Caracelli 2003), and these will be founded both on past experiences and their reflection on these past experiences. In this case, the researchers experience as a physiotherapist and NHS manager, influenced their view of the world and therefore the choice of

methodology for this study. These experiences have provided the researcher with a viewpoint where there is a need to understand if an intervention works through empirical or quantitative enquiry, but also a need to understand more about the context, and the how and why it may work in different contexts through qualitative enquiry. This stance represents a worldview which arises out of actions, situations and consequences and is best described as a pragmatic worldview (Creswell 2009).

Pragmatism is based on the proposal that researchers should use the philosophical and/or methodological approach that works best for the research problem that is being investigated (Tashakkori and Teddlie 1998). It is associated with an ontological stance whereby singular and multiple realities are possible, and so this thesis will seek to test a hypothesis and provide multiple perspectives. This will be underpinned by a practical epistemological approach, where data will be collected by "what works" to practically address the research question. An axiological view based on multiple stances and perspectives will be adopted and achieved by using a methodology that will seek to collect and mix both quantitative and qualitative data (Creswell and Plano Clark 2007). Pragmatism is often associated with mixed-methods (Creswell and Plano Clark 2007), where the focus is on the consequences of research and on the research questions rather than on the methods. It is a worldview or research paradigm that originates from the historical contributions of the philosophy of pragmatism and, as such, embraces and allows for such a plurality of methods (Maxcy 2003).

4.2 Consideration of study design

Quality improvement efforts have become an increasingly important focus of scholarly activity within healthcare (Djulbegovic 2014), however there is no consensus for what defines optimal study design. Therefore, ahead of discussing the relevant options for study design, it is pertinent to acknowledge that quality improvement projects, often have the primary goal of achieving change, in contrast to evaluative studies, where the primary goal is directed at evaluation and scientific advance. The differences between the two approaches lie largely

in the primary motives for the project and whether it was driven from a clinical research or healthcare management perspective (Bowen and Neuhauser 2013). However, the practical and the scientific are not necessarily opposed or in conflict with each other. Many studies, such as the work presented within this thesis will have more than one aim, and effectiveness studies can also be interested in producing improvement (Portela et al. 2015).

A wide range of study designs have been presented in the QI healthcare literature and they can broadly be classified into quality improvement projects, effectiveness studies, process evaluations, qualitative studies, and economic evaluations (Portela et al. 2015). Small-scale quality improvement projects are the most frequently seen, along with a broad range of effectiveness and evaluative study designs from the epidemiology paradigm, and some studies that combine quantitative and qualitative methodological approaches in a mixed-method design to assess what works, how, and in what contexts. Given the nature of the research question and aims within this thesis, a quality improvement project approach, evaluative study approaches, and a mixed-methods approach are all discussed as candidate study design methods

4.2.1 Quality improvement projects

Quality improvement projects are typically defined as improvement activities rather than research studies directed towards generating new knowledge. Therefore, they are set up with the principal aim of improving an identified outcome, pathway, or service. The problem is usually well-defined with a focused and practical ambition. Typically, quality improvement projects focus on measuring and monitoring the target of change. They can therefore be self-evaluating especially if they are prospectively designed and transparently reported (Portela at al. 2015).

SPC is often used for the analysis of data in quality improvement work (Thor et al. 2007). SPC maps variation in an outcome or process over time to combine the

power of statistical significance tests with the chronological analysis of graphs of summary data (Benneyan et al. 2003). The use of SPC is usually planned prospectively but can also be used retrospectively to evaluate time-series data for evidence of change over time. SPC and its use within this thesis is described in detail later (Chapter 4.4.5).

SPC is especially well-suited to dealing with the dynamic, iteratively evolving nature of improvement work. This is in contrast with more traditional statistical methods that are oriented towards hypothesis-testing of clearly defined and bounded interventions. However, SPC charts are constructed using the same statistical rules, and depending on the type and distribution of data, different SPC charts may be used. SPC charts plot the values of an outcome measure at regular time points. They are then annotated to show when various events occurred (such as the baseline period and the introduction of an intervention). Quality improvement approaches that incorporate SPC are favoured because they allow flexibility for testing changes and adapting interventions. They also allow for the incorporation of local knowledge and provide the ability to interactively scale local findings more broadly. However, because reports are frequently of low quality, with little explanation of change mechanisms, appraising the generalisability of findings is difficult.

Reports of quality improvement projects should therefore always incorporate a theoretical base and utilise qualitative methods more systematically to allow for predicting and explaining the mechanisms of change involved. This is because the attribution of any changes to the intervention may be complicated by influences outside the intervention that may interfere and disrupt the pattern of data behaviour (Portela at al. 2015). Therefore, further qualitative (or quantitative) investigations may be needed to understand the system under study. The addition of a qualitative arm of inquiry may be especially valuable in understanding the mechanisms of change and identifying the reasons why particular interventions did or did not work (Dixon-Woods 2019).

4.2.2 Evaluative studies

Compared to quality improvement projects, evaluation studies are characterised by study designs that have a more explicit orientation towards evaluation rather than improvement alone. Whilst evaluative studies are often conceived from the outset as research projects; it is also possible for evaluations of improvement projects to occur where the study is effectively 'wrapped around' the improvement project (Portela et al. 2015). This nuance of how the study is conceived, will influence which type of study designs may be used, along with the practical realities of which study designs are feasible to execute given the complexities of healthcare.

Candidate study designs vary in terms of their goals, their claims to internal and external validity, and their heritage. For example, methods within the quality improvement literature may include approaches from epidemiology, behavioural sciences, educational research, organisational and management studies, economics, and statistics (Grol et al. 2002). More specifically, such study designs could include.

- observational studies of existing change processes
- randomised trials
- in-depth qualitative studies on critical success factors and barriers to change improvement programmes
- systematic reviews of both the impact of different strategies and the influence of specific factors on change
- systematic sampling and interpretation of experiences of change
- meta-analyses of large samples of improvement projects
- methods for evaluation of large-scale implementation and change programmes
- economic analyses of resources needed for quality improvement

In the case of this thesis, the epidemiological paradigm offers a range of experimental, quasi-experimental, and observational study designs that may be used to determine the effectiveness of the model to manage variability. Possible experimental designs include randomised controlled trials, and non-randomised trials, such as uncontrolled and controlled before and after studies, and time

series designs. Studies in quality improvement are nearly always pragmatic because of their conduct in "real world" settings.

4.2.2.1 Experimental study design

When an experimental design is chosen, such as a randomised controlled trial (RCT), participants are randomly allocated into intervention and control groups to be treated identically apart from the intervention. RCTs are considered the gold standard method for evaluating healthcare interventions (Cochrane 1979) and are valued for their potential ability to allow for direct inferences about causality. They are highly relevant to quality improvement for their power, through randomisation, to deal with the effects of critical unknown confounders related to outcome measures. For this reason, they may be especially suitable when interventions are being assessed for scalability based on their face validity and early or preliminary evidence (Auerback et al. 2007). However, quality improvement RCTs may often be difficult to undertake because it may be difficult and problematic to randomise individual patients. This is because even if randomisation is possible, there is a risk of contamination, because it is likely that the treatment given to control individuals will be affected by the organisational experience of applying the intervention to other patients in the experimental group (Eccles et al. 2003).

However, randomisation at an organisational rather than patient level is possible and may avoid such issues. Such trials, which randomise at one level (organisation or professional) and collect data at a different level (patient), are known as cluster randomised trials (Donner and Klar 2000) and still allow data regarding the outcome of care at the individual patient level to be collected. Therefore, cluster randomised trials have been advocated as an alternative to the classic RCT design for studying improvement interventions (Portela et al. 2015). However, the nature of cluster randomised trials means considerable implications for the design, power, and analysis of such studies. For example, the method requires a larger sample size, and when all things are equal (and budget allows), many small clusters are better than a small number of large clusters (Van

Breukelen and Candel 2012). The design also makes data analysis more complex since the assumption of independence among observations, on which classical statistical methods rely, is not secure (Campbell et al. 2007).

Possible types of cluster randomised trials include two-arm, multiple-arm, and factorial designed trials (Eccles et al. 2003). Each has strengths and weaknesses in practical operationalisation and the inferences that can be made (Eccles et al. 2003). Therefore, an alternative approach called the stepped wedge design has gained favour as a promising method for evaluating quality improvement interventions (Portela et al. 2015). The step wedged design is very pragmatic and consists of the sequential roll-out of an intervention to clusters (or organisations). The design reassures organisations that none will be deprived of the intervention, reducing resistance to being randomised to a control group (Hemming et al. 2015). Implementing the intervention in a phased way is advantageous for logistical and practical reasons, and it can be economically efficient when used in pragmatic evaluations with limited funding. However, it requires an extended data collection period compared to other designs and has additional statistical complexity (Brown and Lilford 2006). When choosing a trial design for quality improvement research it is therefore not just the purpose of the evaluation that needs to be considered, but also the needs, timeframe, and resources of the context or circumstance.

Randomised trials may therefore not always be possible, and so alternative evaluations should be considered, whilst still using the most robust design possible to minimise bias and maximise generalisability. In such cases when randomisation is deemed not to be feasible, non-randomised trial designs such as uncontrolled and controlled before and after studies, and time series designs should be considered with the acknowledgement that these quasi-experimental will provide less control over confounding factors.

4.2.2.2 Quasi-experimental study design

The most straightforward quasi-experimental design is the uncontrolled before-and-after study design. It involves measuring outcome measures before and after introducing the intervention to the study site. The method assumes that any difference in measurement "after" compared with "before" is due to the intervention (Portela et al. 2015). Their disadvantage is that they do not account for secular tendencies that may be co-occurring (Shojania and Grimshaw 2005). Therefore, it remains a significant problem determining whether a particular intervention or programme has genuinely produced an improvement over change that was occurring anyway (Portela et al. 2015) unless additional data sources and methods are used to corroborate the difference observed.

A controlled before-and-after study offers some advantages over the uncontrolled design by reducing the potential for secular trends that may be co-occurring and influencing the outcome measure being studied. By providing controls, the method provides an increased ability to detect the effects of an intervention whilst controlling for secular trends and cofounders, particularly when combined with difference-in-difference analyses (Benning et al. 2011). However, in quality improvement projects finding appropriate controls is often extremely difficult (Eccles et al. 2003). When controls are selected, they are frequently inadequate because selection usually occurs by considering healthcare units' most superficial structural characteristics, such as size and location. Such selection does not allow for the nuances of context, which is an acknowledged and influential factor in quality improvement success. Therefore, if controls are used, selection should be based on a criterion relevant to the characteristics and anticipated hypotheses concerning the mechanisms of change involved in the intervention and the contextual influences on how they work (such as organisational culture, leadership, and data informatics). Comparison of the baseline levels of the target outcome measure across organisations is also fundamental since non-comparable baselines or exposure to secular trends may invalidate the effects of the intervention(s) under evaluation.

4.2.2.3 Observational study design

When an uncontrolled or controlled baseline period is not possible, a time series designs may be utilised to detect whether an intervention has had an effect significantly greater than the underlying secular trend (Cook and Campbell 1979), for example, following the dissemination and subsequent testing of national guidelines (Eccles et al. 2003). A time-series design relies on multiple successive measurements to separate the effect of an intervention from the secular trend. Given the difficulty of adjusting for confounding variables among sites, using a time-series design in studies involving multiple locations might be more advantageous than other methods. Therefore, in large-scale projects, such as a quality improvement collaborative, it may be best to leverage the larger sample sizes and utilise a conventional time-series technique over other methods, such as SPC charts routinely used in quality improvement projects and single-site trial design. Different statistical methods used in longitudinal analysis may also allow for identifying changes in the trends attributable to the intervention, accounting for the autocorrelation among observations and concurrent factors (Pinto et al 2011).

4.2.2.4 Summary of quantitative study designs

The epidemiological paradigm offers a range of experimental, quasi-experimental, and observational quantitative study designs that a researcher may use in determining the effectiveness of improvement interventions. These designs attempt to determine whether an improvement has occurred and whether it can be attributed to the intervention(s) under study. However, they are less suited to investigating "how" or "why" any change occurred. Understanding context is essential in quality improvement and means understanding the generalisability of findings is often challenging. Therefore, in addition to quantitative methods, the use of a qualitative methodological approach can play an important and complementary role in assessing what works, how, and in what contexts. Their use can also help understand what form a quality improvement intervention takes in practice (Dixon-Woods 2019).

4.2.2.5 Qualitative study designs

Qualitative methods used in this way may include interviews and ethnographic observation, and documentary analysis methods may capture the degree that an intervention is implemented as intended and explain the mechanisms of change involved (Aveling et al. 2013). Additionally, an explicit grounding in formal theory is also likely to support a fuller understanding of how a quality improvement intervention is expected to make a difference and contribute to building a knowledge base for improvement (Dixon-Woods et al. 2011). When social science theory is combined with qualitative methods implicit ideas of change held by practitioners may be uncovered and empirical facts from normative judgements can be distinguished (Portela et al. 2015). Perhaps most importantly in the case of quality improvement research, it is when quantitative and qualitative approaches are combined, that triangulation can occur in data collection and interpretation, that can help make findings more reliable and robust (Benning et al. 2011). When combining quantitative and qualitative approaches within one study, a mixed-methods approach may be utilised, and it is a recommended for quality improvement research (Kaplan et al. 2010).

4.2.3 Mixed-methods research

Mixed-methods research has been termed the third methodological movement (Teddlie and Tashakkori 1998; Johnson and Onwuegbuzie 2004) in addition to the traditional quantitative and qualitative research movements. It involves the collection and analysis of quantitative and qualitative data either sequentially or concurrently. When utilising mixed-methods research as a methodology, it requires an explanation, because the mixing of the methods is particular for each study, and there are many ways in which this is may be completed. The basic premise of the approach is that the combination of the quantitative and qualitative approaches provides a better understanding of a research problem than either approach alone. The definition of mixed-methods research centres around the mixing of the data, and mixing may occur via merging datasets by bringing them

together, connecting the two datasets by having one build on the other, or by embedding one dataset within the other so that one supports the other (Creswell and Plano Clark 2007). This mixing of the data allows a more complete picture of the problem than either dataset could provide individually.

A mixed method approach was utilised within the validation site (Chapter 5.2) where a sequential explanatory design (QUAN emphasized) consisting of two distinct phases was used (Creswell 2009). Utilising a mixed method approach is becoming more common in QI and health services research in the UK and is motivated by the perceived deficit of using a quantitative a qualitative method alone to address the complexity of research in health care settings. The approach was pragmatically chosen within the validation site to allow both an inductive and deductive approach to help understand if, how, and why the model to manage variability worked as a QI method within the clinical microsystem studied. A mixed method approach was chosen over a purely quantitative and qualitative approach because the combination of both within a single program of inquiry, would allow the complementary strengths of each approach to yield a greater insight into the complex intervention being studied, than either approach alone.

4.3 Methodological overview

Chapter 2 articulates that whilst the empirical and experiential evidence for implementing the model to manage variability is lacking (it has not previously been adapted for use as a QI method in NHS clinical microsystems), there is a strong theoretical basis for the approach. This is important, because it is reasonable to expect that the model will be able to help deliver improvements to quality of care. Walshe (2007) argues that the theoretical framework for a QI approach (why and how it works) is more important than its empirical performance (whether it works). Walshe's (2007) reasoning has particular resonance in this example because of the need to improve outcomes within orthopaedic surgery, and the NHS more generally.

The responsible solution is to therefore implement the model and concurrently evaluate the outcomes and experience thoroughly through rigorous scientific enquiry. This should ideally occur in a process that will not only evaluate whether the model works, but also provide generalisability of any findings to other healthcare settings. The aim should be to establish when, how, and why it works (Walshe 2007), and in doing so, help understand the complex relationship between context, content, application, and outcomes. This will provide a situational understanding of the effectiveness of using the model to manage variability within clinical microsystems to improve care processes.

In healthcare the assessment of whether improved outcomes are found following an intervention can be evaluated in many ways, and the randomised controlled trial (RCT) is often regarded as the optimum. In QI research, adaptions of RCTs such as stepped-wedge cluster-randomised controlled trials are also increasingly being used. These approaches are chosen so that judgements on internal validity and external validity can be made. Establishing external validity or the generalisability of whether an intervention is likely to have similar effects in other settings is important. If methodologies such as an RCT are judged to be not suitable (as is the case in many QI efforts), an attempt to increase the generalizability of findings should be provided and explained.

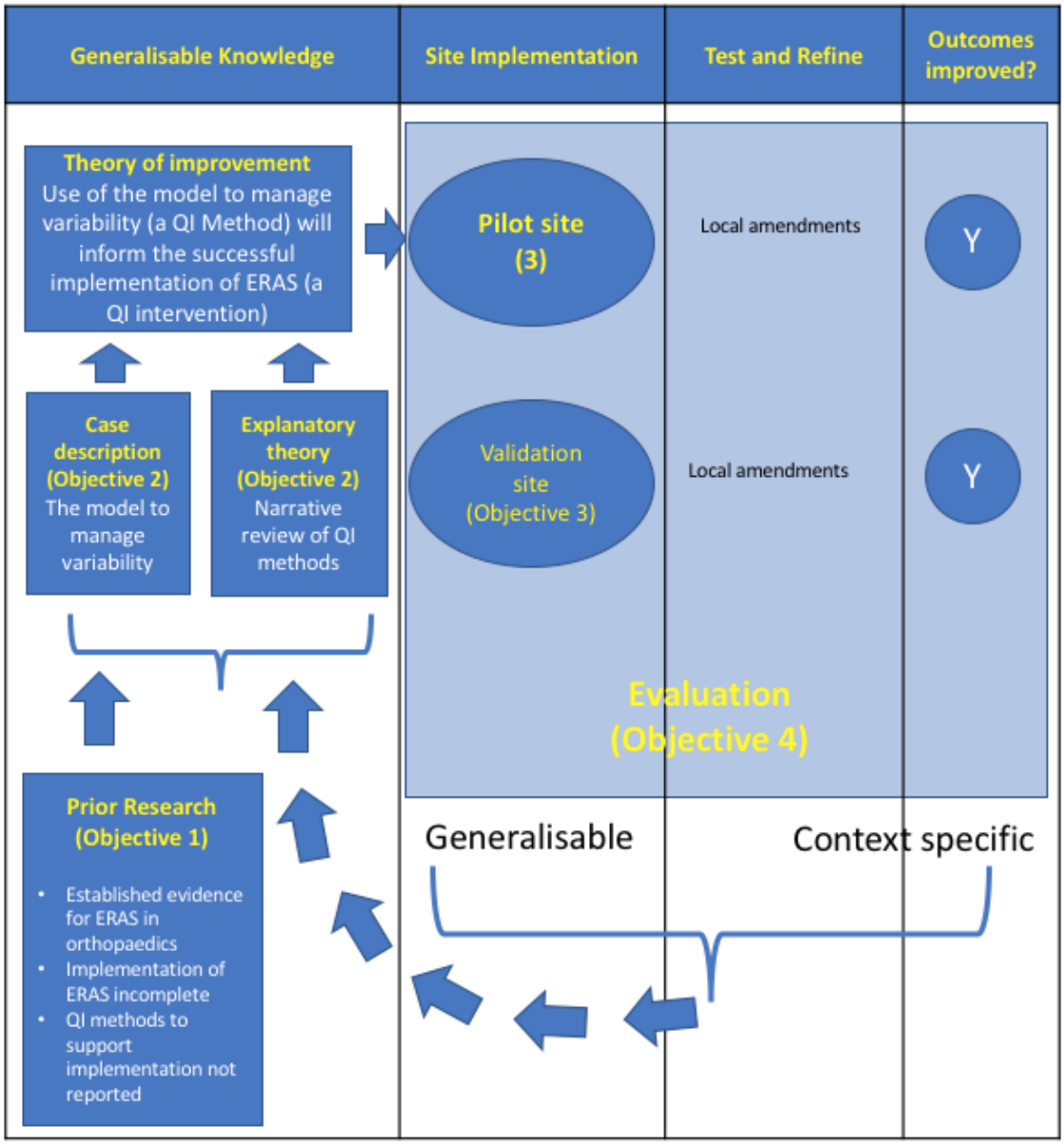
A suitable method of considering the generalisability of a QI method, such as the model to manage variability in this study, is the programme described by Ovretveit et al. (2011). The improvement replication programme is designed to evaluate multiple studies of different implementations of the same QI method (Ovretveit et al. 2011). The programme has been adapted and is shown in *Figure 5.* The aim of the programme is to provide a rationale for a QI approach, before understanding how the QI approach was implemented in different contexts, with the aim of being able to provide information so that judgements on the generalization of implementation and outcomes can be made.

Such a programme evaluation approach is a valuable but underused framework within quality improvement study designs, and programme evaluations are recognised as being able to provide valuable insights (Portela et al. 2015). The

use of programme evaluations has evolved mainly in the field of social care but are now being increasingly used in healthcare. The approach tends to be a theory-driven approach to evaluation, to establish whether something works, as well as seeking to understand the underlying mechanisms or how it works (Weiss 1997). Programme evaluations are pragmatic about what is feasible when it is understood that there are priorities focused on outcome, as well as answering a research question that needs to consider the influence of external contexts and how an intervention may change over time.

The programme described by Ovretveit et al. (2011) has been adapted for the purposes of this research in order to inform the design of a rigorous approach for evaluating the introduction of a model to manage variability within two elective orthopaedic clinical microsystems. The adapted programme provides a link between, and explanation for the stated research objectives. The adapted programme (*Figure 5)* illustrates the relationship of each of the research objectives within the thesis, and how they correspond with the process outlined by Ovretveit et al. (2011). In addition, details of the reporting guidelines to be used for both the pilot and validation site are provided, and these are further outlined in *Figure 6*.

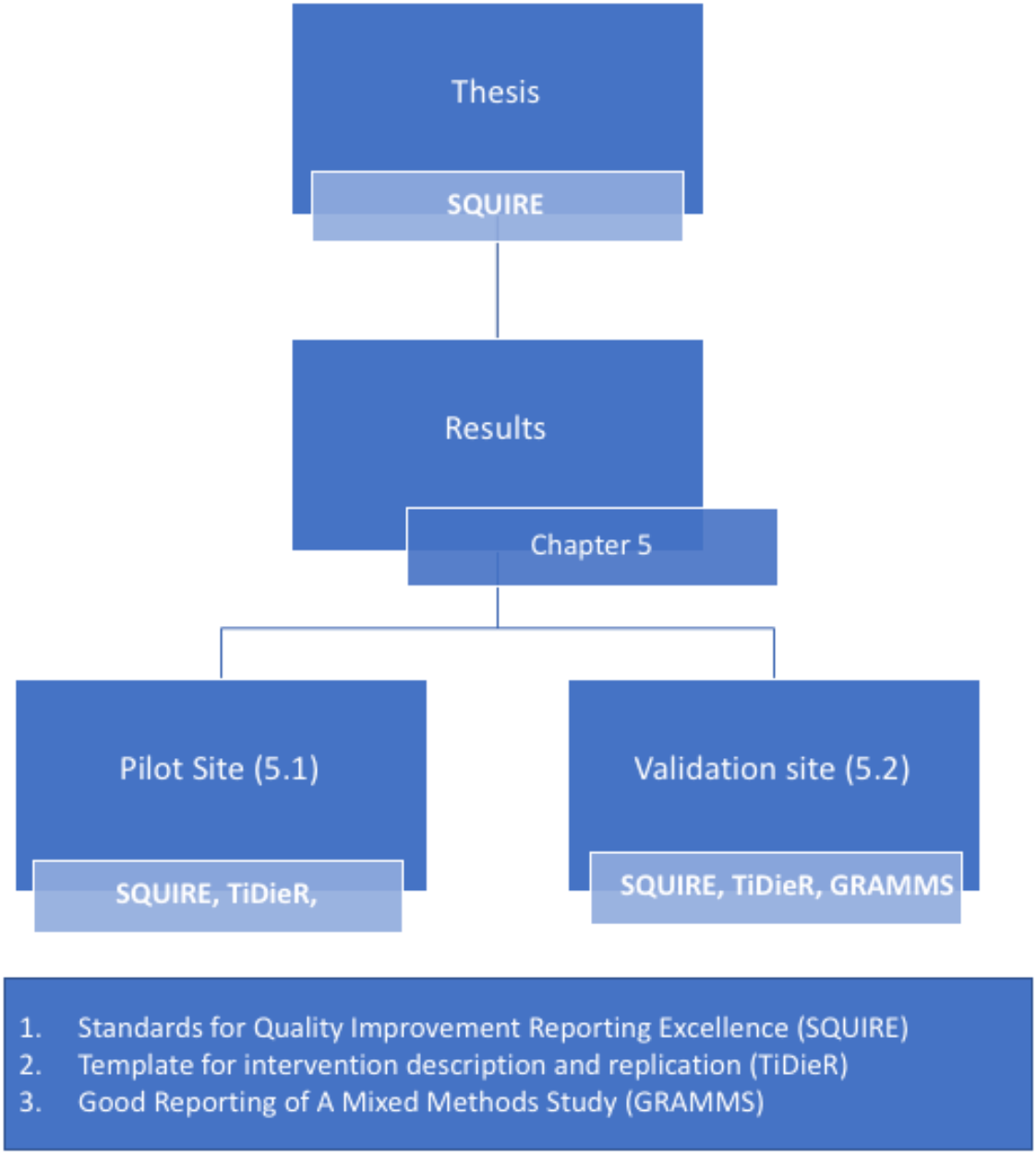
Figure 5 - The improvement replication programme (based on a model to increase the generalisability of research as proposed by Ovretveit et al. (2011))



Research objectives

1. To establish the need for improving the implementation of ERAS pathways within elective orthopaedic clinical microsystems and the potential role of QI methods to help do this
2. To investigate relevant theories and determine a theoretical framework for the model to manage variability to be used as a QI method to improve clinical care processes within clinical microsystems
3. To use the model of variability as a QI method to inform the implementation of ERAS (a QI intervention) within two elective orthopaedic clinical microsystems (a pilot and validation site).
4. To evaluate the success and generalizability of applying the model to manage variability as a QI method, through an improvement replication programme

Figure 6 - Reporting guidelines



4.4 Methods

The SQUIRE guidelines (Ogrinc et al. 2016) have been utilised to structure this thesis and they provide a framework for reporting the method used. However, as outlined in *Figure 6*, they are also used to report the implementation of the model in both the pilot site (Study 1) and the validation site (Study 2). Both Study 1 and 2 are reported as individual studies within Chapter 5, and Study 2 is one of the integrated papers within the thesis. Therefore, this methods section will where possible not duplicate details to be covered in Chapter 5 but will elaborate on methodological details and considerations that are not consequently provided due to the formatting required to prepare the studies for publication, and the requirements of the SQUIRE reporting criteria.

4.4.1 Setting

The clinical microsystems studied in the pilot and validation site were both based in high volume elective orthopaedic centres within the NHS, and specific details of location and surgical volume are provided in Chapter 5. The sites were selected based on convenience and opportunity, and a “judgement sampling” strategy was used (Perla and Provost 2012). Judgment sampling relies upon those with subject expertise to select useful sites for learning about a QI method and QI changes over time. When the research aim is to learn about a specific QI method, judgment samples are not only the most convenient and economical approach, but they may be argued to be the most technically and conceptually appropriate approach. This is because QI research is completed in the real world and in this case, complex clinical microsystems with a specific area of concern and focus (Perla and Provost 2012).

The pilot site, The Royal Bournemouth Hospital was “chosen” as that was where the researcher worked (2007-10) when the idea for this work was first conceived and implemented. Finding the validation site was difficult, there was often interest

from individual clinicians at hospitals, but they were then unable to engage and mobilize the rest of their team to commit to the process of implementing the model. Over the course of 2011/12 several potential sites showed interest but then fell through.

The validation site was therefore selected after the researcher presented the model and results from the pilot site, at the ERAS UK conference in November 2012 (Wainwright 2012). The researcher made an appeal to see if any other sites would like to act as a validation site for the model and the clinical lead from the Golden Jubilee National Hospital (GJNH) approached the researcher afterwards. The researcher subsequently visited the hospital to meet informally with clinical leaders and hospital executives and presented the model and proposal for evaluation. They agreed to proceed, and the project started in January 2013.

Whilst the sites have homogeneity in terms of volume and type of workload, their location and the demographics of patient populations are contrasting. The Royal Bournemouth Hospital is a district general hospital based on the south coast of England serving an elderly population. Whereas the GJNH is based in Glasgow, Scotland. It serves both an inner-city population, and acts as a national centre, taking patients from remote parts of Scotland with no local services.

4.4.2 Planning the intervention

For both studies a thorough explanation of the QI method and the QI intervention will be provided so that they can be reproduced. Details of how the model to manage variability (the QI method) was used to support and facilitate the QI intervention (ERAS pathway changes) will be specified, and summarized using the template proposed by Jones et al. (2014a). This template incorporates the TiDieR checklist which was created to improve the completeness of reporting, so that interventions can be reliably replicated (Hoffmann et al. 2014). The template also collects specific data regarding the QI method. Information concerning what was done and by whom are captured, from the initial stages, through to the training, implementation, and evaluation stages.

4.4.3 Planning the study of the intervention

4.4.3.1 Pilot site – Study 1

The design for the pilot study was a retrospective before and after observational cohort study examining outcomes from routinely collected health data. This was a two-condition design, where the first condition is a baseline, and the second condition occurs after the intervention (Robson 2002). The SQUIRE guidelines (Davidoff et al. 2008) are used as a framework to report the findings, with the TiDieR checklist used to report the intervention (Hoffmann et al. 2014).

4.4.3.1 Validation site – Study 2

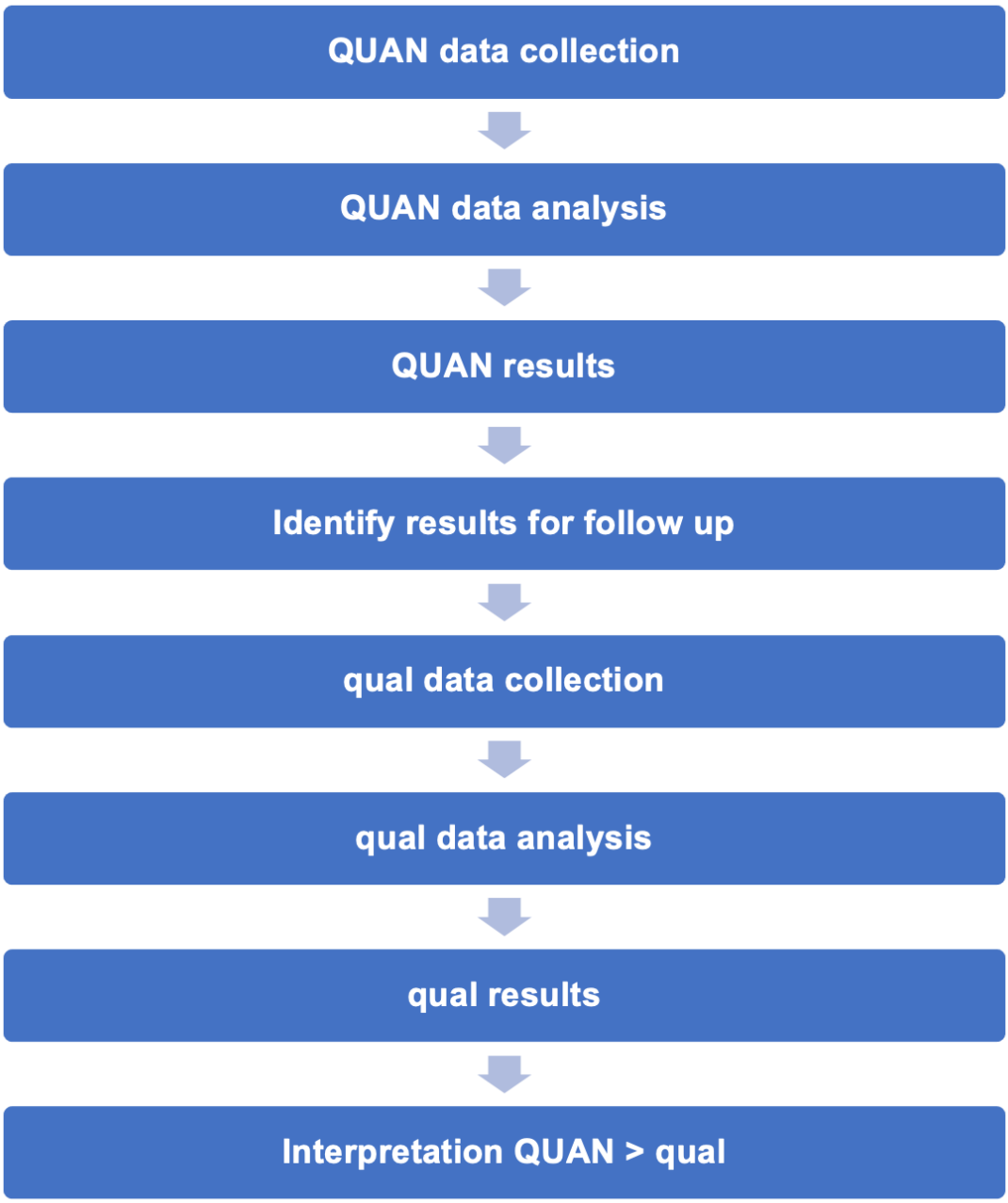
The validation site was a prospective before and after cohort study design, utilising a mixed-methods sequential explanatory design (QUAN emphasized) that consisted of two distinct phases. A quantitative phase followed by qualitative phase was used to evaluate the implementation of the model (Creswell 2009). This is summarised in *Figure 7*. Data from the pilot site in Study 1, informed the choice of this study design so that the process of data analysis could be enhanced to improve interpretation reliability. The use of SPC charts to evaluate the chosen outcome measures was continued, given the success of their use in Study 1, and confirmation from the wider literature that their use in QI research is both suitable and recommended.

The use of qualitative data collection techniques has been recommended in quality improvement research to allow for a better understanding of the outcomes achieved, and to help explain the mechanisms of change involved (Portela et al. 2015). In this case, randomisation and the use of controls was practically impossible. A prospective uncontrolled before and after study was therefore chosen as a practical solution but provided limitations to the generalisability of the findings. Therefore, this limitation was addressed (to a certain extent) by

formally mixing qualitative data collection with quantitative data using a formal mixed-methods approach.

The SQUIRE guidelines (Davidoff et al. 2008) were again used as a framework to plan, structure, and report the findings of this mixed-methods approach. This is because the SQUIRE guidelines are internationally recognised as the Standards for Quality Improvement Reporting Excellence. The checklist consists of 19 items that should be considered when describing formal studies of QI. Most of the items in the checklist are common to all scientific reporting, but virtually all of them have been modified to reflect the unique nature of QI work within healthcare. Within this SQUIRE framework the TIDieR checklist (Hoffmann et al. 2014) is used to describe the intervention, and the GRAMMS checklist was used to inform the reporting of the mixed-methods component (O'Cathain et al. 2008).

Figure 7 - A flow chart to illustrate the explanatory sequential design: Follow-up explanations model (QUAN emphasized) that is used in the validation site*



Explanatory mixed-methods design: Follow up explanatory model and notation adapted from Creswell 2009.

* The primary method is indicated with uppercase letters (i.e. QUAN) and the secondary method with lowercase letters (i.e. qual).

4.4.4 Measures

4.4.4.1 Quantitative phase (Study 1 and Study 2)

In Study 1, and in the first stage of Study 2, quantitative data was collected from the elective care microsystem being studied and then analysed. Routinely collected baseline data (before the introduction of the model) was analysed against data collected following the implementation of the model. SPC charts, in addition to traditional statistical analysis, were used to evaluate process changes over time. The data was a mixture of both process and outcome measures relevant to the project aim and clinical microsystem in which the study was set. Examples of process measures included length of hospital stay, and the achievement of timed milestones. At the end of this quantitative phase the aim was to establish whether the intervention was successful or not at improving the outcomes within the clinical microsystem.

4.4.4.2 Mixing / connecting data (Study 2 only)

Within Study 2, there was a second qualitative phase of the evaluation, that built on the initial quantitative phase, and the two stages were connected by this intermediate stage of the study. The rationale for this approach is that the quantitative data collected and analysed established to what extent the intervention (the model to manage variability) was successful at improving process measures and/or clinical outcomes within the clinical microsystem. This rationale was developed following considerations to the limitations of the first study design (Chapter 5.1.4), and consideration of the wider literature (Chapter 4.2).

Once it was established quantitatively whether the intervention was successful or not, the qualitative data and analysis in the next phase then sought to refine and explain the outcome by exploring the how and why the intervention was either successful or not (Rossman and Wilson 1985; Tashakkori and Teddlie 1998; Creswell 2009).

This explanatory sequential design is a two phase mixed-methods design and was chosen so that the qualitative data in the second phase could help to explain or build upon the initial quantitative results (Creswell 2009). The design was well suited to the validation site because the qualitative data was used to explain the results (Morse 1991). It also provided an understanding from the staff perspective of how easy the model was to implement, use, and manage within the clinical setting. The information generated here was vital for refining conclusions regarding the model before on its generalisability and subsequent potential use in other elective clinical microsystems.

The methodology chosen is considered one of the most straightforward of the mixed method designs (Creswell and Plano Clark 2007) and it had some clear advantages for this study. The two-phase structure made it easier to implement in a clinical setting because one type of data could be collected at a time, and during the first implementation stage staff working within the unit could collect this data independently.

4.4.4.2 Qualitative phase (Study 2 only)

In this second stage of the mixed-methods sequence, qualitative data was collected and analysed and used to help explain and elaborate on the quantitative results achieved in the first phase. This qualitative data was collected using interviews of staff members who led the implementation of the model. The open-ended questions used within the interview were informed by the mixing phase and were designed to explore the contextual factors surrounding the implementation of the model and the project. The contextual factors included in the Model for Understanding Success in Quality (MUSIQ) (Kaplan et al. 2012) were used as a prompt to ensure that all relevant contextual factors were considered. The MUSIQ model is a conceptual model that was designed by QI experts following a systematic review and Delphi methodology. It may be used by organisations and QI researchers to understand the contextual factors affecting the success and/or failures of a QI project. Key members of staff who were centrally involved with leading the use of the model and the project were

interviewed. The aim was to get the perspective of those leading the change, as they are the likely decision makers in terms of choosing which QI method to use in a QI effort. Data collection consisted of observational notes recorded by the interviewer in addition to a recorded transcript.

4.4.4.3 Synthesis and evaluation (Study 2 only)

In this phase the results of both the quantitative and qualitative stages were interpreted and synthesized in relation to the evidence base. A summary of the most important successes and difficulties in implementing the model, and the main changes observed in care delivery and clinical outcomes because of the model. A comparison and evaluation of the study results considering the evidence base was drawn on the broad review of context in Chapter 3, the theoretical aspects discussed in Chapter 2, and the results from the pilot site. Consideration was given to possible sources of bias or imprecision in design, measurement, and analysis that might have affected the study outcomes (internal validity). Factors affecting external validity such as the generalisability of the model due to elements such as the representativeness of participants or features of the clinical microsystem setting were also considered. Consideration was also given in relation to the sustainability of any changes i.e., the likelihood that any observed gains might weaken over time.

4.4.5 Analysis

4.4.5.1 Statistical analysis of the quantitative phase (Study 1 and Study 2)

Outcomes such as LOS were assessed in both studies by using Statistical Process Control (SPC). The use of SPC to monitor process change requires at least two phases, which have two different objectives. In the first phase, the initial step is to apply SPC to baseline data, which can then be used to provide the control limits for monitoring the future process (Mohammed et al. 2008). At this stage the SPC defines what outcome the process is capable of producing given its current design and operation. The second phase, in this case occurring

successively in time after the first phase and the introduction of the implementation, then evaluates the change in process and assesses whether it has been enough to statistically change the process by introducing special cause variation.

SPC is widely used when evaluating QI interventions in healthcare because statistically derived interpretation rules can be applied to an SPC and then used to determine whether there is a causal relationship between an intervention and a related outcome (Benneyan et al. 2003; Thor et al. 2007). This is important to ensure internal validity, because it is acknowledged that not all QI interventions and process changes will result in an improvement to the desired outcome (Chetter 2009b).

The control charts used for SPC analysis were created using the QI Macros software in Windows Excel (KnowWare International Inc, http://www.qimacros.com). For outcomes such as LOS, data was charted using an XmR (X stands for observation, and mR stands for moving range) chart. The control charts created in QI Macros display each measurement of process performance, along with the mean and upper and lower control limits (UCL and LCL respectively). The UCL and LCL represent three standard deviations (SDs) from the mean, and when a process is in "statistical control" define the range of variation in performance expected.

Statistical theory states that 99.73% of all data points should fall between the two control limits when a process is stable or unchanged (Callahan and Griffen 2003). The likelihood of a value falling outside of the control limits when a process is unchanged is 0.27%, and so therefore the value is unlikely to have resulted from random variation in the process (Chetter 2009a). Any outlying values are said to represent special cause variation and are highly relevant. They indicate when a process is being influenced by an extrinsic non-random event that causes the performance of the process to change.

In accordance with other studies in healthcare (Chetter 2009b), the following five tests were selected to detect special cause variation when the control charts were constructed in QI Macros:

- One point occurring more than three SDs from the mean
- Eight points in a row above or below the mean
- Six points in a row increasing or decreasing
- Two out of three successive values falling above or below the 2-sigma line
- 15 points in a row fall within 1 sigma from the mean.

4.4.5.2 Analysis of the qualitative phase (Study 2 only)

For the qualitative data, the process of analysis started with familiarization of the data, before organising and preparing the data for analysis. Thematic analysis was then undertaken through a process of coding themes from the interviews relating to the contextual factors included in the MUSIQ (Kaplan et al. 2012). The data was then interpreted considering both the quantitative and other qualitative findings. Thematic analysis was chosen as a method because of its flexible approach that could be modified to the need of the study, whilst providing a rich and detailed account of the data (Nowell et al. 2017). The aim of the analysis was to enable an understanding of how the intervention worked or failed to work from the perspective of the individuals involved in leading the project. There were 6 phases to the analysis, as recommended by Nowell et al. (2017). After familiarization with the data, initial codes were then created (accompanied by reflexive journaling), and then themes were searched for. These themes were then reviewed and triangulated before they were defined and named.

Thematic analysis was employed to analyse the qualitative data obtained from the open-ended questions informed by the MUSIQ framework and was chosen to search for and identify the common themes running throughout the data (Morse & Field, 1995). Specifically, thematic analysis was used because it allows for higher induction levels than other qualitative techniques such as content analysis (Ezzy 2002). Furthermore, Boyatzis (1998) confirms that a thematic approach to qualitative data analysis is recommended when conducting preliminary studies,

and it “helps the researcher focus, formulate hypotheses, or build a mode of probably causality” (p.129).

The use of thematic analysis is advantageous because of its accessibility for use (Nowell et al. 2017) whilst at the same time being recognised as a powerful method for analysing data that can be applied across a wide range of data sets. However, the flexibility that thematic analysis offers can also be seen as a drawback because it is perceived by some as lacking rigour (Clarke and Braun 2013). This may be due to the flexible nature of its method, that can make it challenging for some researchers to determine which aspects of data to focus on for their analysis (Braun and Clarke 2006). Therefore, the fact that the MUSIQ has been proven to be useful in helping QI implementers reflect on aspects of context that are important in the ultimate success of their QI project in a systematic way (Kaplan et al. 2012), was an important determinator and rationale for its use in the study. Indeed, the creators of the MUSIQ have highlighted that the MUSIQ is suitable for guiding both the collection and analysis of data in QI projects occurring in real-world, especially those that have the goal of creating generalisable knowledge to support more effective implementation of QI methods in healthcare (Institute of Medicine 2007).

4.4.6 Ethical issues

The project was provided with ethical approval by Bournemouth University (Reference ID:177) *(Appendix 3)* and did not require NHS Research Ethics Committee approval according to the Health Research Authority decision tool which utilises the UK Policy Framework for Health and Social Care Research. However, full ethical consideration was given to the project by utilising published guidance and policy templates from the Healthcare Quality Improvement Partnership (HQIP). This ensured that participants’ interests and rights were properly protected throughout the study. The HQIP template provided outlines for best practice structures and mechanisms that provided an ethical oversight and formed the basis of a thorough governance framework. For example, the interviews in Study 2 were entirely voluntary. Before conducting the interviews, the participants (who were already familiar with the purposes of the study) had

the opportunity to ask questions about the process. They also signed a consent form and provided consent to use extracts of the recorded transcript data within the final thesis before taking part.

5.0 Results

This chapter presents the results found when the model to manage variability was used as a QI method to inform quality efforts in the pilot and validation site. In accordance with the methodological approach described in Chapter 4, the two studies are presented separately (Section 5.1. and 5.2), and the SQUIRE guidelines are used to report them both. Study 2 is one of the integrated publications as stated in *Table 1*, and a third paper (an integrated publication) is also presented within the results section, which is a retrospective QI report detailing subsequent work in the pilot site (Section 5.3). It presents the outcomes of an improvement effort when the model to manage variability (or any other QI method) was not used.

5.1 An observational study to evaluate a novel QI method (the model to manage variability) used to inform the implementation of an ERAS pathway to reduce LOS for hip and knee replacement (Study 1)

5.1.1 Introduction

This section (5.1.1) reports the details of implementing the model to manage variability within the pilot site. It is written and represented as a stand-alone paper, utilising the SQUIRE guidelines (Ogrinc et al. 2016), but has not been submitted for publication and so is not an integrated paper. The clinical details and outcomes of this work have been previously been published (Wainwright and Middleton 2010; Starks et al. 2014), however this paper provides the specific details of how the model to manage variability was utilised, and provides details of the context so that the generalisability of the model may be considered.

5.1.1.1 Problem description

From 2001 onwards there were a number of national programmes that aimed to improve quality and efficiency in elective orthopaedic services. However, considerable variation in practice still existed across providers. In 2005, the mean LOS for hip and knee replacement across NHS providers ranged from 4 days to 15 days, and the national mean for hip replacement was 10.6 days, and 9.7 days for knee replacement (Institute for Innovation and Improvement 2006). This variation in outcome was accompanied by an ongoing increasing demand for orthopaedic services, and a new referral-to-treatment target of 18 weeks in 2008. The concurrent introduction of the payment by results model also necessitated a focus on productivity not experienced before. Therefore, the challenge to orthopaedic services was to continue to deliver high quality care and high levels of patient satisfaction, but to do so for greater numbers of patients within existing or reduced capacity and facilities.

In 2007 the orthopaedic department at the Royal Bournemouth Hospital needed to maximise bed capacity in order to meet the 18-week referral-to-treatment target, and reduce individual procedure costs due to the payment by results tariff and foundation trust status of the hospital. When benchmarked nationally, there was also evidence for the potential to reduce LOS. The national mean LOS for hip replacement was 7.5 days, and for knee replacement it was 6.9 days, and data for the Royal Bournemouth Hospital indicated a mean LOS of 7.8 and 7.1 days for hip and knee replacement respectively. LOS was therefore acceptable, but some way behind the top performing trusts, where patients stayed an average of 4 days for both hip and knee replacement. The case-mix adjusted LOS for patients is presented in *Appendix 1 and 2.* The data is case-mix adjusted, and the methodology accounts for age, sex, method of admission, socio-economic deprivation, diagnosis, co-morbidities, ethnicity, source of admission, number of emergency admissions in the last 12 months, palliative care, year, and month of admission (Jen et al. 2011). The longer LOS at the hospital in comparison to the top performers, was therefore not due to a different case mix, but instead highly likely to be due to local care processes.

5.1.1.2 Available knowledge

Prior to the project, it was recognised that pathway changes and QI efforts were required in order to reduce LOS. A national report highlighted that entire service redesign was required, driven by clinical leadership, process changes, and the engagement of the whole multi-disciplinary team (Institute for Innovation and Improvement 2006). Multi-disciplinary clinical pathways were also being increasingly utilised to co-ordinate the care of hip and knee replacement patients, and the first report of fast-track in hip and knee replacement from Denmark found that 95% of patients needed a maximum of 5 days (mean LOS of 3.9 days) before they could be safely discharged home (Husted and Holm 2006). The improvements to care achieved by using these pathways were thought to be mainly due to the increased organisation of care processes. Further, it was noted that if the patient pathway was highly structured and standardised, and if the

multi-disciplinary team were involved in the development and production of the pathway, then improvements to patient care were possible.

5.1.1.3 Rationale

The need for the multi-disciplinary team to utilise a specific QI method that could inform the changes and interventions required to implement the new ERAS pathway was identified. The model to manage variability was chosen because it was identified as a QI method that could help to reorganise care process, and was felt to have the required sensitivity and format for managing variability that could be understood by the clinical team.

The model to manage variability works as a QI method by identifying sources of variability within the clinical microsystem that may affect the outcome measure seeking to be improved. Sources of variability are identified by using a driver diagram (or cause and effect diagram), and then sources of variability are either classified as artificial or natural variability. This is a distinguishing factor from the other QI methods such as Lean or Six Sigma (and other interventions described in the narrative review, Chapter 2.2). An outline of the approach has been provided in in *Figure 2*.

The model, adapted from Litvak (2005) proposes that the artificial variability of care processes is the most likely barrier to providing efficient and high quality healthcare. Artificial sources of variability should therefore be removed, and natural sources of variability should be managed.

5.1.1.4 Specific aims

The project used the model to manage variability as a QI method, in order to inform the implementation of a new ERAS pathway within an elective orthopaedic

clinical microsystem. The specific aim within this clinical microsystem was to reduce the current LOS of over 7 days for hip and knee replacement to an average of 4 days for both procedures. This was to be achieved without changing discharge criteria or negatively effecting patient care. This aim was chosen because at the time of planning the new pathway, 4 days was the LOS achieved by the best units in the country (Institute for Innovation and Improvement 2006). The intended outcome was therefore clearly defined, and the study aim was to determine whether the model for managing variability was successful at helping to identify the required pathway changes within the local context, that would improve the pathway so that LOS was reduced.

5.1.2 Methods

5.1.2.1 Context

The work was undertaken by a clinical microsystem specializing in performing hip and knee replacement operations within an elective orthopaedic department serving a population of around 550,000 people. In the year preceding the pathway change the unit performed 1533 joint replacement operations. A clinical microsystem is described as a group of people working together to provide care to a specific group of patients (Nelson et al. 2007) and in this case it represents the entire inter-disciplinary team involved in the care of joint replacement patients.

The decision to change the service was led by a lead surgeon, who created the vision and belief that the goal could be achieved. This individual ensured board level support, and the necessary co-operation of his consultant colleagues to enable the project to commence. A pathway manager conceived and led the QI effort and coordinated a project team, consisting of a lead anaesthetist, lead surgeon, ward sister, senior physiotherapist, and a theatre sister. This core team worked closely and coherently, allowing changes to be introduced along the patient pathway and across the whole inter-disciplinary team. The team had the opportunity to move the physical location of the ward and so coincided the start of the intervention with the move to the new ward.

5.1.2.2 Intervention

The model to manage variability explained in Chapter 2 was used to identify, classify, and manage the intrinsic sources of variability contributing to the current patient LOS within the clinical microsystem. By employing this framework, the team was able to co-ordinate improvement efforts to focus on the specific objective of the project.

The first stage was to undertake an analysis of current processes and to identify sources of variability that were contributing factors to the current LOS experienced by patients. This was coordinated by the Pathway Manager, and a workshop involving leaders from across the multi-disciplinary team was held in order to identify and agree causes of variability within the system that affected LOS. The team included a surgeon, anaesthetist, ward sister, theatre sister, therapy lead, radiographer, pharmacist, administrative staff leader, and the orthopaedic directorate manager.

This was completed in June 2007 and the outputs were summarised by the group in a cause-and-effect diagram (*Appendix 4)*. This was used to depict and identify all of the possible sources of variability that affected the current patient LOS. Once these variables or causes of variability were identified, they were classified into either “natural” or “artificial” causes of variability in accordance with Litvak’s (Boston University Health Policy Institute 2006) definitions (Chapter 2.3.1). Natural variability can be thought of as the naturally, and randomly occurring differences of one patient from the next, and so causes that were naturally variable and thought to affect LOS included factors such as the age and sex of patients. Conversely, artificial variability is not naturally occurring and does not randomly occur. It arises in a care process because of management decisions, and so because it is not randomly occurring may be altered or removed. An example of artificial variability thought to affect LOS was the staffing levels and rotas of physiotherapists at the weekend.

Following the identification and classification of variability, the first active step was to eliminate the artificial variability from the care processes of the system. Litvak (Boston University Health Policy Institute 2006) explains that artificial variability should not be accepted or worked around. Changes were therefore introduced to remove artificial variability from the delivery of care processes, and the details of what was changed, and by whom can be seen in *Table 4*. Once artificial variability had been eliminated, causes of natural variability were managed where possible. Details of changes made to the care processes to manage natural variability are also provided in *Table 4*. Changes were reported in accordance with the TiDieR principles (Hoffmann et al. 2014) and the TiDieR checklist is available in *Appendix 5.*

Table 4 - Identification, classification, and management of variability in Study 1

	Identification		**Classification**	**Management**	
	Factors from the cause and effect diagram that the MDT identified as influencing current LOS	**Detail of cause and description of variability**	**Type of variability**	**Change to care process to be introduced (all changes introduced from when the intervention commenced)**	**Evidence for success of change to care process (data and evidence source provided where appropriate)**
1	Time between admission and operation	All patients were admitted the day before surgery at the same time independent of their order on the operating list	Artificial	Remove variability and unnecessary waiting time for patients. The theatre scheduling team, arranged to admit all patients on day of surgery and introduce staggered admission times depending on order of operating list.	Achieved. 99.9% of patients were admitted on the day of surgery. Mean time from admission to operation was 2hr 45min (Wainwright and Middleton 2010)
2	Time to first mobilisation	Physiotherapy staffing levels varied throughout the	Artificial	Remove variability of staffing levels. The physiotherapy team introduced a	Achieved. Mean time from recovery to first physiotherapy

		week and meant that the day of operation and time of return from theatre would affect the time to first mobilisation. No weekend cover.		7-day rota, with 8am-8pm working hours (Mon-Friday), and 8am-4pm at the weekend.	was 7hr 31min (Wainwright and Middleton 2010)
3	Type of anaesthetic	Some types of anaesthetics allowed patients to be mobilised earlier than others and there was variability in practice between health professionals	Artificial	Remove variability. The anaesthetist's introduced a standardised anaesthetic protocol	Achieved. Standardised anaesthetic and analgesic protocol were provided, but with some exceptions due to patient preference or medical rationale (Wainwright and Middleton 2010) Over 95% compliance to the pathway reported (Webster et al. 2009)
4	Analgesia	Pain was managed for some patients better than others, and there was variability in practice between health professionals	Artificial	Remove variability. The anaesthetist's, nursing staff, and pain team introduced a standardised analgesic protocol	
5	Nursing pathway	There was no standardised nursing care pathway and so the timing of nursing interventions varied from patient to patient	Artificial	Remove variability. The nursing and therapy staff led the introduction of an MDT care pathway document with daily milestones and timeframes	Achieved. New pathway document introduced.
6	X-ray	X-rays were only available once a day and there was no x-ray available at the weekend, which both could delayed discharge	Artificial	Remove variability. Radiographers and introduced x-ray provision on Saturday and worked with nursing staff to provide flexibility for timings of x-ray	Achieved. New way of working implemented.
7	Discharge process	Waiting for medications and discharge letters frequently	Artificial	Remove variability. Nursing staff, ward doctors, and pharmacy introduced a	Achieved.

		delayed discharge. There was no accepted standard and so time for completion varied		proforma for discharge letters and ordering medications to go home with	
8	Ward environment	Patients appeared to recover better in different wards, and in also in single rooms when compared to shared bays	Artificial	Remove variability. Ward and department managers agreed to treat all patients on the same ward which had single rooms for all patients	Achieved.
9	Staff expectations, knowledge and skills	Expectations of how long patients should stay in hospital varied between staff and staff groups	Natural	Variability managed. Pathway manager introduced and led monthly MDT training and teaching so that all team members were updated and new members of staff were trained. Weekly feedback of LOS data and patient outcomes to the whole MDT.	Achieved. Evidence form NHS staff survey that staff received regular training.
10	Patient expectation	Patients had different expectations of how long they would stay in hospital	Natural	Variability managed. Nurses, physiotherapists, and occupational therapists introduce a pre-operative education class that all patients had to attend before admission. Patient information and letters were updated.	Achieved.
11	Patient demographics	The age, sex, functional and social status of each patient was variable	Natural	Variability managed. Occupational Therapist led the introduction of using the RAPT scoring system. A validated system for identifying patients preop at risk of an extended LOS. Discharge provisions and plans put in place	Achieved. The RAPT score correlated with LOS, and so could be used prospectively to make discharge plans for those patients likely to stay longer in hospital (Wainwright and Middleton 2010)

				ahead of time for these patients.	
12	Patient symptoms	Each patient's response to treatment, initial degree of symptoms, anxiety, and perception of pain was different	Natural	Variability managed. Nurses, physiotherapists, and occupational therapists introduce a pre-operative education class that all patients had to attend before admission. Patient information and letters were updated	Achieved.

Once the methods to remove artificial variability, and manage natural variability were identified, the new care processes were introduced together (at the same time) to the clinical microsystem at the start of intervention period. There was no change phase. The team decided to work on the new pathway "offline" and then implement the changes all together when the clinical microsystem moved to a new ward.

5.1.2.3. Study of the intervention

The design was a before and after retrospective observational longitudinal cohort study examining the impact of introducing changes to care processes (as identified by the model to manage variability), on LOS for hip and knee replacement patients. It was a two-condition design, where the first condition was a baseline period, and the second condition was the intervention period. The effect of the process changes described in *Table 4* were measured by collecting and analysing data for LOS, the outcome measure of the improvement aim. It was the working assumption that if the observed outcome improved, then this would be due to the interventions made, and the subsequent inference that the model to manage to variability had been an effective QI method.

5.1.2.4 Measures

The primary outcome measure used to evaluate the outcome of the intervention was LOS. LOS is commonly used as a proxy indicator of quality and is the widely used outcome measure for the implementation of ERAS. Regarding this project, LOS was also considered a relevant, reliable, and valid outcome measure, that was both feasible to obtain and had good usability. LOS was measured as the number of midnights between the date of admission and the date of discharge. Data was extracted from the hospital administrative data system and checked for accuracy and completeness against local (clinical microsystem level) audit data.

The following clinical balancing measures were also evaluated and were chosen to ensure that the changes introduced by the intervention to reduce LOS did not have unintended negative consequences.

- 28-day re-admission rate - A readmission was defined as being readmitted to an English trust as a non-elective emergency admission within 28 days of discharge. Data accuracy and completeness was ensured by asking patients at their one-year post surgery follow up appointment, and by interrogating national HES data via the Dr Foster software portal.
- Complication rate - A complication was defined as any complication requiring medical referral and management. Data accuracy and completeness was ensured by asking patients at their one-year post surgery follow up appointment, and by interrogating local hospital records via the hospital patient record system.

A further measure to provide insight into the related context of the clinical microsystem was also evaluated.

- Staff satisfaction – All staff working within the clinical microsystem were invited to complete the annual national NHS staff survey, and the results were compared with the rest of the hospital and the national results.

5.1.2.5 Analysis

Statistical Process Control (SPC) was used to monitor the change in LOS between the baseline and intervention stage (the theory and rationale for utilising SPC charts has previously been explored in Chapter 4.4.3). In the baseline phase, the initial step is to apply SPC to the data, which can then be used to provide the control limits for monitoring any change to LOS in the intervention phase (Mohammed, Worthington, and Woodall 2008). There are many different types of control chart, but because LOS can be considered to be continuous data, the xmr-chart was judged appropriate (Mohammed et al. 2008). LOS was evaluated by calculating mean LOS monthly, and then presenting the monthly data as consecutive points. Data for the year prior to the intervention (August 2006 – July 2007) is presented, along with data from the start of the intervention until the end of the 2008/09 financial year (August 2007 - Mar 2009). The data from the baseline and post-intervention phases is presented continuously, and the mean and control limits were re-calculated at the time of intervention. The re-admission rate, complication rate, and staff satisfaction were analysed with simple descriptive statistics.

5.1.3 Results

The project team came together in May 2007 and began planning the QI effort. The pathway manager worked full-time on the project and led the team using the model to manage variability. The team shared an office and worked collaboratively throughout the intervention. In May 2007 a series of meetings with stakeholders across the inter-disciplinary team and hospital management helped to clearly define the project aim. The Pathway Manager conducted a scoping exercise of current best practice within orthopaedics and adapted the model to manage variability for use as a QI method. Staff members from all professional groups contributed to a cause-and-effect diagram, which aimed to identify all of the causes of variability that contributed to the current LOS. The core team then pulled out the key themes and factors that they felt most strongly influenced the current LOS following this consultation process (as shown in *Appendix 4* and *Table 4*. Where data was required to analyse specific factors, it was extracted

from the hospital patient record system, and HES data were interrogated using Dr Foster software. An example of this is shown for physiotherapy provision in *Appendix 6* and is a poster publication presented at the International Forum for Quality and Safety in Healthcare 2011 (Wainwright and Middleton 2011).

Following the identification of factors that were influencing current LOS, the team decided on the changes required to care processes to either remove artificial variability or manage natural variability. The results of this process are summarised in *Table 4*. The team then planned how the necessary changes would be implemented and agreed to initiate all the changes simultaneously when they moved into a new ward setting. This included the production of new protocols and clinical pathways of care, as well as changing staffing rotas, and re-organising the ward and theatre environment to be conducive to the proposed changes. These changes worked very well and the specific details of the clinical elements to the new pathway has been previously published (Wainwright and Middleton 2010).

It was decided that the new care processes that made up the intervention would change in August 2007 to coincide with the re-arrangement and movement of orthopaedic wards at the hospital. The changes were not made gradually; the decision was taken to introduce all the new care processes at once when the team moved into the new ward space. Once the change in care processes was introduced, weekly and monthly process management of LOS using SPC was continually undertaken to monitor LOS performance. This provided the inter-disciplinary team with a joint focus and ensured high visibility of the performance against the improvement aim.

5.1.3.1 Changes in LOS associated with the intervention

The SPC chart shows data for the baseline period, which was 12 months prior to the intervention, and then for 20 months following the introduction of the intervention. The data series presented includes 3492 patients, with 1298 patients in the baseline phase, and 2194 patients in the intervention phase. The

data is continuous and accounts for all patients operated on within that time period. There is no missing data. To present the data cleanly, monthly mean LOS was calculated to produce the xmr-chart. The xmr-chart consists of two charts, the x-chart and the mr-chart. The x-chart is a control chart of the 32 observed values, and the mr-chart is a control chart of the moving ranges of the data.

The charts show that prior to the intervention (in the baseline period) the process was stable. Immediately the intervention was introduced, there was a non-random reduction in the LOS, and given the timing of this change, it is highly likely to be a causal effect. The process within the intervention period them continued to remain stable. The mean LOS for joint replacements reduced from 7.8 days to 4.3 days.

Figure 8 - SPC (mr-chart) for monthly LOS (Study 1)

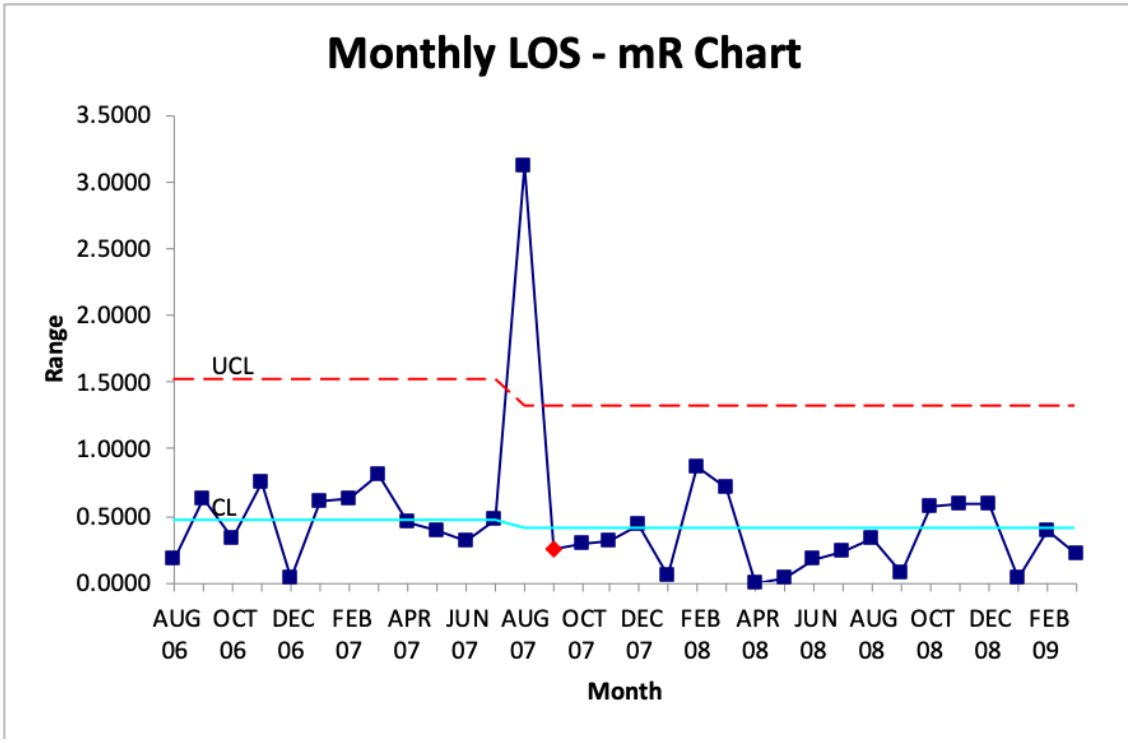
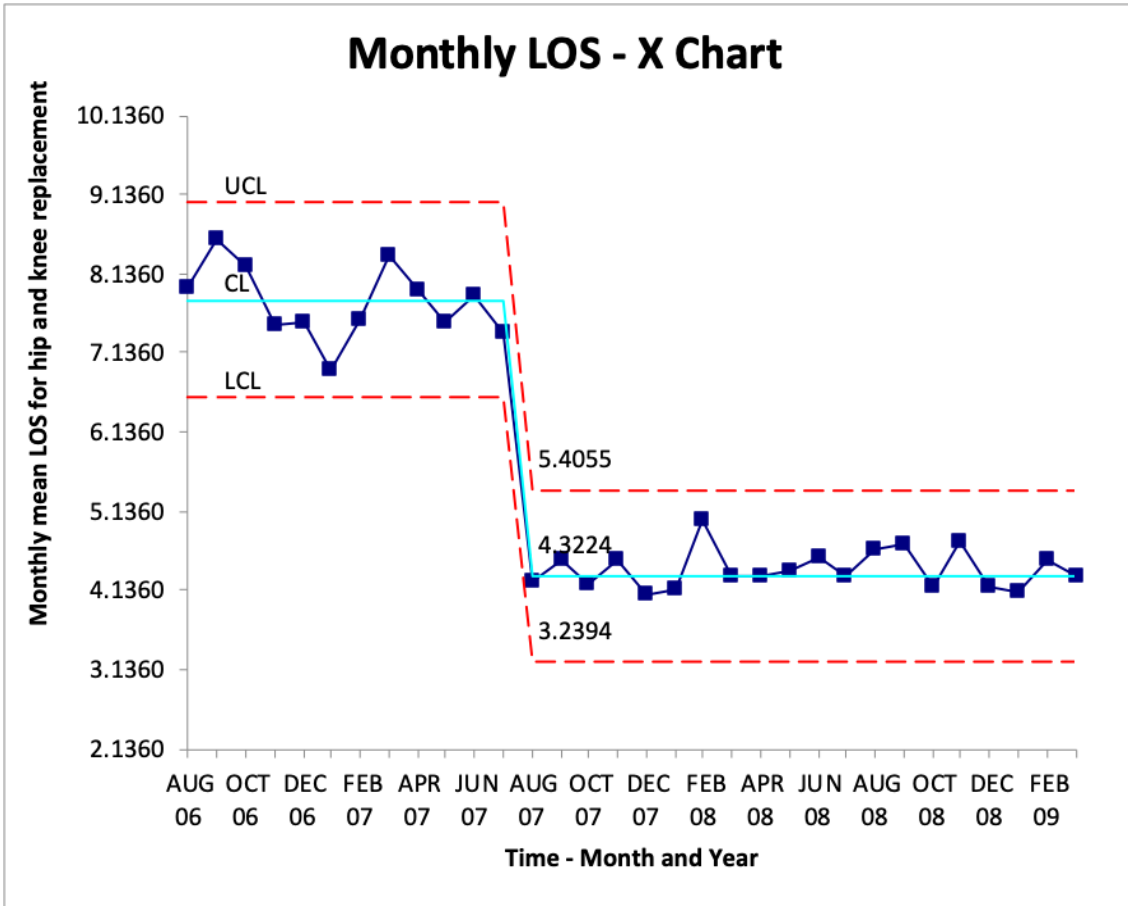


Figure 9 - SPC (xmr-chart) for monthly LOS (Study 1)



5.1.3.2 Balancing measures

28 day re-admission rate for patients within the intervention phase was 5.4%, and whilst accurate data was not available for the baseline phase to compare this to, this rate was lower than reported in other equitable ERAS studies at the time (O'Brien et al. 2005; Husted and Holm 2006). The changes to care processes did not adversely affect clinical outcomes such as complication rates post intervention. Full details of these results are provided in below in *Table 5* and *Table 6* and the rates reported are all within internationally recognized standards for joint replacement and have been reported previously (Wainwright and Middleton 2010).

Further analysis was subsequently completed to compare the effects of the pathway change in comparison to national data. This case-mix adjusted data has been published (Starks et al. 2014), and demonstrates that re-admission rate in the intervention phase was lower than the national re-admission rate (6.2%) over the same period of time. Additionally, 30-day mortality rate was also reduced (0.0% for all patients in the intervention group, compared to 0.1% in the baseline group, and 0.2% for patients nationally over the time of the intervention phase).

Table 5 - Complication rates for knee replacement patients post intervention

Detailing complication rates for primary hip replacements within the Bournemouth ERP series.

	Number	Percentage of all hip cases
Dislocation	18	1.7%
DVT	3	0.3%
Infection/wound problem	16	1.5%
Medical	21	2.0%
Nerve palsy	4	0.4%
Intra-operative fracture	6	0.6%
Post-operative peri-prosthetic fracture	1	0.1%
Head liner mismatch	1	0.1%
Stem failure	1	0.1%

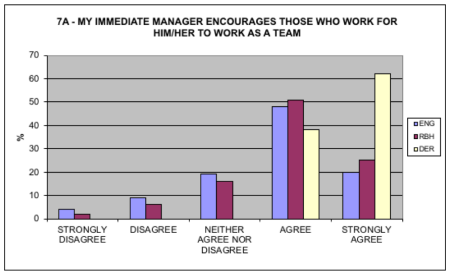
Table 6 - Complication rates for hip replacement patients post intervention

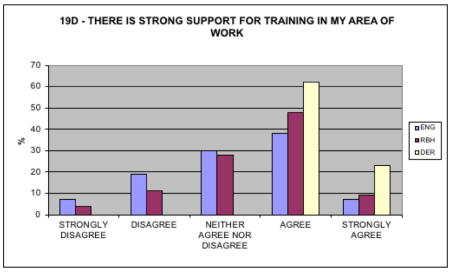
Detailing complication rates for primary knee replacements within the Bournemouth ERP series.

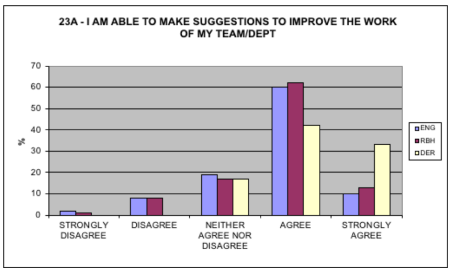
Unicompartmental	Number	Percentage of all Uni cases
Infection/wound problem	2	3%
Total knee replacement	**Number**	**Percentage of all TKR cases**
Haemarthrosis	6	0.5%
Stiffness	21	1.6%
Dislocation of rotating bearing	4	0.3%
Infection/wound problem	17	1.3%
Medical	25	1.9%
DVT	13	1.0%
PE	7	0.5%
Nerve palsy	1	0.1%
Intra-operative fracture	2	0.2%
Vascular problem/compartment syndrome	3	0.2%

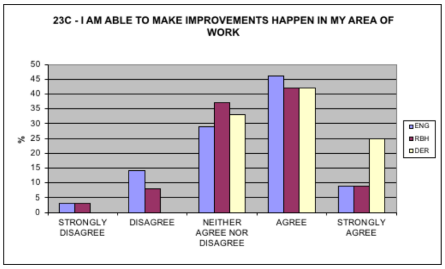
Further to the clinically related balancing measures, staff opinion was also surveyed via the NHS Staff Survey. Each year NHS staff are invited to take part in the NHS Staff Survey, and so in 2008 all team members of the clinical microsystem involved in this project were invited to complete the survey, so that results could be compared against the rest of the hospital and national benchmark. The average response from staff working within the clinical microsystem was higher than the hospital and national average across all questions. Some results are highlighted below, relating to questions known to influence QI efforts. Staff working within the clinical microsystem, reported a strong team ethic, support for training, and importantly all agreed or strongly agreed that they were able to deliver the patient care that they aspired to. Responses also indicated that staff felt able to suggest and make improvements to care, and that managers acted on this feedback.

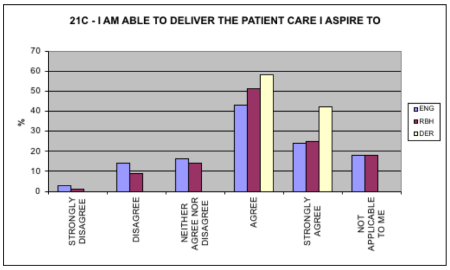
Figure 10 - Graphs to show staff responses to the NHS staff survey

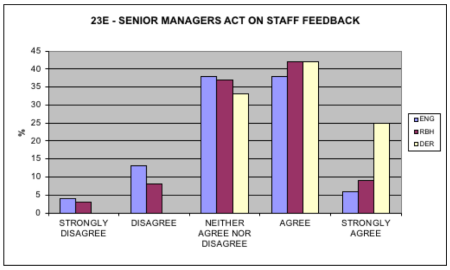












Key
ENG – National average for England
RBH – Hospital average
DER – Clinical microsystem involved

5.1.4 Discussion

5.1.4.1 Summary

A successful QI effort is one where a clinical team is able to deliver the intended improvements. Reducing mean LOS to 4 days was the specific improvement aim of the project, and this was achieved by a reducing mean LOS from 7.8 days to 4.3 days. This 45% reduction was both clinically and statistically significant, and was accompanied by low re-admission rates and complication rates. The clinical outcomes therefore compared very favourably with best practice (O'Brien et al. 2005; Husted and Holm 2006), and comparison to peers (Starks et al. 2014). The proposed changes to clinical process (informed by using the model to manage variability as a QI method) that made up the intervention, were all implemented successfully. This successful implementation process, accompanied by the explicit reporting of the intervention through utilization of the TIDieR checklist is a strength of the project. However, judgement on the generalisability of utilising the model to manage variability as a QI method in other settings, requires more consideration. The study methodology did not allow for explicit conclusions on the relative contribution to success of the model to manage variability against other factors. It is likely that other contextual factors known to also influence QI effort success, such as strong leadership, motivated staff (as evidenced in the staff survey), the move to a new ward, and a strong focus on staff training may have also played a role.

5.1.4.2 Interpretation

The team found the intervention straightforward to implement, and the introduction of the model was well supported by strong clinical and senior leadership, factors that are essential for managing change in healthcare (Leonard et al. 2004). The stated improvement aim was achieved, and the reduction to LOS can be considered both clinically and statistically significant. The quantitative data presented is a strength given that other descriptive accounts of QI often have poor quantitative evidence (Walshe and Freeman 2002).

Litvak and Long (2000) proposes that artificial variability in care processes is the most likely barrier to providing health care that is both efficient and of high quality, but this model has not previously been adapted so that it may be applied in an NHS elective care clinical microsystem. The results are therefore a valuable starting point in the programme of investigation outlined in Chapter 4.3 and give credibility to the proposal that the model which has been previously successful in managing the variability of processes in critical care, emergency departments, waiting times, and theatre efficiency programs is potentially adaptable for use within elective care clinical microsystems (Litvak and Long 2000; Aiken et al. 2002; McManus et al. 2004; Morton and Bevan 2008). It also supports the strong theoretical basis for the intervention described previously (Chapter 2) and provides some empirical evidence that the model works when applied within this NHS elective care setting.

However, a limitation of the results from the development site is the absence of formal experiential data. The need for empirical, experiential, and theoretical evidence when evaluating a QI intervention has previously been outlined and it is acknowledged in the proposed methods detailed in Chapter 4 that experiential data will need to be collected when evaluating the implementation of the intervention within the validation site. Whilst the absence of experiential data is not ideal, it is not uncommon within the QI literature, where at best only partial sets of evidence on both new and existing QI interventions are mostly presented (Walshe 2009).

However, the presence of a sound underpinning theory, and clear quantitative results illustrating improvement is a persuasive argument for further evaluation of the models' ability to be used within the NHS, even in the absence of more empirical studies and experiential data. Walshe (2007) argues that the theoretical framework for an intervention (why and how it works) is more important than empirical performance (whether it works). Despite this rationale, the heterogeneity of different contexts and settings can still be considered a threat to the generalisability of any QI findings (Ovretveit et al. 2011). In similarity to many

QI reports the problems of external validity in this study are not logically solvable in any neat, conclusive way (Campbell and Stanley 1963).

In order to determine the generalisability of the results found in this study, readers must be able to consider whether the same effects would be found elsewhere, and if the changes could be implemented in another setting (Ovretveit et al. 2011). The detailed and accurate descriptions of the intervention and context provided are therefore appropriate and helpful (Department of Health 2007; Davidoff et al. 2008). Details of the model are explicitly given, and it is proposed that the model's inherent ability to help health professionals identify and classify the local artificial variability in care processes will help to ensure that the model can be adapted to different contexts and situations.

As with any QI initiative, contextual factors can act as enablers or barriers to success, and it must be noted that in line with observations from elsewhere, there were a number of supportive factors at the time of change. Due to the 18-week referral-to-treatment target, there was strong organizational support for the initiative, and the business case for change was robust due to the economic and capacity savings associated with the reduction in LOS. This provided executive support, which was accompanied by strong clinical and managerial leadership within the clinical microsystem, factors identified as being crucial in the implementation of ERAS (Roberts et al. 2010). This leadership was accompanied by a willing and motivated inter-disciplinary team, as evidenced in the staff survey results *(Figure 10*). The staff were engaged, felt part of a team, received training, and felt able to suggest and make improvements to care, and most importantly felt able to provide the level of care to patients that they aspired to. These factors resonate with themes that have subsequently been found to be associated with high performing teams delivering ERAS for hip and knee replacement within the NHS (Hughes et al. 2019).

5.1.4.3 Limitations

In order to further validate the model, the role of some specific contextual factors must be explored further. In the systematic review completed by Kaplan et al. (2010) to examine the influence of context on QI success within healthcare settings, it was concluded that leadership from top management, a good organisational culture, strong clinical leadership, and also the clinical microsystem's motivation for change were all factors shown to be important to QI intervention success. These elements were all present in this development site, and so whilst the introduction of the model was successful, it may be said that the conditions for its introduction were favourable. Whilst this means that caution should be extended when making judgments about the causal effects of the intervention on improvements, the SPC chart in *Figure 9* gives credibility to the variability model, because changes have been sustained over a long period of time. The sustainability and consistency of improvements suggests that the changes are system and process driven, rather than dependent on motivation, will to change, and leadership alone. This sustainability of the improvements made within the development site is important because the interpretation of quality not only depends upon individual perspectives, but also the timescale over which it is examined, and the purpose of any measure applied (Chin and Muramatsu 2003; Currie et al. 2005).

5.1.4.4 Summary

The findings that implementing the model within the pilot site improved a desired measure of quality provides empirical evidence that the intervention can be effective in delivering improvements to quality within an NHS elective care clinical microsystem. However, as with any QI intervention its success is likely to also have a contextual element, and the contextual factors were undeniably supportive within this study. Therefore the aim within the validation site will be to assess whether the approach is successful in another elective care NHS setting, from both an empirical and experiential perspective so that we can explore further the details of when, how, and why it works (Walshe 2007).

5.2 A mixed-methods observational study to evaluate a QI method (the model to manage variability) used to inform the improvement of clinical processes within an ERAS pathway for hip and knee replacement (Study 2)

5.2.1 Introduction

This section (5.2) reports the details of implementing the model to manage variability within the validation site. It is one of the integrated papers (Wainwright and McDonald 2021) and utilizes the SQUIRE guidelines (Ogrinc et al. 2016). It has been published in The TQM Journal and is reproduced in full in this chapter. The published version is available in *Appendix 16*. The study adopts a mixed-methods approach to allow for judgements regarding the generalisability of the model.

5.2.1.1 Problem description

The orthopaedic service at the GJNH, in Glasgow, Scotland, is the recognised national centre for hip and knee replacement within Scotland. The service was set up in 2003, and the enhanced recovery pathway was initiated in 2007 following a visit by members of the inter-disciplinary team to Copenhagen in Denmark to observe a fast-track hip and knee replacement service (Husted and Holm 2006). The GJNH team then developed a designated Enhanced Recovery Programme (ERP), which they named The CALEDonian® Technique. Its implementation resulted in improvements to patient outcomes whilst reducing LOS following surgery (McDonald et al. 2012).

From 2010, a national programme within Scotland to establish ERP as the normal pathway of care for all patients undergoing joint replacement was launched and strongly supported by the GJNH. This programme resulted in improved patient

care throughout Scotland including; reductions in urinary catheterisation use, the need for blood transfusion, and the mean post-operative LOS for patients across Scotland (Scott et al. 2013).

However, whilst the national ERP improved outcomes nationally, outcomes at the GJNH remained consistent but did not continue to improve. Therefore, with the ongoing national improvement work driving hospital boards across Scotland to improve, the outcomes at the GJNH became average when benchmarked nationally. Therefore, in order to sustain its position as a recognised national centre of excellence, and to accommodate a change in referral sources and the continuing increasing demand on its services, it was vital that a review of the current ERAS pathway was undertaken. This would help ascertain where further improvements could be made that would improve clinical outcomes and maximize capacity.

5.2.1.2 Available knowledge

To instigate change it was recognised by local leadership that a systematic QI effort was required in order to understand how to make improvements relevant to the GJNH current pathway. A clinical leader from the GJNH approached an external QI researcher to help with the QI effort after participating in a workshop at the 2012 ERAS UK Conference (ERAS UK Conference 2012). In the workshop, a QI method used to advise the implementation and improvement of an ERAS pathway in hip and knee replacement was presented. The clinical leader identified that this QI method could be used at the GJNH, and so the QI researcher was invited to visit the GJNH hospital to meet with clinical leaders and hospital executives. The QI method, which was a model to manage variability (adapted from Litvak (2005) for use in clinical microsystems to improve care processes) was presented, and the GJNH leadership team agreed to engage the QI researcher to help them with the project.

The need for external help, and the need to use a specific QI method to inform change, was recognised by the GJNH team due to their work nationally to help other sites implement ERAS. They recognised that process changes were required, and these needed to be driven by the whole inter-disciplinary team, and this resonated with guidance from the NHS Institute for Innovation and Improvement (Institute for Innovation and Improvement 2006). The team also acknowledged how the fast-track hip and knee replacement service they had observed in Denmark had continued to improve. Patients were now being routinely discharged at a median of 2 days post-surgery (Husted et al. 2011). The improvements to care achieved by the Danish team were achieved by carefully analysing the specific barriers to discharge within their clinical context (Husted et al. 2011), and areas for improvement were highlighted as improvements to care processes.

Further, it was acknowledged that if the patient pathway was highly structured and standardised, and if the inter-disciplinary team were involved in the development and production of the pathway, then improvements to patient care were possible.

5.2.1.3 Rationale

Leadership at the GJNH identified that a specific QI method was required that would help to structure, analyse, implement, and sustain improvements. The model to manage variability was chosen because it was identified by the project leads as a QI method that could help to reorganise care process. It was felt to have the required sensitivity and format for managing variability that could be understood by the clinical team. This was supported by the fact it had been utilised in another orthopaedic clinical microsystem successfully, and the leaders were aware of the results and process (Chapter 5.1).

As described previously (Chapter 2), the model to manage variability works as a QI method by identifying sources of variability within the clinical microsystem that

may affect the outcome measure seeking to be improved. Sources of variability are identified by using a driver diagram (or a cause-and-effect diagram), and then sources of variability are either classified as artificial or natural variability. This is a distinguishing factor from the other QI methods such as Lean or Six Sigma (and other interventions described in Chapter 2). An outline of the approach has been provided in *Figure 2*.

The model, adapted from Litvak (2005) proposes that the artificial variability of care processes is the most likely barrier to providing efficient and high quality healthcare. Artificial sources of variability should therefore be removed, and natural sources of variability should be managed.

5.2.1.4 Specific aims

The objective of the project was to maximize capacity at the GJNH in order to help meet the increasing demand in Scotland for hip and knee replacement, whilst re-establishing the GJNH as the exemplar unit in Scotland for outcomes following hip and knee replacement. The project utilised the model to manage variability as a QI method, in order to inform improvements to the ERAS pathway within the GJNH elective orthopaedic clinical microsystem.

The clinical microsystem team decided on two improvement aims

1. To ensure all patients are pre-assessed and fit for surgery two weeks prior to their operation (more specifically, to improve from the current rate of 65% to 100%)
2. To reduce average LOS for hip and knee replacement by two days (more specifically, to reduce LOS from the average of 5.5 days to 3.5 days)

The first aim was chosen as the team recognised a high number of patients were attending for pre-assessment less than two weeks prior to surgery. This would often lead to theatre slots not being filled, cancellations when patients were found to be “not fit for surgery”, and preparing patients appropriately pre-operatively with the right education and information was difficult and often rushed. Appropriate discharge planning could also be a problem, as there was not enough time to make arrangements before admission. Reducing LOS was chosen by the team as the second improvement, as they felt LOS was an appropriate proxy indicator of quality, and it was the comparator outcome measure used in Scotland to nationally benchmark.

5.2.2 Methods

5.2.2.1 Context

The GJNH is Scotland’s specialist hospital for reducing patient waiting times, and as such, as well as serving local patients, referrals are received from across the country. The hospital is a busy and large elective care centre, performing over 57,000 procedures per year, with over 1800 members of staff, more than 200 in-patient beds, and 16 operating theatres. The GJNH is home to one of the largest elective (planned care) orthopaedic centres in Europe, performing over 3500 hip and knee replacements each year. The orthopaedic clinical microsystem has an inter-disciplinary approach to care, with consultants, nurses, physiotherapists, and occupational therapists all working together.

5.2.2.2 Intervention

The principles of Litvak’s (Boston University Health Policy Institute 2006) variability methodology explained in Chapter 2 were adapted to identify, classify, and manage the intrinsic sources of variability contributing to the delays in the pre-assessment process (improvement aim 1), and the current patient LOS within

the clinical microsystem (improvement aim 2). By employing this framework, the team was able to co-ordinate improvement efforts.

The first stage was to undertake an analysis of current processes and to identify sources of variability that were contributing factors to delays in the pre-assessment process and the current LOS experienced by patients. This was coordinated by the two clinical managers. A workshop facilitated by the external QI researcher involving leaders from across the inter-disciplinary team was held in order to identify and agree causes of variability within the clinical microsystem related to the improvement aims. Attendees at the workshop involved representation from the pre-op, intra-op, and post-op care teams, and included surgeons, anaesthetists, nurses, theatre staff, therapists, radiography staff, pharmacists, and administrative staff.

This workshop was held in January 2013, and photographs for the workshop can be seen in Appendix 7 and the outputs were summarised by the group into a cause-and-effect diagram for each improvement aim (*Appendices 8 and 9)*. This was used to depict and identify all of the possible sources of variability that affected the two improvement aims. Once these variables or causes of variability were identified, they were classified into either “natural” or “artificial” causes of variability. The definitions and examples of natural and artificial variability provided from Study 1 (Chapter 5.1) were used with the team to demonstrate how they could be defined.

Following the identification and classification of variability, in accordance with the model described in Chapter 2, and the process undertaken within Study 1 the first active step was to eliminate the artificial variability from the care processes of the system. Litvak (Boston University Health Policy Institute 2006) explains that artificial variability should not be accepted or worked around. Changes were therefore introduced to remove artificial variability from the delivery of care processes, and the details of what was changed, when, and by whom can be seen in *Table 7*. Once artificial variability had been eliminated, causes of natural variability were managed where possible. Details of changes made to the care

processes to manage natural variability are also provided in *Table 7*.

When it was identified that artificial variability needed to be removed from a more complex process, a thorough approach to staff engagement was adopted, so that a team-based decision-making approach could be undertaken. A good example of this is the introduction of a 7-day physiotherapy service, which was needed to reduce the (previously unrecognised) artificial variation in the time to first mobilisation. In this example, the staff involved in the workshops had to firstly promote a wider organisational awareness that the provision of therapy services was variable and unequitable across patients.

The therapy lead identified all the key stakeholders, including clinical staff, management, union representatives and human resources staff. An impact analysis was undertaken, along with the development of a communication plan, and consultation workshops with groups of staff, and one-to-one meetings. This developed a deep level of engagement and a departmental consensus that 7-day working would remove artificial variability and provide a more equitable and high-quality service to patients. Implementation of these changes involved careful rearrangement of staff rotas, and individual negotiations with staff, along with the prospective collection of data to check that the changes were improving outcomes for patients, so that clinical buy-in to the changes could be cemented. The changes increased the therapy hours delivered to patients by 50% on Saturdays and by 400% on Sundays and were accompanied by an increase in early mobilisation rate, amount of weekend discharges, and a reduction of LOS (Divers and Shirley 2014).

Table 7 - Identification, classification, and management of variability in Study 2

	Identification		Classification	Management	
	Factors from the cause and effect diagram that the MDT identified as influencing current LOS	**Detail of cause and description of variability**	**Type of variability**	**Change to care process to be introduced (all changes introduced from when the intervention commenced)**	**Evidence for success of change to care process (data and evidence source provided where appropriate)**
Improvement aim 1 – to increase the number of patients with more than 14 days between pre-assessment and admission					
1	Referral process from host board to GJNH	Different Service Level Agreements (SLA), methods of referral, and timing of referral	Artificial	Remove variability. Introduce a standardised SLA with all health boards and single waiting list management system.	This was completed and implemented by July 2013
2	Clinic and theatre booking process	Patients not booked in order. Multiple booking systems	Artificial	Remove variability. Consolidate and introduce a single booking system for both clinic and theatre	This was completed and implemented by July 2013
3	Out-patient clinic capacity	Variable capacity depending on day, and variable number of pre-assessment slots	Artificial	Remove variability. Change to increase clinic schedule and organisation of clinic capacity	This was achieved and the orthopaedic out-patient clinics were redesigned in June 2013
Improvement aim 2 – to decrease LOS by 2 days					
1	Time between admission and operation	All patients were admitted the day before surgery	Artificial	Remove variability. Increase day of surgery admissions by completing anaesthetic review at the	Changes to increase anaesthetic cover in the pre-assessment started in May 2013, however the increased

				pre-assessment stage	cover for clinics remained hard to fulfil due to staff shortages, until Physicians associate were recruited in September 2013 to assist
2	Time to first mobilisation	Physiotherapy staffing levels varied throughout the week and meant that the day of operation and time of return from theatre would affect the time to first mobilisation. Limited weekend service.	Artificial	Remove variability. Re-education of Caledonian Technique, to increase focus of early mobilisation, and increase staffing levels by introducing a 7-day service.	Training and education were provided by Clinical leaders at the start of the intervention period in July and August 2013. The new 7-day therapy service was not introduced until January 2014 (the start of post-intervention period)
3	Patient expectation of LOS	Patients had different expectations of how long they would stay in hospital	Natural	Manage variability. Updated patient information resources and conducted staff training	A new discharge criteria booklet was produced by the clinical team, and created with the hospital communications department. This was piloted and launched in July 2013 at the start of the intervention period
4	Staff understanding of the Caledonian Technique and ERAS	Expectations of patient pathway varied amongst staff	Natural	Manage variability. Regular training sessions instigated and organised. Regular feedback on current LOS and outcomes introduced	Training and education were provided by Clinical leaders at the start of the intervention period in July and August 2013. A mechanism for weekly data analysis and feedback was developed with the IT department and started in July 2013

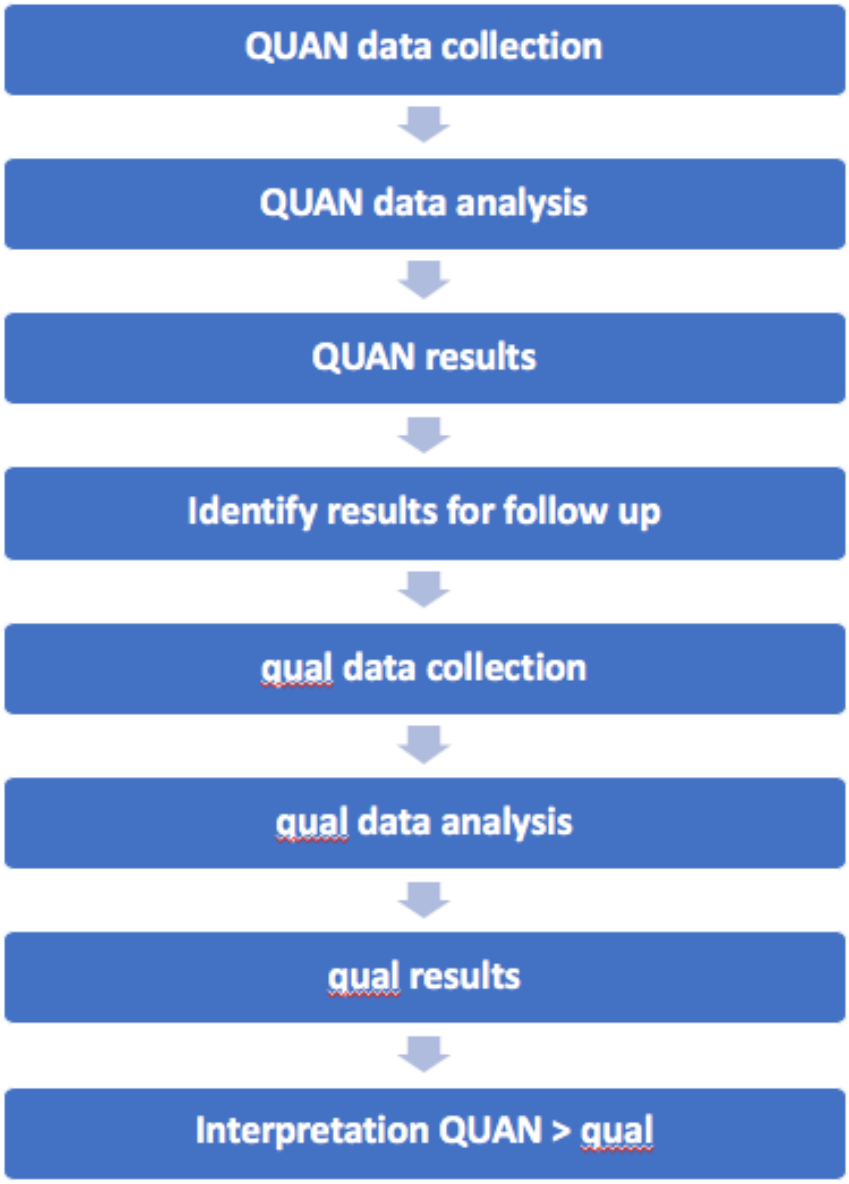
Once the methods to remove artificial variability, and manage natural variability were identified, the new care processes were introduced. Following the initial workshop in January 2013, the change phase of the project was defined as being from January 2013 – June 2013, and this describes the period when the identified changes were prepared and introduced as they became ready. The intervention phase from July 2013 - December 2013 describes when all of the changes were implemented, and the post-intervention phase from January 2014 – December 2014 describes the period post implementation, where there was no project activity, but outcomes were continually monitored to evaluate sustainability. This was to see whether the changes observed within the project were sustained, part of an external ongoing trend, or could be concluded to be a result of the intervention.

5.2.2.3. Study of the intervention

A before and after prospective observational cohort study design was used, with a mixed-methods sequential explanatory design (QUAN emphasized) that consisted of two distinct phases (Creswell et al. 2003). A quantitative phase followed by qualitative phase was used to evaluate how successful the model to manage variability was as a QI method (Creswell 2009). In this design, the quantitative data was collected and analysed first, and then the qualitative data was collected second in the sequence, in order to help explain the quantitative results achieved in the first phase. This is summarised in *Figure 11* below. Creswell (2009) uses capital letters to emphasise whether the quantitative or qualitative component is dominant.

The SQUIRE guidelines (Ogrinc et al. 2016) were used as a framework to plan, structure, and report the findings. Within this SQUIRE framework the TiDier checklist is used to describe the intervention and the GRAMMS checklist was used to guide reporting of the mixed-methods component.

Figure 11 - A flow chart to illustrate the explanatory sequential design: Follow-up explanations model (QUAN emphasized) that will be used in the validation site



5.2.2.3.1 Quantitative analysis

Quantitative data was collected and then analysed. It was a four-condition design, where the first condition was a baseline phase, the second condition was the change phase, the third condition was the intervention phase, and then the fourth condition was a post-intervention phase. The effect of the process changes described in *Table 7* were measured by collecting and analysing data for the time

from pre-assessment to operation (improvement aim 1) and LOS (the outcome measure of improvement aim 2). SPC charts were used to evaluate process changes over time. At the end of this quantitative phase the aim was to establish whether the intervention was successful or not at improving the desired outcomes within the clinical microsystem.

5.2.2.3.2 Mixing / connecting data

Following the quantitative analysis there was a second qualitative phase of the evaluation, that built on the initial quantitative phase, and was connected by this intermediate stage of the study. In mixed-methods research integration may occur via connecting, building, merging, or embedding (Fetters et al. 2013). Integration in this study occurred through building, whereby the quantitative data collection informed the data collection approach of the qualitative, with the latter building on the former. The rationale for this approach was that the quantitative data that was collected and analysed established to what extent the project aims were met. Once it had been established quantitatively whether the intervention was successful or not, the qualitative data and analysis in the next phase was used to explore how and why the intervention was either successful or not, and the relative role of the model to manage variability as a QI method (Rossman and Wilson 1985; Tashakkori and Teddlie 1998; Creswell 2009).

This explanatory sequential design is a two phase mixed-methods design and was chosen so that the qualitative data in the second phase could help to explain or build upon the initial quantitative results (Creswell 2009). The design was well suited to this study because the qualitative data was used to explain the outcomes of the project (Morse 1991). It also provided an understanding from the staff perspective of how easy the model was to implement, use, and manage within the clinical setting. The information generated here helped to refine conclusions regarding the model on its generalisability and subsequent potential use in other elective clinical microsystems.

5.2.2.3.3 Qualitative phase

In this second stage of the mixed-methods sequence, qualitative data was collected and analysed and used to help explain, and/or elaborate on, the quantitative results achieved in the first phase. This qualitative data was collected using interviews of the two clinical managers who led the implementation of the model. Interviews were conducted after completion of the intervention stage. These two individuals were tasked with leading the project and led the deployment of the model to manage variability as a QI method. They therefore had the greatest insight into its usability and success. Open ended questions were used and informed by the mixing phase described previously. Contextual factors surrounding the implementation of the model and the project were explored. The contextual factors included in the MUSIQ (Kaplan et al. 2012) were used as a prompt to ensure that all relevant factors were considered. Data collection consisted of observational notes recorded by the interviewer in addition to a recorded transcript.

5.2.2.3.4 Synthesis and evaluation

The results of both the quantitative and qualitative stages were interpreted and synthesized in relation to each other and the wider evidence base. Then a summary of the most important successes and difficulties in implementing the model was made, and the main changes observed in care delivery and clinical outcomes because of the model was stated. A comparison and evaluation of the study results in light of the evidence base is made. Consideration was then given to possible sources of bias or imprecision in design, measurement, and analysis that may have affected the study outcomes (internal validity). Factors affecting external validity such as the generalisability of the model were also considered. Consideration was also given in relation to the sustainability of any changes i.e., the likelihood that any observed gains might weaken over time.

5.1.2.4 Measures

The outcome measures used to evaluate the outcome of the intervention in relation to both improvement aims are provided below.

1. In relation to the first improvement aim, time from pre-assessment appointment to operation date was calculated (days were measured as the number of midnights between the pre-assessment appointment and day of admission to hospital)
2. In relation to the second improvement aim, LOS in hospital was calculated (days were measured as the number of midnights between day of admission and discharge from hospital)

For both outcome measures, data was extracted from the hospital administrative data system, and checked for accuracy and completeness against local (clinical microsystem level) audit data. LOS is commonly used as a proxy indicator of quality and is the widely used outcome measure for the implementation of ERAS. In regard to this project, both outcome measures were considered relevant, reliable, and valid outcome measures, that were feasible to obtain and had good usability.

5.1.2.5 Analysis

For the quantitative data, Statistical Process Control (SPC) was used to monitor the change in outcome measures for both improvement aims. Change was evaluated between each of the four project phases (baseline, change, intervention, and post-intervention stage. For both outcome measures, the data was considered to be continuous data, and so the xmr-chart was judged the appropriate SPC to use (Mohammed et al. 2008). Both outcome measures were evaluated by calculating the mean on a monthly basis, and then presenting as monthly data in consecutive points. Data for the 6 months prior to the project (July 2012 – December 2012) is presented as the baseline phase, along with data from the start of the project for the next two years (January 2013 – December 2014), to cover the change, intervention and post-intervention phases as described

previously. The data from the baseline and project phases is presented continuously, and the mean and control limits were re-calculated at the start of each phase.

For the qualitative data, the process of analysis started with familiarization of the data, before organising and preparing the data for analysis. Thematic analysis was then undertaken through a process of coding themes from the interviews relating to the contextual factors included in the MUSIQ (Kaplan et al. 2012). The data was then interpreted in light of both the quantitative and other qualitative findings.

Thematic analysis was chosen as a method because of its flexible approach that could be modified to the need of the study, whilst providing a rich and detailed account of the data (Nowell et al. 2017). The aim of the analysis was to enable an understanding of how the intervention worked or failed to work from the perspective of the individuals involved in leading the project. There were 6 phases to the analysis, as recommended by Nowell et al. (2017). After familiarization with the data, initial codes were then created (accompanied by reflexive journaling), and then themes were searched for. These themes were then reviewed and triangulated, before they were defined and named.

5.1.2.6 Ethical considerations

Details of ethical approval for the project are provided in Chapter 4, however in specific reference to this Study 2, the following details are provided for clarification. The project was presented to the Head of the Research Department at the GJNH in November 2012. It was defined as a QI activity and therefore the need for submission to the hospital and local NHS Research Ethics Committee was confirmed as not being required. However, full ethical consideration was given to the project by utilising published guidance and policy templates from the HQIP. This ensured that the patients' interests and rights were properly protected throughout the study. The HQIP template provided outlines for best practice

structures and mechanisms that provided an ethical oversight and formed the basis of a thorough governance framework.

5.2.3 Results

Following the decision to improve the service, the external QI researcher was invited to facilitate an introductory workshop in January 2013. This was to meet staff, initiate the project, and introduce the model to manage variability. It was also important for the external QI researcher to establish credibility with the local team and to start to build relationships with staff. Internally the project was supported by an executive sponsor, two clinical managers with service improvement experience, and lead clinicians from surgery, anaesthetics, nursing and therapies. The two clinical managers led the QI effort locally and coordinated the project team. This core team was supported externally by the QI researcher who over the course of the project made 12 site visits to the hospital (every 2-4 weeks) and assisted remotely.

The initial workshop in January 2013, was followed by a change phase of the project, defined as being from January 2013 – June 2013, and this describes the period when the identified changes from the workshop, were prepared and gradually introduced as soon as they ready. The intervention phase from July 2013 - December 2013 describes the period when all of the changes were implemented and regularly monitored by the project team, and the post-intervention phase from January 2014 – December 2014 describes the period post implementation, where outcomes were monitored but the formal project had finished.

The two clinical managers leading the project, both worked part-time on the project around their normal duties and led the local team through the use of the model to manage variability. Staff members from all professional groups attended the workshops and contributed to a cause-and-effect diagram, which aimed to identify all of the causes of variability that contributed to the short period of time between pre-assessment and admission, and the current LOS which was felt could be reduced. The core team then pulled out the key themes and factors that

they felt most strongly influenced the current outcome measures of the two project aims following this consultation process. Where data was required to analyse specific factors, it was extracted from the hospital patient record system.

Following the identification of factors that were influencing both improvement aim outcome measures, the team decided on the changes required to care processes in order to either remove artificial variability or manage natural variability. The results of this process are summarised in *Table 7*. The team then planned how the necessary changes would be implemented and agreed to initiate all of the changes as soon as they were able, within the change phase (January 2013 – June 2013). It was decided that the new care processes that made up the intervention would all be in place by July 2013 and would be actively monitored by the project team from July 2013 – December 2013. Once the change in care processes was introduced, regular review using SPC was undertaken by the project team to monitor performance.

5.2.3.1 Quantitative results

SPC charts are presented for the outcome measures defined for both improvement aims. They show data for the baseline phase, change phase, intervention phase, and post-intervention phases. The data is continuous and accounts for all patients operated on within that time period. There is no missing data. In order to present the data cleanly, and in accordance with routine outcome monitoring at the hospital, monthly means were calculated in order to produce the xmr-chart. The xmr-chart consists of two charts, the x-chart and the mr-chart. The x-chart is a control chart of the 30 observed values for each outcome, and the mr-chart is a control chart of the moving ranges of the data. At each phase the control chart is recalculated, and the processes remain stable within each phase for both outcome measures.

Figure 12 - SPC (mr-chart) for improvement aim 1 (Study 2)

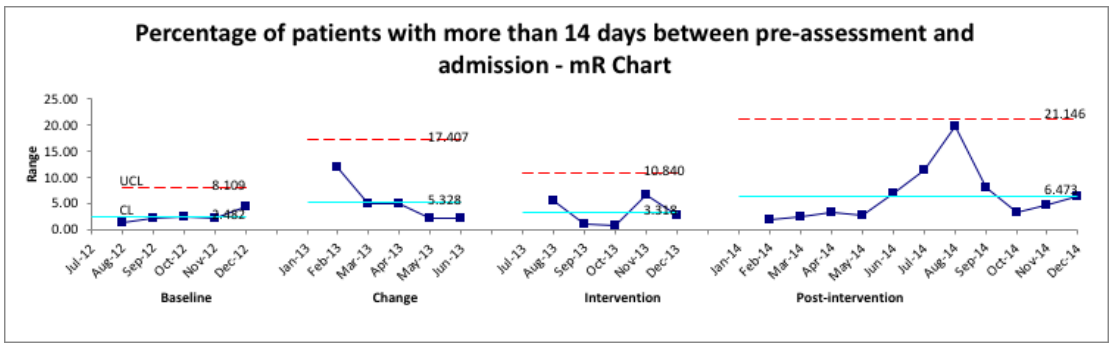


Figure 13 - SPC (xmr-chart) for improvement aim 1 (Study 2)

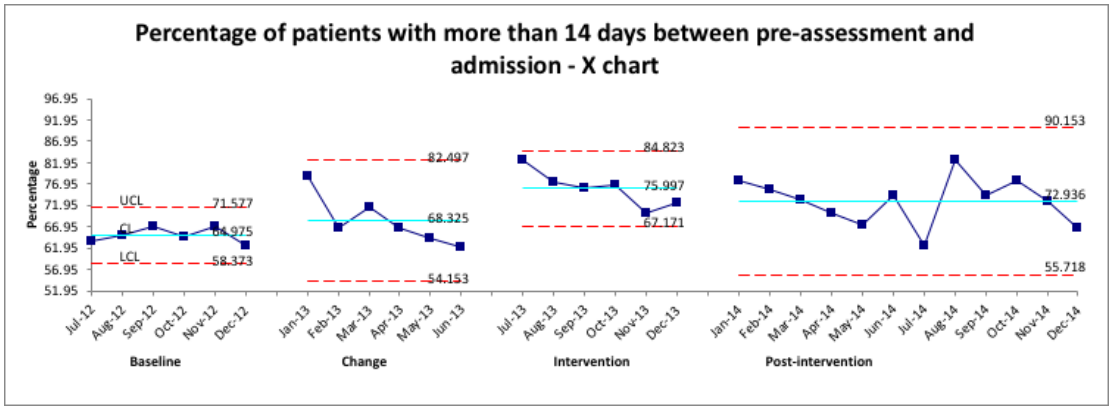


Figure 14 - SPC (mr-chart) for improvement aim 2 (Study 2)

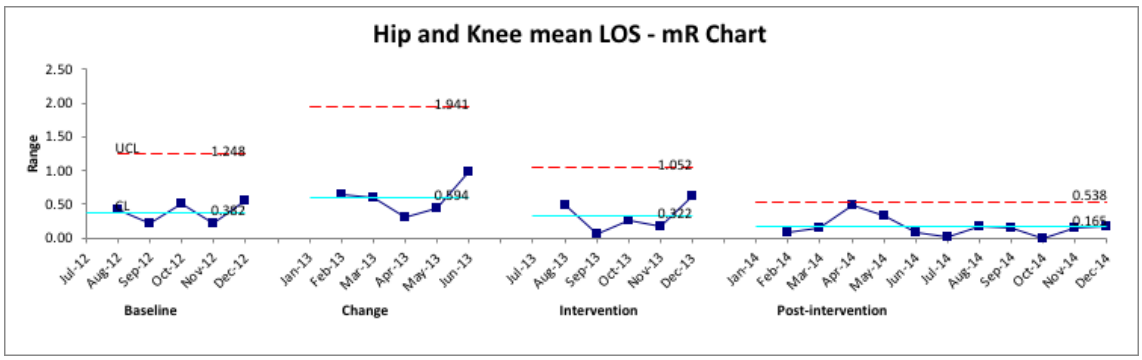
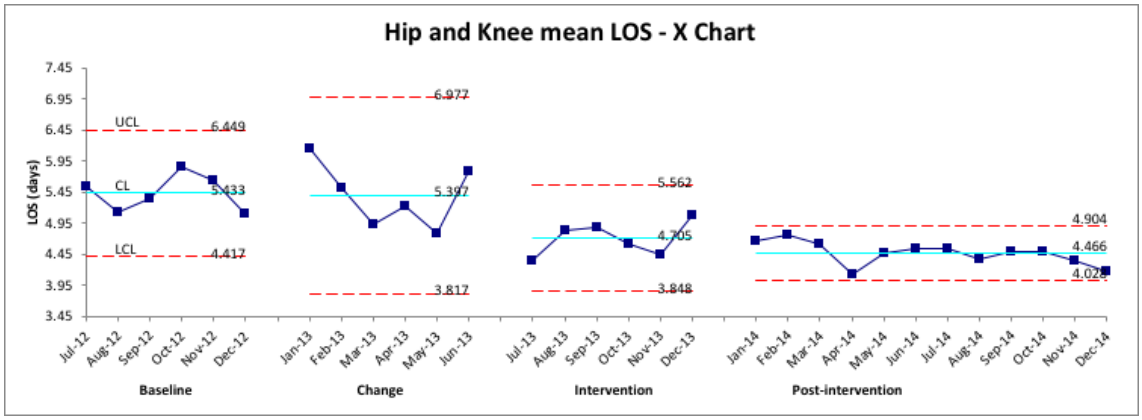


Figure 15 - SPC (xmr-chart) for improvement aim 2 (Study 2)



5.2.3.2 Qualitative results

Following the quantitative analysis, the results were shared with the two Clinical Managers, and the second qualitative phase of the evaluation was conducted. Integration with the mixed-methods design occurred through building, whereby the quantitative data collection informed the data collection approach of the qualitative interviews. The qualitative data collection and analysis aimed to explore how and why the intervention was either successful or not, and the experience of utilising the model to manage variability.

Project Success

Both interviewees felt the project had been successful, in that the procedural elements of the QI method (the model to manage variability) had been executed as planned and that the outcomes had improved. However, there was acknowledgment that the team had not managed to change all the care processes identified by the model and had not achieved their initial improvement aims entirely. Both interviewees judged success based on the relative improvement to the outcome measures linked to the improvement aims. This was opposed to reviewing whether each change to care process had been achieved, or whether there had been any other wider benefits of the project.

> *I would say it has been successful because we have achieved change and we have achieved a degree of change that has been sustained since it has been changed, and we have evidence to support that. (Clinical Manager 1)*

> *When we're looking at the data now, we've been partially successful, if we look at the two aims, we've improved, but not fully achieved what we had planned.* (Clinical Manager 2)

Consequently, the viewpoints of the two clinical managers leading the project were explored to understand why the project had not been more successful.

Views on model to manage variability

The role of utilising the model to manage variability as the QI method used to inform the intervention was explored with the interviewees. Both interviewees viewed the model positively and did not think that the model was associated with why the improvement aims had not been fully achieved. Specifically, they both reported advantages of the model, and found it intuitive to use.

> *I just feel the model to manage variability pulls the group together, you get the information you need, you get the data to support it and you work through a process that's actually reasonably quick to do as well.* (Clinical Manager 1)

> *I firmly believe the model is an easy and simple method of getting improvement projects up and running and to get everybody looking at a problem in a much more holistic way*. (Clinical Manager 2)

Advantages of the model over alternative QI methods that both interviewees had previously used were also highlighted.

> *I had experience of using other models, LEAN and things like that and I've never warmed to them just because of the complexity of the language… I've found the model to manage variation much more simplistic and easier to explain to people, to utilise, and to make the improvements. I found it very useful.* (Clinical Manager 2)

And both interviewees described how the model had impacted their other work in the hospital, either by reporting that they had used the model in other projects, or by describing how the concepts within the model where now used routinely by other members of staff.

> *And I think it's really funny now when you go into a meeting and the head of services will talk about artificial and natural variation and they use it*

quite routinely now and people know what they are talking about and nobody would have known that at the beginning. (Clinical Manager 1)

I went on to utilise the model in another specialty in the hospital and being that external person and asking the questions was of benefit. I had no expertise in that surgical specialism whatsoever, but being able to use the model, stimulates them to think even harder about what they're doing and how they do it and look at the processes by which they're managing their patient's pathway. (Clinical Manager 2)

Both Clinical Managers felt that the model to manage variability was easy to use, had been implemented appropriately, and had impacted the organisation more widely that just within this specific project. Therefore, the relative roles of other contributing factors to the project's outcomes were discussed. Contextual factors thought to both facilitate and limit the project were considered.

The role of an external agent

Both interviewees thought that the role of the external QI researcher and the credentials and expertise of that person played an important facilitative role within the project.

I think a lot of the people around the table respected the fact that you had done similar work in other places using this model and had a successful outcome. And you were able to answer a lot of the questions right at the beginning that I couldn't have answered. I think that very much got us buy-in at an early stage with the consultants. I don't think I would have got that buy-in. (Clinical Manager 1)

The role of leadership and engagement

Conversely, when invited to discuss why the project had not been as successful as planned, both interviewees perceived that increased leadership and engagement from within the clinical microsystem would have improved

outcomes. They reflected on the role of leadership from a personal perspective, and in relation to the participation and leadership of others involved in the project.

> *I think using the model was good. However, I was part-time, and wasn't fully able to push and drive the changes as much as I would have liked. Would it be better if you had somebody who was full-time… It may just have meant we'd have got things done quicker and would have got better results and a bit more focus on it.* (Clinical Manager 2)

> *Responsibility, somebody taking responsibility to keep joining up the dots and I think that's what probably not happened for various reasons.* (Clinical Manager 1)

In addition, there were other organisational factors that were highlighted by both interviewees regarding staffing. They both noted frustration that it had been hard to adequately organise anaesthetic cover within the pre-assessment clinic in order to increase the number of day of surgery admissions. They explained that the Human Resource process to change to a 7-day therapy working model had also taken longer than anticipated. One of the clinical managers noted a frustration in regard to knowing what they wanted to implement but not being able to do it.

> *What we identified using the model to manage variability to change was correct, and these are still the same issues that are preventing us from further improvement, however staffing constraints have not allowed us to make the change.* (Clinical Manager 1)

5.2.4 Discussion

A successful QI effort is one in which the intended improvements are successfully achieved. In this project the primary outcome measures associated with both improvement aims improved, although they did not meet their targeted improvement. For improvement aim one, the percentage of patients who had

more than 2 weeks between their pre-assessment clinic visit and their operation increased from 65% in the baseline phase to 76% in the intervention stage. This 11% improvement then reduced by 3% to 73% in the post-intervention monitoring period. All the changes to the care processes identified as being required to increase the percentage of patients who had more than 2 weeks between pre-assessment clinic visit and their operation were made. However, the 100% aim was still not achieved. This outcome may have been due to the fact there were not enough patients on the waiting list at any one time, in order to plan operating lists more than 2 weeks in advance.

For improvement aim two, mean LOS decreased from 5.4 days in the baseline phase to 4.7 days in the intervention stage, and 4.5 days in the post-intervention monitoring period, representing an 18% overall decrease in LOS. This reduction, whilst not as significant as the reduction reported in Study 1 (Chapter 5.1) is analogous with reductions reported in other implementation studies of ERAS in joint replacement. Saunders et al. (2016) reported a 17% reduction in LOS for primary joint replacement following the introduction of an ERAS pathway, and a reduction of 19% was reported by Ricciardi et al. (2020) in their report of utilising lean as a QI method when seeking to improve a knee replacement pathway. It should also be noted that in a recently published report from NHS England (GIRFT 2020), national average LOS reduced for hip replacements by 19%, and for knee replacements by 17.8%, in the period between 2014-2019. The improvement made by the team at the GJNH within the project, could therefore be argued to be highly significant compared against the background trend LOS. It was also lower than the national average in 2014 for both hip (5.18 days) and knee (5.25 days) replacement in Scotland (Scottish Arthroplasty Project).

The reasons for failing to achieve a greater reduction in LOS may be assumed to be because the proposed changes to clinical processes (informed by using the model to manage variability as a QI method) that made up the intervention were not all implemented as planned. There were difficulties and delays to organising and changing the artificial variability of staffing levels. The 7-day therapy service took longer than anticipated time to implement, and the provision of anaesthetic cover within the pre-assessment clinic was difficult due to inadequate staff

numbers and difficulties with scheduling rotas. These were both changes to the care processes that aimed to decrease LOS by increasing the rate of day of surgery admission (as anaesthetic review would be undertaken in clinic rather than on admission), and to expediate early mobilisation and avoid delays to discharge (through earlier access to therapy). This difficulty to implement post-operative elements of an ERAS pathway, is not uncommon, and it has been found in reviews of ERAS implementation that postoperative elements related to mobilization and rehabilitation, often demonstrate much lower levels of compliance compared to other stages of the peri-operative pathway (Coxon et al. 2017).

The mixed-methods approach to the evaluation, accompanied by the explicit reporting of the intervention through the utilisation of the TIDieR checklist is a strength of the project. QI reporting in surgery is acknowledged to be generally poor (Jones et al. 2016) and the explicit reporting of intervention and QI method used, along with context has been recommended (Jones et al. 2019). Research evaluating QI success is strengthened by utilising approaches from the social sciences such as mixed-methods (Kaplan et al. (2010). In this case, the connecting component, and qualitative interviews conducted with Clinical Managers provided experiential data from those involved in leading the project to explain some of the specific contextual factors that influenced the outcomes of the project. This qualitative data confirmed that the two clinical managers felt the project had been successful, although only partially. They thought that it had been leadership, staffing, and organizational related issues that had prevented the outcomes improving further. Such issues are consistent with the wider QI literature (Kaplan et al. 2010) and experience of teams working to implement ERAS pathways (Paton et al. 2014). It may be argued that more qualitative data could have been collected from the wider team, and this could have confirmed that saturation was achieved. Indeed, whilst it may be argued that sampling the total population of the staff working within the clinical microsystem and involved in the project would have been optimal, it must also be understood that the adequacy of a qualitative sample is evaluated by the quality and amount of the data, not the number of participants (Jeanfreau and Jack 2010). However, unfortunately in this case, data saturation was not confirmed. Due to the number of people involved across the peri-operative pathway, it was felt that if more value

was to be gained, then at least one person from every department/profession would need to be interviewed, and time and resources did not allow for the additional 10-20 interviews.

The two clinical managers interviewed, were however the most important sample according to the aims of the study, and as such could be considered a purposive sample and the most relevant and useful to understand if, how, and why the model to manage variability was successful? Regarding the QI method used, the two Clinical Managers highlighted that the model to manage variability had been received well by the inter-professional team. It had engaged them in the QI process and led to the technique being used in other projects within the hospital, and the terms natural and artificial variability had made their way into common usage amongst the team. More specifically in relation to the model to manage variability, both Clinical Managers thought it offered advantages over other QI methods they had used in the past, and both felt that the external input of the QI researcher to help introduce it was an important facilitating factor.

These findings confirm the evidence from the wider literature discussed in Chapter 2, where it is acknowledged that the use of a QI method (in this case the model to manage variability) can be helpful to inform improvement efforts. However, it was other contextual factors that were highlighted by the two Clinical Managers as being key contributing factors to the project outcome. Context is well understood to be a critical factor in QI research (Stevens and Shojania 2011), and despite the GJNH being a recognised national centre for hip and knee replacement, it was hard for the team to lead and manage change within the organisation, in order to make the required staffing changes, and drive the project forward. Knowing how to improve, is not always the same as being able to improve. Successful implementation of ERAS pathways is known to be associated with an organisation having a change agent to fully drive the implementation process (Roberts et al. 2010; Coxon et al. 2017). Given that both Clinical Managers acknowledged that they could only dedicate part of their time to the project, it may be judged that the absence of a full-time change agent with overall responsibility for the project was a contributing factor to the only partial achievement of the project aims.

The mixed-methods design and the use of qualitative data was justified and appropriate given the desire to seek a descriptive, and in-depth insight in regard to the use of the model to manage variability from the users perspective, and it was entirely appropriate approach for the research question. The use of in-depth interviews to collect the data was also justified, although focus groups or participant observation are other techniques that could have been employed. However, the selection of interviews was appropriate given the subject matter, available resources, as well as the researcher's skills and experience (Streubert-Speziale, 2007).

As well as describing the data collection methods, researchers must also describe the methods used to manage and analyse the qualitative data, as this is important to evaluate the rigor of the findings. This is important because the goal of rigor in qualitative research is to accurately represent study participants' experiences (Streubert-Speziale, 2007). Therefore, the prospective plan for data collection, management, and analysis utilising the MUSIQ framework described in this study is a strength, as was the process of triangulation and confirming the themes and findings with the interviewees. This effort to established trustworthiness of the study findings, helped to ensure the "truth value" of the study's findings and confirmed how accurately the researcher interpreted the clinical managers' experiences of the project and using the model to manage variability.

5.2.4.1 Limitations

In regard to the generalisability of the work, as with many QI reports, the failure to include a comparison group, means that external causes for change cannot be ruled out. However, the attempts made to ensure transparency within the reporting, and the mixed-methods explanatory design should be highlighted as efforts made on behalf of the reader to counteract this potential bias. This is important because consideration should always be given to possible sources of bias within the design and reporting of a study. It is therefore acknowledged that the role of the QI researcher as both an external change agent within the project

and as the researcher evaluating the project is important to recognise. Reflexivity is an accepted issue within the reporting of QI, and again the mixed-methods approach, and thorough reporting of the implementation can help to mitigate for this. In the absence of external and independent evaluation (which of course may also introduce its own bias), it is a valid method to enable the reader to make their own judgements.

5.2.4.1 Summary

This study sought to improve clinical processes within an orthopaedic clinical microsystem, and to ascertain details of when, how, and why the model to manage variability should be used as a QI method. The mixed-methods approach revealed in the first quantitative phase that the outcomes measures for both project aims improved, although only partially. The secondary qualitative phase which built on the initial quantitative phase provided insight on the generalizability of utilising the model, by helping to understand its implementation and other contextual factors. The model to manage variability was felt to be utilised successfully to inform the planned interventions, however contextual factors relating to leadership, staffing levels, and organizational factors meant that not all of the interventions were implemented. This provides further information in regard to the model to manage variability, in that it can be considered a useful QI method. However, as with other QI methods it is not independent of contextual factors which can influence the relative success or failure of the planned interventions following its use.

5.3 Wanting to improve is not always the same as knowing how to improve – An example from a TKR pathway (Study 3)

5.3.1 Background

In this third study presented within the results section, a retrospective QI report detailing QI efforts undertaken at the pilot site in the years subsequent to performing Study 1 is presented (Wainwright and Craig 2020). The paper was not part of the improvement replication programme chosen to evaluate the model to manage variability but offers further insight into the role of using a QI method within QI efforts, and also the dynamic nature of contextual factors. The study was prompted when the data for the national analysis of LOS was evaluated (presented in Chapter 3.4). Whilst undertaking this analysis the updated outcomes from the pilot site (The Royal Bournemouth Hospital) were reviewed.

At the time of Study 1, the LOS within the pilot site had been improved so that it was a mean of 4.3 days for joint replacement, and the median LOS for TKR was 4 days (Starks et al. 2014). This data from 2009 compared favourably to a national median at that time of 5 days. However, data from the national analysis (presented in Chapter 3.4) from 2018-19 showed that the national median LOS had improved to 3 days for TKR, yet the median at The Royal Bournemouth Hospital had remained unchanged at 4 days for TKR. Subsequently, the team at the Royal Bournemouth was approached to see why no improvement had been made in the intervening years. The lead anaesthetist who had been involved in the QI efforts of Study 1 explained that attempts had been made to improve, however they had been unsuccessful, and he was unsure why. A retrospective analysis was therefore undertaken to analyse the results of the QI efforts, and further understanding as to why the efforts had not been successful.

The report offers a valuable reminder and insight that well-intentioned improvement efforts may be unsuccessful if a QI method is not used, and also if the contextual domains known to support QI efforts are not present. Namely, leadership, organisational characteristics, a change agent, and inter-professional and cross department collaboration (Coles et al. 2020). It also offers a prompt that to improve future performance, it is important to revisit, reflect, and learn from previous unsuccessful as well as successful QI efforts. QI efforts are frequently narrow in focus and do not utilise a QI method such as the model to manage variability that allows for a more holistic framework. Therefore, the interactions amongst the many factors that may affect the outcome you are looking to improve are not always captured. The paper (Wainwright and Craig 2020) is presented below and is reproduced in full.

5.3.2 Introduction

ERAS protocols for TKR can be considered a QI intervention, i.e. their implementation may be defined as a purposeful effort to improve care processes that will result in improved patient outcomes (Batalden and Davidoff 2007). ERAS protocols are a multi-modal approach that improves the quality of patient care, including reducing LOS for TKR (Kehlet 2020). ERAS protocols seek to optimise the peri-operative pathway by using and combining techniques such as minimally invasive surgery, regional anaesthetic techniques, multi-modal opioid sparing pain management, and early mobilisation. ERAS protocols have been detailed and include procedure specific evidence-based guidelines for TKR (Wainwright et al. 2020).

This report evaluates efforts to improve an ERAS pathway for TKR patients at a NHS district general hospital, where ERAS had previously been implemented (Wainwright and Middleton 2010). Within the hospital there was a desire to further reduce LOS. Local audit data was interpreted, and it was proposed that factors related to the anaesthetic (such as pain, motor block, symptoms of orthostatic intolerance) where delaying discharge. The anaesthetic protocol was changed 5 times in an attempt to improve outcomes and this process is presented in this

report. The stimulus to reflect on past improvement efforts is prompted in order to guide successful future QI efforts.

5.3.3 Methods

This is a retrospective analysis of routinely collected data from the hospital's administrative and clinical record systems. 652 patients undergoing TKR were evaluated between January 2008 and March 2015. Within this time, the type of anaesthetic was changed 5 times, in consecutive change cycles.

Each patient received the same standardised post-operative prescription including regular paracetamol, oxycontin, non-steroidal anti-inflammatory drugs (NSAID), omeprazole, ondansetron, Mg(OH)2, senna and as needed oramorph. In phase 1, the standard of care at that time was a regime of a spinal anaesthetic including intrathecal opiate (ITO) with a femoral nerve block (FNB) and a sciatic nerve block (SNB). In phase 2, a spinal anaesthetic with ITO, a FNB, and local incision anaesthesia (LIA) was used; in phase 3, a spinal anaesthetic with ITO and LIA was used; in phase 4, a spinal anaesthetic with ITO, LIA, and gabapentin was used; and in phase 5, a spinal anaesthetic with ITO, LIA, gabapentin, and an adductor canal block (ACB) was used. No other elements of the pathway were changed.

The outcome measures evaluated were LOS (days), time until first walk (hours), pain on movement (10-point Visual Analogue Scale (VAS)), and oramorph consumption before 1300 on the first post-operative day.

5.3.4 Results

652 patients were included and outcomes for each phase are presented in Table 8. There was no clinically significant difference in outcomes across the groups

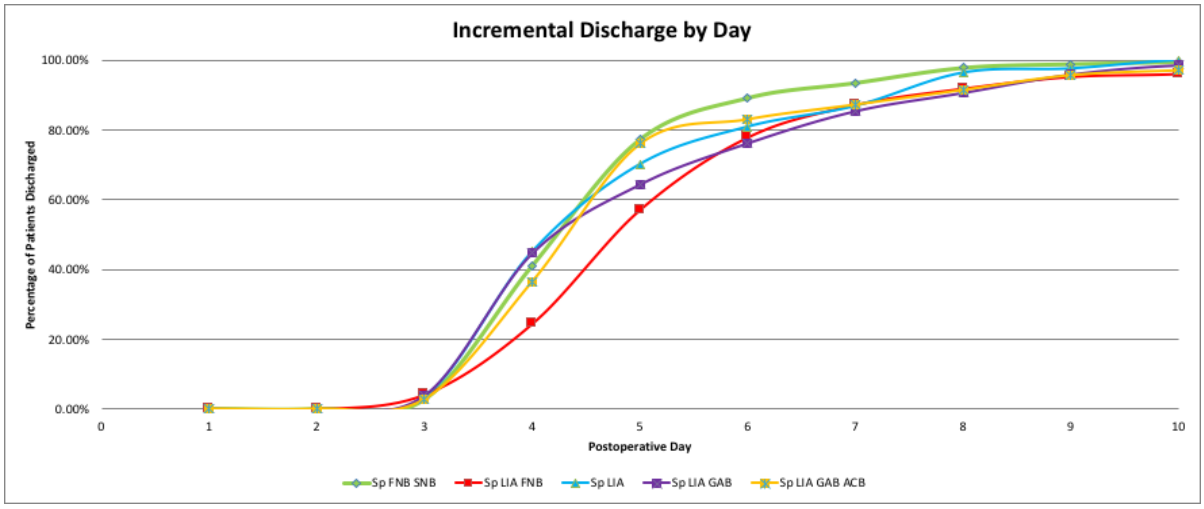
for LOS (*Figure 16*), time to first mobilisation, pain on movement, or oramorph consumption.

Table 8 - Table to show impact of anaesthetic technique on LOS, pain on movement, time to first walk, and oramorph consumption

	Phase 1	**Phase 2**	**Phase 3**	**Phase 4**	**Phase 5**
Anaesthetic technique	Sp FNB SNB	Sp LIA FNB	Sp LIA	Sp LIA GAB	Sp LIA GAB ACB
Number of cases	185	236	84	76	71
LOS (days) *Mean (min-max, SD)*	4 (2-10, 1.3)	4.7 (2-18, 2.0)	4.2 (2-9, 1.6)	5.3 (2-10, 1.8)	4.3 (2-11, 1.8)
LOS (days) *Median*	4	4	4	4	4
Pain on movement (VAS 0-10) *Mean (min-max, SD)*	4.88 (0-10, 2.7)	4.38 (0-10, 2.84)	5.24 (0-10, 2.71)	5.46 (0-10, 2.37)	5.69 (0-9, 2.4)
Time to first walk (Hours) *Median (min-max)*	Not available	31 (27-100)	29 (26-80)	29 (27-104)	29 (27-102)

Oramorph consumption before 1300 1st post-op day *Median (min-max)*	Not available	10 (0-70)	10 (0-130)	20 (10-90)	15 (0-140)

Figure 16 - Graph to show incremental percentage discharge of patients by day for each of the different anaesthetic techniques



5.3.5 Discussion

Optimizing anaesthetic technique is a key factor to facilitate early mobilisation and accelerate recovery following TKR (Wainwright and Kehlet 2019). The aim of this project was therefore well directed. However, despite the team's endeavour, LOS failed to improve across the different techniques. In regard to the choice of anaesthetic, it is acknowledged that the evidence base for TKR is hard to interpret, however in many centres patients are discharged within 0–2 days and these anaesthetic protocols are available to replicate (Gromov et al. 2017; Wainwright and Kehlet 2019).

When considering the success of this QI effort, the choice of anaesthetic technique is obviously important. However not considering the role of other contributing factors to delayed mobilisation is also significant. Patient (e.g. expectation), organisation (e.g. limited staff and time constraints), and cultural (e.g. lack of staff “buy in”) factors have all been previously highlighted as barriers to early mobilisation (Wainwright and Immins 2020) but were not considered in this project. This highlights the challenge for individual professional groups to improve care on their own within a multi-disciplinary pathway, and that more objective and exhaustive methods to identify barriers to discharge should be used (Husted et al. 2011). To move towards the goal of a “pain and risk-free surgery”, clinical evidence of individual techniques must be combined with a whole clinical microsystem QI effort in order to do “the right things in the right way” (Wainwright and Immins 2020).

5.3.5.1 Summary

Teams focused on QI efforts that seek to improve outcomes of multi-modal ERAS pathways need to remember that outcomes are influenced by many inter-relating factors. To improve outcomes in a dynamic system, across multiple stakeholders, a whole clinical microsystem approach is needed. The future use of a specific QI method is recommended, so that the transition from a will to improve, to an understanding of how to improve can be made.

6.0 Discussion

This chapter describes the key findings of the studies presented within the thesis. An interpretation of these discoveries, and the nature of the association between the model to manage variability and the outcomes found in Study 1 and Study 2 is contemplated. The outcomes are compared and discussed against the context of Study 3 and the wider evidence from the orthopaedic, ERAS, and QI specific literature. The impact of the project is considered, and the influence of context is examined and emphasized. The reasons for the achievement of, or the reasons for not achieving the desired outcomes in each study are explored.

The two studies demonstrated that the outcome measures associated with the project aims within Study 1 (Chapter 5.1) and Study 2 (Chapter 5.2) both improved. The improvement to LOS in Study 1 was 45%, and the improvement to LOS in Study 2 was 18%. Both increases outperformed the secular improvements expected. The improvement reported in Study 1 is particularly striking, given that it represented a reduction in LOS of over 3 days, over a short period with an immediate effect. The improvement seen in Study 2 was less but also significant given that without any intervention the same decrease to LOS would have taken much longer, if the background rate of LOS reduction, as described by NHS England (GIRFT 2020) is used as a gauge.

This external comparison of the changes achieved against the secular trend is essential given the use of an uncontrolled before and after design in both Study 1 and Study 2. Whilst such a study design is practicality advantageous compared to randomised and controlled designs, it is an intrinsically weak evaluative design because when secular trends are unknown, or if a sudden change occurs, it is difficult to attribute observed changes to the intervention. This is because uncontrolled before and after study designs assume that observed differences in performance are due to the intervention, and previous evidence suggests that such study designs may overestimate the effects of interventions (Eccles et al. 2003). So, when an uncontrolled design is used and improvements are seen,

results should be evaluated with an understanding of the secular trend, and additional explanatory data collection (such as in Study 2) is recommended.

Therefore, when a mixed-methods approach was used in Study 2, the explanatory qualitative data could be used to interrogate to what extent outcomes had improved due to the QI method, and how and why it did or didn't work. The qualitative data in Study 2 revealed that staff thought the model to manage variability was simple, effective, and had contributed to the success of the project. However, the participants did not feel that the outcomes of the project were exclusively associated with the model to manage variability. Interestingly, they thought greater improvements would have been possible if the context at the time of the study had been more conducive to allow changes to be made. As with other QI methods, and QI efforts in general, they reported that contextual factors around leadership, the availability of staff, and the associated organizational issues of resolving these issues had prevented further improvement. This was in comparison to Study 1, where supportive contextual factors were reflected on, and it was acknowledged (although not formally evaluated through the study design) that leadership and a supportive organisational culture played important roles in contributing to the project's success. Interestingly, in Study 3 (Chapter 5.3) a separate improvement effort failed within the same site (as Study 1) when a QI method was not used and when the contextual factors were not deemed to be as supportive.

As discussed previously (Chapter 3.5), the role such contextual factors play in the relative success of QI efforts, is consistent with the wider QI literature (Kaplan et al. 2010), and it is acknowledged that differences in context are thought to be responsible for the large degree of the variation seen in the outcomes of QI projects (Kaplan et al. 2012). Therefore, further to this, Kaplan et al. (2012) developed a conceptual model, the Model for Understanding Success in Quality (MUSIQ), that can be used by QI researchers to better understand the contextual factors that may affect the outcomes of a QI project. Their work was used as a prompt within the interviews in Study 2 to ensure that all relevant contextual factors were considered and acknowledged. The specificity of MUSIQ to QI

means that by using it, the potential to explicitly delineate the relationships among the contextual factors experienced, has helped the findings of this study provide a deeper understanding into the mechanism of action by which context influenced the success of using the model to manage variability. This is very important, because often the conditions that create a positive context for quality improvement efforts, are often invisible to those who work within them, and/or may not always be straightforward to articulate (Davidoff et al. 2015).

The addition of the qualitative component was therefore extremely valuable to unpack the outcomes of Study 2, because it has been previously proposed that a clinical microsystem team utilising a QI method is also the kind of team with all the required characteristics to facilitate improvements to quality and safety (Dixon-Woods and Martin 2016). In the case of Study 2, despite the use of the model to manage variability, the qualitative data collected via interviews with the two clinical managers highlighted that they thought that it had been contextual issues relating to leadership, staffing, and the wider organisation that had prevented the outcomes improving further. The notion therefore that the model to manage variability – or any other QI method – is an off-the-shelf 'solution' with repeatable results is consequently misguided. The features of context (clarity of vision, infrastructure, organisational systems, values, and skills) that made the model to manage variability work in Study 1 need to be reproduced too. This is important because a clinical microsystem differs markedly from a factory production line (where many QI methods originate), just as human bodies are not widgets. The acknowledgment of the role of social and cultural context is vital if improvement interventions are to work, and as such the prospective, mixed-methods study design utilised in the validation site is an important strength of the study and one that should be utilised by other future investigators of QI methods and QI interventions.

If the QI literature is looked at more broadly, confirmation of critical contextual success factors can be found. Recently, eight key contextual factors linked to the success of QI efforts have been proposed following a systematic realist review

(Coles et al. 2020). These factors are listed below and resonate with the findings from each of the three studies.

1. active, supportive, and engaged leadership
2. multi-disciplinary collaboration
3. a supportive organisational culture
4. staff with the right individual skills and capabilities
5. organisational capacity and capability for QI
6. supportive data and technical infrastructure
7. a shared readiness and belief in change
8. a change agent to drive and lead the change

Within Study 1, there was clearly a supportive environment at that time for using the model. There was a blended leadership approach (top-down/bottom-up) from the hospital executive, the lead surgeon, and the project manager (or change agent). A clear external incentive to improve (the need to deliver the 18-week referral to treatment target), and this was accompanied by a supportive organizational culture (as evidenced by the responses to the staff survey), and there was clear evidence of multi-disciplinary working. In addition, there was a data reporting infrastructure, and the move to a new ward provided a commitment and readiness (or need) to change. The project manager utilised a QI method and trained staff, which provided the QI skills, expertise, and capacity.

In contrast, within Study 2 even though there was executive, clinical, and multi-disciplinary team support for the project, the qualitative data revealed that the clinical managers did not believe that the leadership from themselves and others was sufficiently present (due to other commitments), engaged, and able to drive improvements as much as they had wanted. They knew what they wanted to do, and believed it was the right thing to do but hadn't been able to execute. Issues with staffing availability/capacity and the organizational ability to make changes were highlighted, which further underlines the level of engagement and support from executive sponsors and management.

In Study 3, the dynamic nature of contextual factors was revealed and where once (at the time of Study 1) there had been a supportive context for QI efforts, it had now shifted. The failure to improve over five change cycles is striking, as is

the failure to improve on outcomes for knee replacement over the 10 years from the initial work to the latest data. In this case there was an absence of multi-disciplinary collaboration, a QI skills gap, and clearly a lack of engaged leadership from the other professions and departments. The departure of the project manager after the completion of Study 1, and subsequent abandonment of the role, also meant the absence of a change agent, to drive and lead multi-disciplinary collaboration.

Contextual factors can therefore be argued to have played an influential role in the outcomes presented within the results of the studies (Chapter 5), and they are undoubtedly contributing factors. This of course is not surprising, given the relative heterogeneity of each hospital setting and context, as well the complexity of undertaking QI within such high-volume orthopaedic centres. QI efforts are, of course, likely to be critically influenced by the contexts into which they are introduced and by the processes of implementation into those contexts (Ovretveit 2004; Walshe 2007). The association between the use of the model to manage variability and the outcomes achieved is therefore hard to differentiate, and it may be argued that this dynamic interplay between intervention and context means that it will always be complicated to try and separate intervention from context (Hawe et al. 2009).

It is almost always difficult to replicate an intervention in its entirety from one setting to another. Excessive attention to the QI method used (e.g., the model to manage variability) in the narrowest sense will always overlook the impact of context on intervention implementation and, perhaps more importantly, the critical role of context itself as a generative of safety and quality (Dixon-Woods 2019) unless an appropriate study design is used. The mixed-methods approach utilised within Study 2 therefore helps to provide some crucial insight. This is because the experiential evidence it generated, provided the third type of evidence needed to assess whether a QI approach should be implemented in other settings, in addition to the theoretical (provided in Chapter 2) and empirical (provided in the quantitative results of Chapter 5) (Walshe 2009).

The experiential evidence to support the model to manage variability when used as a QI method was positive. Within Study 2, the two Clinical Managers interviewed, and who had led the use of the model, reported that it had been very well received by the inter-professional team. It had engaged the team in the QI process and led to the technique being used in other projects within the hospital, and the terms natural and artificial variability (key components of the model) had made their way into common usage amongst the team. More specifically in relation to the model to manage variability, both Clinical Managers thought it offered advantages over other QI methods they had used in the past. In addition, one of the clinical managers reported that they had subsequently applied the model to other projects, and had since applied the concept of removing artificial variation within a different organisation and context, and published the results (Beckett et al. 2018).

The improvement replication programme used with this research (Chapter 4.3) provides the link between the theoretical, empirical, and experiential evidence for the model of variability and can be considered a strength of the work, especially when viewed in comparison to the poor standard of reporting in surgical QI research (Jones et al. 2016). This allied with the use of the SQUIRE guidelines for reporting and the TiDiER checklists makes decisions regarding generalisability of the findings easier for the reader, and the thoroughness and quality of reporting is very unusual within the surgical QI literature (Jones et al. 2016). This can be illustrated by the results of a systematic review of another candidate QI method, in which of the 120 QI projects included, only 32 (27%) described a specific, quantitative aim and reached it, and only 72 projects (60%) documented the QI method in sufficient detail for inclusion in a full analysis of its key features (Knudson et al. 2019). Of those studies who were fully reported, only three (4%) adhered to all four of the key methodological features of the QI method. These findings highlight the importance of this research, not only as a report of the implementation of a novel QI method, but also as a high-quality example of QI reporting, and an example of how a mixed-methods design can help to improve the generalisability of findings.

The need for good study design but also transparent QI reporting is therefore vital because what often happens is that the superficial or outer appearance of the QI method or intervention is reproduced, but not the internal mechanisms that produced the outcomes in the first instance (Dixon-Woods et al. 2011). These effects may arise because what is implemented in subsequent settings, is a diluted, distorted, or diminished version of the original intervention. In the case of this thesis, the mechanics of the QI method are described in detail, along with a thorough reporting framework of the research methods used. This should be an example for other investigators to follow and improve upon.

QI research (and the studies within this thesis) is undertaken within the real world, and the interventions are normally at a system or unit level and are complex with many people and components involved. For that reason, traditional approaches to provide external validity (such as the RCT) are mostly not feasible or appropriate, and so generalisability must be provided through transparency. Both in the study design used, and the reporting of the QI method used, so that the reader can make their own judgements about transferability of both the QI method and the results to their own setting. This is very important because it has been highlighted that often when new QI methods are proposed and tested, the learning is often not shared or is challenging for others to discover (Dixon-Woods and Martin 2016). In doing so it contributes to an ongoing cycle of reinvention in quality improvement and associated waste of time and energy. The fact that the model to manage variability was utilised in Study 2 with success, shows that its introduction, explanation, and ease of use, make it an attractive candidate QI method for future study and utilisation to improve patient outcomes.

In summary, the findings from this thesis are especially important when viewed against the backdrop of QI research. For example, a 2016 review of another QI method (Lean) concluded that Lean approaches were not significantly associated with patient satisfaction or improving outcomes, had inconsistent effects on process outcomes, and had a negative association with financial costs and staff satisfaction (Moraros et al. 2016). Therefore, despite a widespread advocacy for, and acceptance that we need QI in healthcare, the research evidence that QI

methods and interventions produce positive impacts in healthcare settings remains mixed, and even the better-designed studies have disappointing results (Benning et al. 2011). Improved study design is therefore required, along with the publication of both negative and positive results of QI efforts. This is in combination with improved reporting of interventions, and the consideration that more traditional QI methods (such as Lean) may be improved on, and new techniques such as the model to manage variability might be considered.

7.0 Conclusions

This chapter begins by summarising the key findings of the thesis, including their relevance to the background rationale and specific research aims of the project. Conclusions are then drawn on the contribution of the work to the existing knowledge base, the implications of the work on future practice. and the potential for spread of the model to other contexts is considered. The relative strengths and limitations of the work are considered and recommendations for future work and research are provided.

7.1 Attainment of research objectives

This thesis has sought to evaluate the use of the model to manage variability (a novel QI method) within two elective orthopaedic clinical microsystems when utilised to inform improvements to clinical care processes. The model to manage variability was successfully adapted, and then deployed to improve hip and knee replacement ERAS care processes within a pilot site (Study 1) and a validation site (Study 2). The project aims for both studies were achieved, and LOS was reduced by 45% in Study 1, and by 18% in Study 2. A mixed-methods sequential explanatory design (QUAN emphasized) was used in Study 2 and the Clinical Managers who led the project and deployment of the model were interviewed as part of the qualitative phase. They felt the model to manage variability, was simple to use and had advantages over other QI methods. However, independent of the model, they found their improvement efforts were influenced by contextual factors previously acknowledged to influence both QI efforts and ERAS implementation.

The project was therefore successful in relation to its aim (Chapter 1.3) of evaluating the use of the model to manage variability as a QI method to help improve ERAS processes within an elective orthopaedic clinical microsystem setting. More specifically, regarding the research objectives (Chapter 1.4) the

need for improving the implementation of ERAS pathways within elective clinical microsystems was demonstrated in Chapter 3. Here, the results from a national analysis of English NHS providers showed that there is still significant opportunity for improvement regarding LOS for hip and knee replacement in comparison to international exemplars (Chapter 3.4). Further to this, the viewpoint article in Chapter 3.5 summarized that despite the evidence for ERAS protocols (discussed thoroughly in Chapter 3.3), the universal implementation of ERAS across hospitals has not occurred. The paper highlighted that whilst previously identified local contextual factors may be barriers to implementation, ERAS teams should be encouraged to use a QI method when seeking to implement or improve an ERAS pathway (which is a QI intervention). This perspective within the ERAS literature has not been previously highlighted and set the scene to review the relevant QI methods that could be used to improve care processes within a clinical microsystem within Chapter 2.

Objective 4 was achieved through a narrative review evaluating the evidence-base for relevant QI methods and outlining the model to manage variability was outlined as an intervention (Chapter 2). The advantages it may offer when adapted as a QI method to manage the variability of care processes within clinical microsystems over other QI methods was proposed, and a theoretical framework to underpin the model was generated. An improvement replication programme was then used to evaluate consecutive studies of different implementations of the model to manage variability so that they could be completed and evaluated (outlined in Chapter 4). The aim was to generate data so that a judgement on the generalizability of the model to manage variability could be made, and in doing so, to provide a link between the rationale and the stated research objectives.

7.2 Contributions to knowledge

This thesis is a very timely addition to the literature that provides a novel and valuable contribution to both the QI and ERAS knowledge base. It has generated new subject knowledge in the QI literature through the innovation of the model to manage variability as a new and viable QI method. It has strengthened the QI

research methods knowledge by the successful use and transparent reporting of an innovative mixed-methods study design that can be replicated for other studies. And the integrated papers make an important collective contribution to clinical practice by providing a new perspective to the understanding of how to improve the implementation of ERAS pathways.

This clinical contribution to knowledge is especially important given the pressures that the NHS and health systems around the world currently face. Extreme capacity pressures following COVID-19 exist and there is an elective surgical backlog that will require significant QI efforts to treat patients in an effective and efficient manner. This challenge comes against a backdrop of understanding that despite the known benefits of QI interventions such as ERAS, and a will to be involved in QI efforts, there persists a knowing-doing gap between wanting and knowing how to improve surgical care.

7.2.1 Subject knowledge in QI

This thesis started by clearly articulating the need for QI in surgery, and a general introduction to the concepts relating to QI and ERAS was presented. ERAS was then defined as a QI intervention and the difference between a QI intervention and QI method was distinguished. This perspective has been presented within the QI literature but is novel in the context of ERAS implementation research and stresses the importance of perioperative care teams using a recognised QI method to implement ERAS protocols (which are a QI intervention) successfully. This crucial distinction between what constitutes a QI method from QI intervention set the scene and rationale for the development of a new QI method.

The development of the model to manage variability as a brand-new QI method, to be used to improve care processes within a surgical clinical microsystem is a novel contribution to the QI knowledge base. An introduction to the model to manage variability was provided before the context and rationale for the adaption and introduction of the model to manage variability within an elective orthopaedic

clinical microsystem was made and justified. The theoretical framework behind the model was explored in detail and its potential advantages were discussed in comparison with a thorough review of other candidate QI methods. These proposed advantages were then found to be supported via the qualitative data collected in Study 2.

By distinguishing and differentiating QI methods from QI interventions, the narrative review of candidate methods also offers a fresh perspective to the literature. It highlights that whilst current QI methods all have a strong theoretical theory to support their use, rigorous evidence to support their use is lacking, and user experience suggests there are limitations associated with all the techniques when considering their use by teams within a clinical microsystem. The decision to adapt the model to manage variability was therefore underpinned by a rationale that QI methods could be improved. The use of the model was identified as being an attractive option because it acknowledged the need to remove unintended artificial variations in clinical practice as a central objective whilst providing consideration of the natural differences between individual patients.

7.2.2 QI research methods

As highlighted previously in the discussion (Chapter 6), QI methods are often reported very poorly within the literature, and so replication is difficult and informed judgements regarding generalisability are not possible. Therefore, the fact that the newly adapted model to manage variability was described in such detail, along with transparent reporting of the research methods, process, and outcomes makes this thesis an extremely important contribution to the QI literature within surgery. The study design used in Study 2, is a practical, low cost, and repeatable method that has not previously been utilised in the ERAS implementation literature. It therefore offers a new template for others to adapt and utilise within future research in this area.

The mixed-method study design utilised in Study 2, was informed by the evaluation of Study 1 and it was introduced to increase the generalisability of findings and unpick details regarding the if, how, and why the model to manage variability worked as a QI method. Importantly, the users interviewed within the validation site (Study 2) provided experiential evidence of using the model and felt that from their perspective it had important advantages over other QI methods that enabled them to engage colleagues and lead the QI effort more successfully. This is a hugely valuable insight and helps to generate new knowledge, not only that the model to manage variability may be a viable QI method for perioperative teams to use, but also that the study design utilised offers a solution for other to replicate. The before and after prospective observational cohort study design, with a mixed-methods sequential explanatory design (QUAN emphasized) that has previously not been used in the ERAS literature and offers a practical and useful solution for evaluating QI efforts.

As described and discussed previously (Chapter 6), the design of Study 2, and the subsequent reporting using the SQUIRE guidelines also make it a high-quality contribution to the QI literature in comparison to the other QI studies which are acknowledged as generally being of poor methodological quality. The findings, therefore, that contextual factors relating to leadership, staffing levels, and organizational factors meant that not all the changes to care processes were implemented, confirms the need for an explanatory qualitative component to the study design, and adds to the general QI knowledge base by providing insight into the conditions needed to support the use of the model to manage variability as a QI method.

7.2.3 Clinical Practice

This thesis, and the six integrated papers make an extremely valid and important contribution to clinical practice. Viewed collectively they summarise the current evidence for the deployment of ERAS in orthopaedics, highlight that current outcomes could be improved, propose that an increased knowledge of QI methods is required to close the knowing doing gap, show that when a QI method

is used outcomes can be improved, and outline how a QI method (such as the model to manage variability) may be used in the future to help the implementation of future ERAS pathways.

Chapter 3.3 detailed the components and outcomes of ERAS within orthopaedics and confirmed it as a proven and widely adopted QI intervention for improving outcomes in hip and knee replacement. However, it also emphasised that whilst outcomes had improved dramatically over the last 10-15 years, there were still challenges in achieving widespread adoption and implementation of ERAS across all hospitals and for all patients. This variability in clinical outcome was emphasised further in Chapter 3.4 where an observational study was performed, and national NHS data was analysed and presented. This important data revealed considerable variation across NHS providers, that was not explained by case-mix alone, and demonstrated that the mean LOS within the NHS for hip and knee replacement was still significantly higher than international comparators. This data is a vital contribution to the existing knowledge base as it clearly articulates the need and valuable contribution of this research, and future QI research, to allow more understanding of how to implement QI interventions such as ERAS successfully.

In Chapter 3.5 this notion was expanded, and it was argued that despite the production of evidence-based ERAS protocols, there is a need to increase awareness of how to use QI approaches to successfully implement ERAS protocols. In particular, the argument is made that ERAS teams should be encouraged to use a QI method when seeking to implement or improve an ERAS pathway (which is a QI intervention). This is a novel and important perspective within the ERAS literature, which continues to focus on a general instruction to increase compliance to protocols, without due attention to understanding how to nuance implementation activities considering local systems and processes. This is important because implementing an ERAS protocol normally challenges existing working traditions, across a varied network of departments and professions, all within a dynamic environment that is continuing to treat patients whilst change efforts are made. Therefore, to improve the success of

implementation, perioperative care teams should be advised to reflect on the findings of Study 1 and Study 2 and understand the role of utilising a QI method to adapt and implement ERAS protocols (a QI intervention) to their specific context and setting.

This is consistent with the wider QI literature (Kaplan et al. 2010), where it is acknowledged that differences in context are thought to be responsible for the large degree of the variation seen in the outcomes of QI projects (Kaplan et al. 2012), but are very often not reported or examined within research designs. This important role of context and the need to utilise a specific QI method to guide QI efforts, was further confirmed by the findings of Study 3, where the results of an unsuccessful improvement effort were presented. In this case, it was acknowledged that that a QI method was not used, and that supportive leadership, multi-disciplinary working, and a will to change were not present.

7.3 Implications for practice

Building on the contributions to knowledge highlighted in Chapter 7.2, this work has significant implications for helping others to successfully implement ERAS protocols. It provides a reminder of the importance of context, and especially local leadership of implementation and the use of QI methods to help implement. This is highly relevant at a time when the implementation of ERAS globally is being driven by the production of guidelines and protocols. These documents are of course important, and they provide information on what to do, but not how to adapt and implement within individual contexts. This is clearly something that needs attention, given the relatively poor adoption of well proven ERAS protocols across the surgical specialties.

The need to improve the implementation of ERAS pathways has therefore been highlighted throughout the thesis, and the findings from the three studies (Chapter 5) confirm that we must strive to learn from the past if we are to improve outcomes. The findings of this thesis provide a timely reminder, that whilst

knowing what should be done is one factor, being able to understand how to change, and how to coordinate across departments and inter-professional groups is quite another. This thesis confirms the need for strong clinical and managerial leadership at all levels, along with a supportive organisational culture and structure to allow change, and a collaborative inter-professional approach.

If the recommendations of this thesis and its findings are applied to the present day, the implications to practice are extremely strong, given the challenges of resuming orthopaedic surgery after the COVID-19 pandemic. An integrated paper has been published in the journal Medicina, examining this topic (Wainwright 2021) and is available in full within *Appendix 16*. It is a perspective article where possible adaptations to current ERAS pathways in light of COVID-19 are suggested, and the need for employing a QI method (such as the model to manage variability) to make these changes is proposed.

During the COVID-19 pandemic there has been a reduction in hip and knee replacement surgery across healthcare systems. When regular operating returns, there will be a large volume of patients and an importance on a short hospital stay. This will be because patients will be keen to return home, and hospital capacity will need to be maximised to catch up with the surgical backlog. Therefore, strategies to reduce the associated risks of surgery and to accelerate recovery will be needed, and so ERAS will need to be promoted and adopted as the standard of care.

ERAS protocols are proven to reduce hospital stay safely; however, they will require adaption to ensure both patient and staff safety. This is because the risk of exposure to possible sources of COVID-19 will need to be limited, and so hospital visits should be minimised. To do this, the use of technology such as smartphone apps to provide pre-operative education, wearable activity trackers to assist with rehabilitation, and the use of telemedicine to complete outpatient appointments are examples of changes that may be introduced. In making these pathway changes, units will need to learn from the past to expedite the implementation of or adaption of existing ERAS protocols. Therefore, the

argument for the use of a recognised QI method (such as the model to manage variability) to contextualize these improvement efforts (as detailed in throughout this thesis) is strong.

7.4 Quality of research

Throughout this research a high degree of comment on quality assurance has been undertaken, and the limitations of the individual study designs have been acknowledged and discussed previously in Chapter 5. However, from a thesis perspective, the fact that these limitations to study design have been highlighted, along with details of how Study 1 informed the design of Study 2, helps to improve the generalisability and contribution of the work. The attempts made throughout the thesis to ensure transparency of reporting, is rare within the QI literature, and the use of a mixed-methods explanatory design in Study 2 is an approach that should be highlighted as an effort made on behalf of the reader to counteract potential inherent bias.

In Study 2, the triangulation of the data and corroboration of findings with the interviewees in the qualitative component of the mixed-methods design helped to establish the trustworthiness (or “truth value”) of the findings. However, as with all research endeavours with QI, it may be argued that improvements could have been made by the researcher to further establish the study’s confirmability, credibility, and transferability (Jeanfreau and Jack 2010). Regarding confirmability, field notes were taken, interview transcripts were kept and ratified with the participants, and the researcher kept a reflexivity journal. Whilst these are not overtly reported, they did form part of the inductive analysis which was a strategy utilised throughout the research. This ratifies that there was a documented paper-trail, of the researcher’s thinking, decisions, and methods related to the study and helps to inform the confirmability of the study (Polit et al. 2006; Streubert-Speziale 2007).

To ensure credibility the following strategies were used throughout the conduct of the thesis to ensure confidence in the trustworthiness (or believability) of the study's findings (Polit et al. 2006). For example, data and method triangulation (use of independent/multiple sources of data and/or methods) was used, peer debriefing occurred (sharing questions about the research process and/or findings with a peer or supervisor), and member checking (returning findings to participants to determine if the findings reflect their experiences) was integral with the study design of Study 2.

Regarding the transferability of research findings, by using the SQUIRE reporting guidelines and TIDieR checklist, an accurate and rich description of the research process provides adequate information for evaluating the methods and analysis of data used. This enables the reader to judge whether the thesis findings' fit outside the work and provides confirmation that the results could be replicated when repeated in another context (Streubert-Speziale 2007).

When the quality of the research is considered, a statement regarding the reflexivity of the researcher also needs to be made, this is because as with many PhD studies and unfunded research, the researcher had multiple roles within the study. Reflexivity relates to the ways in which the researcher and the research process may have shaped the data collected. In this thesis, this could undeniably have occurred, given the role the researcher played in both Study 1 (Project Manager) and Study 2 (QI researcher). However, the role of context has been explicitly discussed, and the transparency of reporting assists the reader to make their own judgements on the influence that the researcher had on the outcomes in both studies.

The researcher's reflexivity contributes to the study's credibility as it helps make the reader more aware of possible influences on the study. Reflexivity involves the researcher's self-awareness and the strategies used to manage potential bias while maintaining sensitivity to the data (Jeanfreau and Jack 2010). Crucially, the researchers' awareness of his role in Study 1 helped inform the design and conduct of Study 2. This necessary mitigation was significant because

researchers must acknowledge that there is a possibility that their values and beliefs may influence their research studies (Jootun et al, 2009). Therefore, the researchers' self-awareness of his operational role within the clinical microsystem examined in Study 1, and how this may have affected the study's credibility, subsequently informed the design of Study 2. Thus, in Study 2, a prospective mixed-methods design was used to increase the confidence in the truth value or believability of the study's findings.

The researcher also considered how to engage, communicate, and interact with the site in Study 2, carefully adopting the role of the researcher. An example of this is when the researcher attended the initial workshops. This workshop was coordinated and led by the two local clinical managers; however, the researcher played a facilitation role, acting outside the hospital team, and intentionally set aside personal conscious thoughts and potential biases. This was done by stating explicitly at the start that he would not be playing an active role in decision making or providing input via opinion or specific clinical subject knowledge.

This clarification was necessary because the underlying belief systems of the researcher and their connection to adapting and developing the model for managing variability could inherently mean that their beliefs would be predisposed to interpret the findings of the study in a positive way. However, the results presented, independent of any inherent assumptions, show that the prospectively chosen outcome measures improved over and above the secular trend, and the experiential data from the interviews explained and appraised the use and role of the model to manage variability in achieving these outcomes.

A reflexive process is vital to help validate qualitative research findings; however, placing too much emphasis on reflexivity may lead to pairing each decision with unnecessary frames of reference, which may overcomplicate the final disposition of research findings. Therefore, it may be argued that the approach taken in this thesis whereby the interactions between the researcher and the research have been explained is the most pragmatic way to incorporate reflexivity into your process without creating unintentional cerebral gridlock.

7.5 Recommendations for future work

This thesis emphasises the value of utilising a recognised QI method to contextualize and implement process changes within clinical microsystems if they are required. The model to manage variability certainly shows promise as an option to do this and may offer important advantages over other candidate QI methods. Therefore, future study of the model is recommended, with equally or more rigorous study designs, complete and transparent reporting of context, and a description of the methods and interventions that can be replicated. As has been advocated with this research, future study designs should consider using mixed-methods, and the study designs could be strengthened in the future research by development and expansion of the qualitative approaches used. To do this, data collection techniques such as focus groups and practice observation could be considered, and in studies where interviews are used, increasing the number of interviewees across stakeholder groups will also be important. Only then will we strengthen the QI literature and increase the generalizability and transferability of our findings.

Specifically, the model to manage variability could be evaluated by surgical teams both in orthopaedic and other surgical specialties, to improve a range of different improvement aims and outcome measures. The studies in this thesis focused on process outcomes and particularly LOS (which may be argued to be a process or clinical outcome measure). Future work could look to validate the model to inform interventions that seek to improve other outcomes of quality within orthopaedics, such as complications, PROMs, and objective measures of functional recovery. Moreover, the use of the model in as a QI method in other surgical specialities, and medical clinical microsystems may also be considered, so that it's utility can be evaluated.

The model to manage variability could also be evaluated across sites with a broad range of background quality, so that it may be decided if the model works better

to help poor performers (with more inherent artificial variation in their systems), and/or whether it is useful at helping clinical microsystems move from good to great performance. On a larger scale, using the model to manage variability could also be evaluated against other QI methods, however in such studies, many sites would be required, along with a study design that would be able to account for and quantify the role of contextual factors across involved sites.

7.6 Closing summary

This thesis, and its findings are extremely timely, given that our health systems will need to carefully navigate their way out of the surgical backlog following the current COVID-19 pandemic. The need for high quality and efficient elective surgical care has never been greater. To increase their chances of success, it is proposed that peri-operative teams must seek to employ suitable QI methods when re-introducing and refining their ERAS protocols post COVID-19. The model to manage variability is a novel QI method which has been developed and shown through this this thesis to be a viable and attractive option for clinical teams to use as a QI method.

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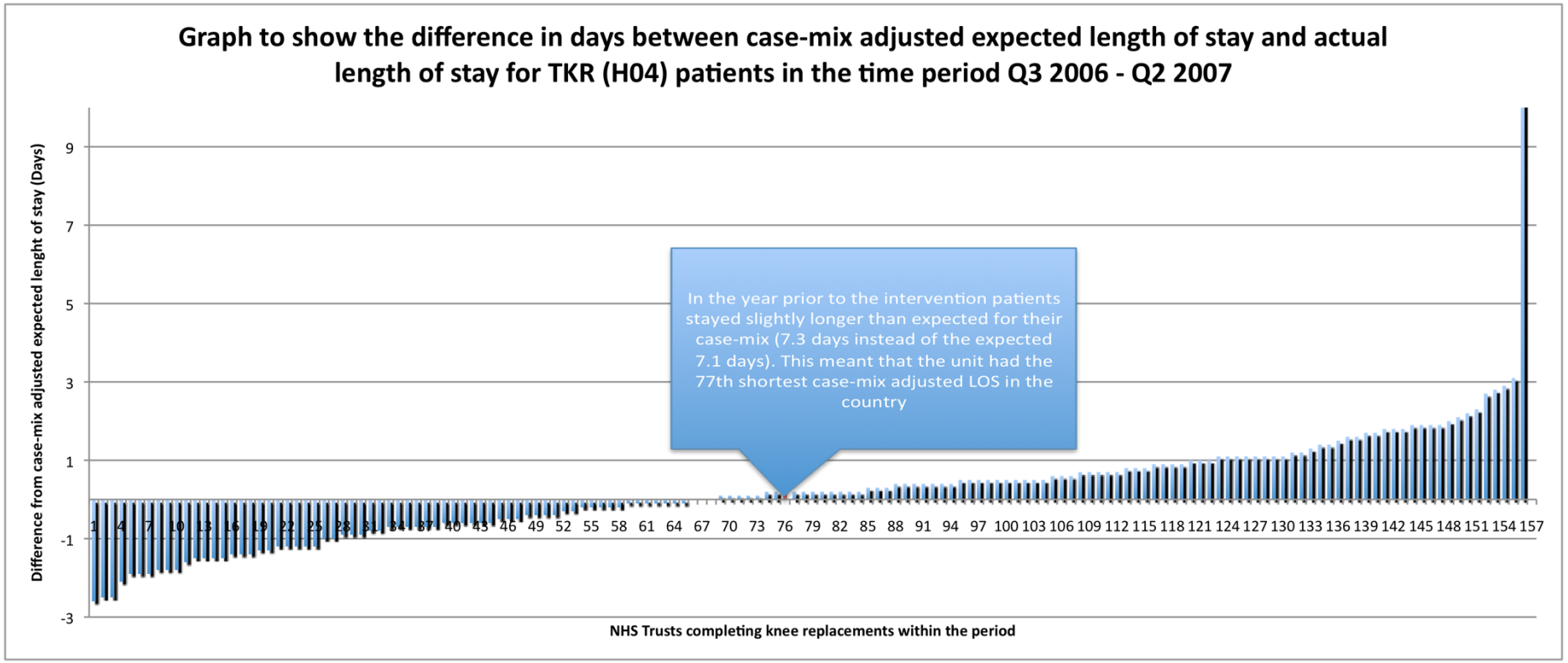
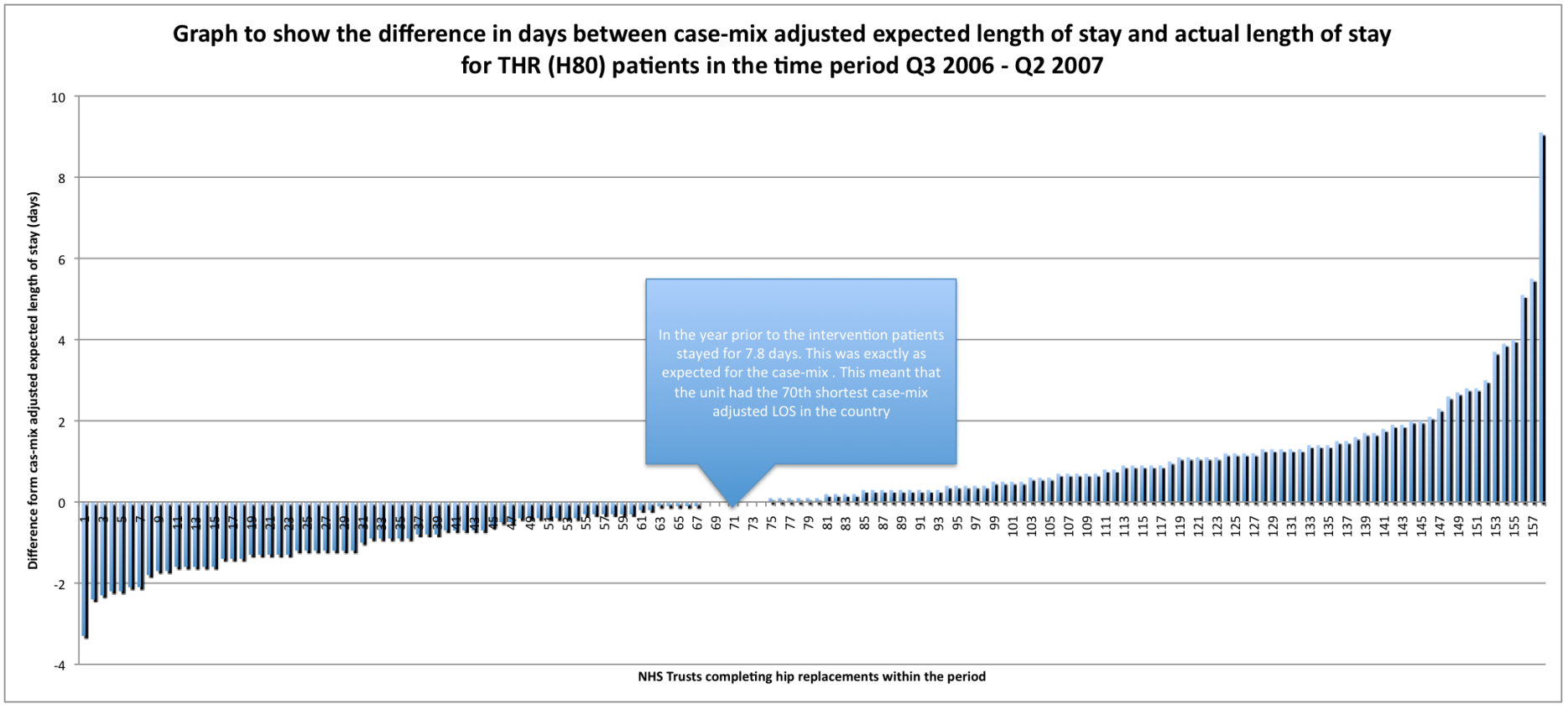
Appendices

Appendix 1 – *Graph to show case-mix adjusted LOS performance for knee replacement pre implementation*



Appendix 2 – Graph to show case-mix adjusted LOS performance for hip replacement pre implementation



Appendix 3 – *Ethical Approval*

Bournemouth University

Research Ethics Checklist

Reference Id	177
Status	Approved
Date Approved	26/03/2014

Researcher Details

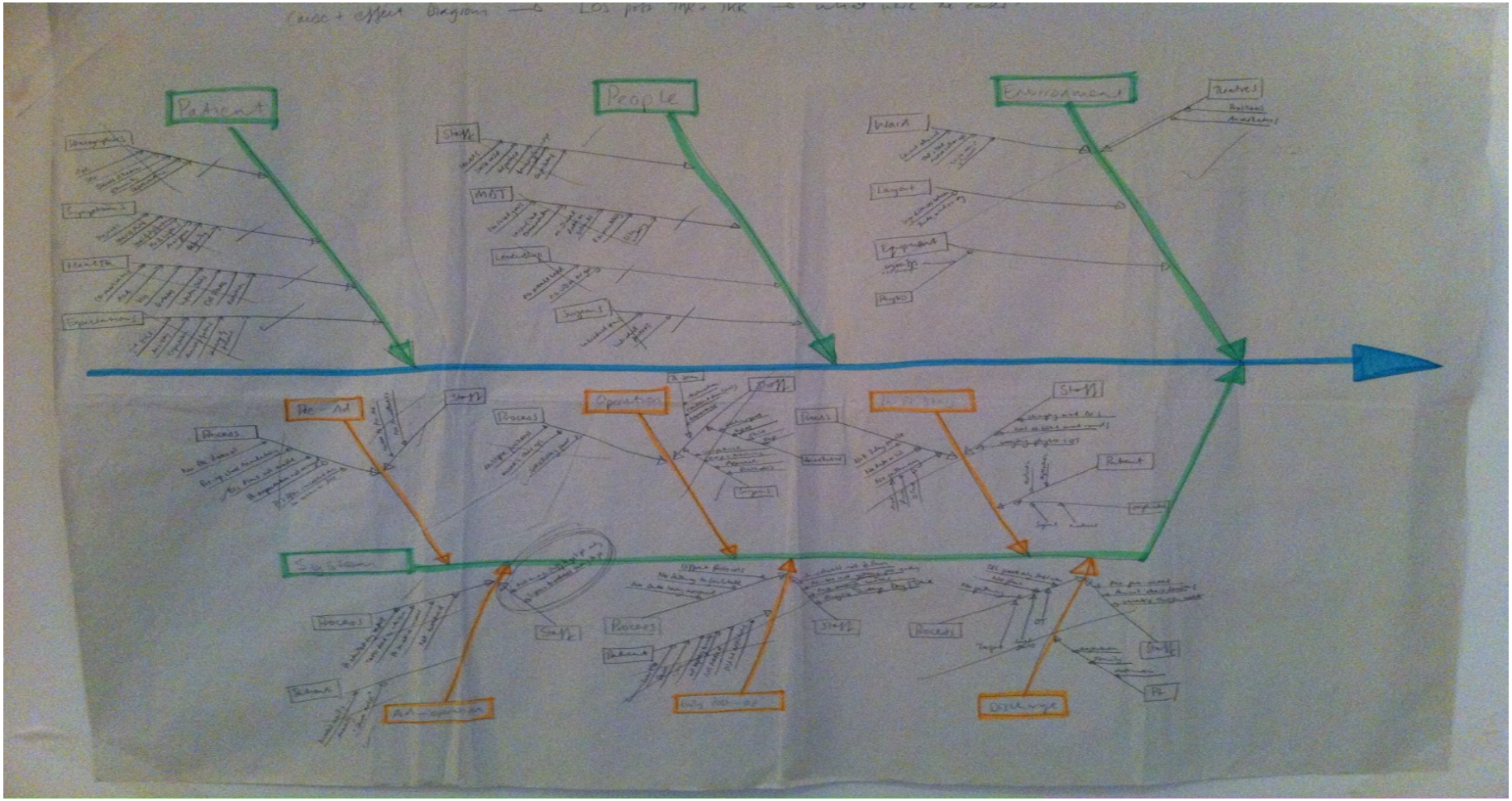
Name	Tom Wainwright
School	Health and Social Care
Status	Postgraduate Research (PhD, MPhil, DProf, DEng)
Course	Postgraduate Research
Have you received external funding to support this research project?	No

Project Details

Title	A model for managing the variability of care processes within a National Health Service elective care clinical microsystem
Proposed Start Date	30/11/2012
Proposed End Date	31/12/2013

Appendix 4

Cause and effect diagram created in order to identify causes of variability



Appendix 5 – *Table to report inclusion and location of information describing the intervention utilising the adapted TIDieR checklist and QI method checklist proposed by Jones et al. (2016) for Study 1 (Chapter 5.1)*

	Intervention (TIDieR parameters)			QI method	
1	Brief name	✓	1	Name of QI method	✓
2	Why: rationale for intervention	✓	2	Baseline measurement	✓
3	What: materials used to apply intervention	✓	3	Data collection schedule	✓
4	What: procedures undertaken	✓	4	Data analysis (e.g. driver diagrams)	✓
5	Who: provided the intervention, including level of training	✓	5	Data volume/duration (e.g. length of PDSA cycle)	✓

6	How: the interventions were delivered	✓	6	Explicit description of prediction of change	✓
7	Where: location	✓	7	Missing data (and reasons given)	✓
8	When and how much: duration, dose, intensity	✓	8	Description of generalisability	✓
9	Modifications: to intervention over the course of the study	✓	9	Named primary outcome	✓
10	How well (planned): strategies to improve or maintain intervention compliance	✓			
11	How well (actual): the extent to which the intervention was delivered as designed	✓			

Appendix 6 – *Removing artificial variability from a physiotherapy service helps to reduce LOS*

Removing artificial variability from a physiotherapy service helps to reduce length of stay in an orthopaedic enhanced recovery pathway.

Tom Wainwright and Robert Middleton Orthopaedic Department, The Royal Bournemouth Hospital, and the Centre of Postgraduate Medical Research and Education, Bournemouth University.

International Forum on Quality and Safety in Health Care, 5-8 April 2011, Amsterdam.

Context

This work was completed in the orthopaedic department of a district general hospital in the United Kingdom. The project involved patients having a hip or knee replacement operation. It was identified that patients who had operations on different days of the week experienced different standards of rehabilitation after their operation. There was unacceptable variation in patient experience and quality of care provided.

Assessment of problem

Analysis was completed using Dr Foster software. This illustrated differences to length of hospital stay depending on the day of operation. The analysis used case-mix adjustment methodology to control for natural differences in demographics. Staff then completed a root cause analysis to ascertain why this was happening.

Intervention

The physiotherapy service was changed to remove artificial variation in the provision of rehabilitation to patients who had operations on a different day. A business case was made and supported to change the physiotherapy service from a 5-day Monday to Friday service, to a 7-day a week service with extended working hours until 8pm from Monday to Friday. Standardised operating procedures were also introduced so that each patient received the same physiotherapy program and timings of physiotherapy interventions were recorded.

Lessons learnt

Effective pathways need to be supported by organisational structures and staffing arrangements which allow them to work. Pathways usually centre on clinical processes, but we have learnt that these must be accompanied by managerial changes in order to allow the clinical changes to be performed for every patient.

Key Message

High quality patient pathways should remove all possible sources of artificial variation. We have illustrated the improvement to quality possible by removing the variability in our physiotherapy service provision.

Excess bed days are the number of days patients have stayed longer than expected for their case-mix. In the year before the change most excess bed days occurred for patients operated on Thursday and Friday.

This graph shows the dramatic reduction in excess beds days across all days of the week.

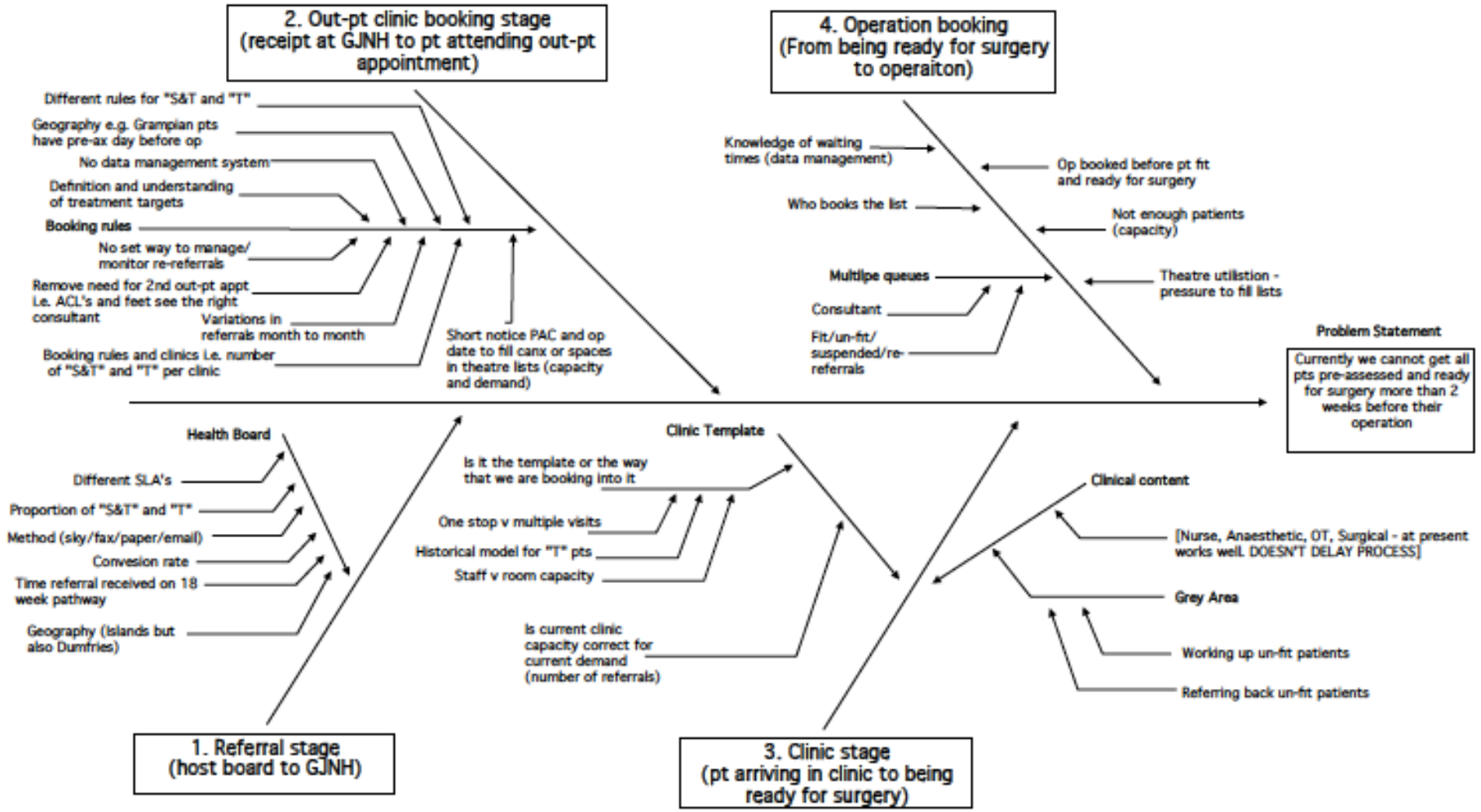
Before the change there were fewest discharges at the weekend and so consequently there was a backlog of patients to receive physiotherapy on a Monday and Tuesday.

This graph shows the high number of weekend discharges following the introduction of a 7 day physiotherapy service.

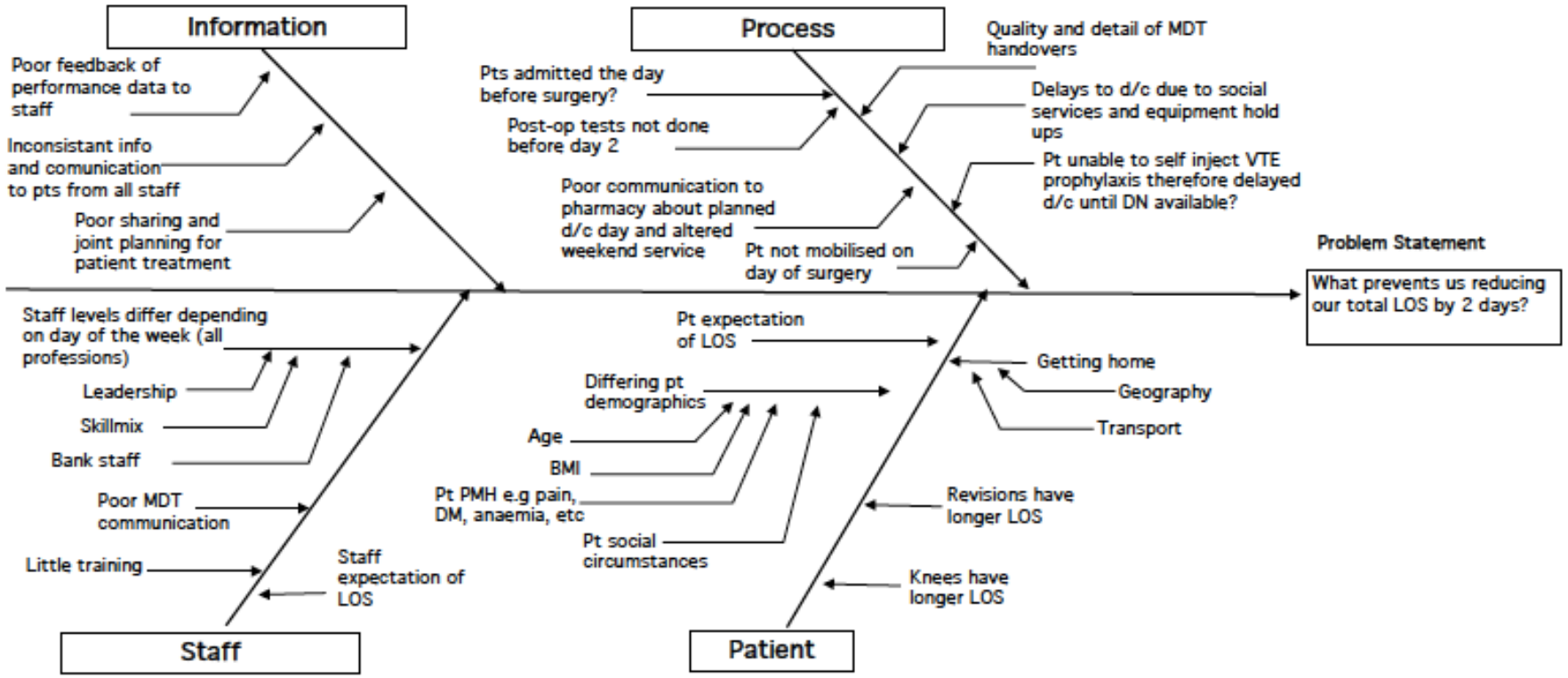
This graph shows the case-mix adjusted length of stay for patients after the service change. As you can see patients stayed between 2.1 and 2.7 days shorter in hospital than what was expected for their case mix. There was little variation between the day of operation.

Appendix 7 – *Photographs from the GJNH*

Appendix 8 – *Cause and effect aim for improvement aim 1 at the GJNH*



Appendix 9 – *Cause and effect aim for improvement aim 2 at the GJNH*



Appendix 10 – *Table to report inclusion and location of information describing the intervention utilising the adapted TIDieR checklist and QI method checklist proposed by Jones et al. (2016) for Study 2 (Chapter 5.2)*

	Intervention (TIDieR parameters)			QI method	
1	Brief name	✓	1	Name of QI method	✓
2	Why: rationale for intervention	✓	2	Baseline measurement	✓
3	What: materials used to apply intervention	✓	3	Data collection schedule	✓
4	What: procedures undertaken	✓	4	Data analysis (e.g. driver diagrams)	✓
5	Who: provided the intervention, including level of training	✓	5	Data volume/duration (e.g. length of PDSA cycle)	✓

6	How: the interventions were delivered	✓	6	Explicit description of prediction of change	✓
7	Where: location	✓	7	Missing data (and reasons given)	✓
8	When and how much: duration, dose, intensity	✓	8	Description of generalisability	✓
9	Modifications: to intervention over the course of the study	✓	9	Named primary outcome	✓
10	How well (planned): strategies to improve or maintain intervention compliance	✓			
11	How well (actual): the extent to which the intervention was delivered as designed	✓			

Appendices 11-16 *– Integrated papers*

Wainwright, T. W., 2021. The current status of daycase hip and knee arthroplasty within the English National Health Service – A retrospective analysis of Hospital Episode Statistic data. *The Annals of the Royal College of Surgeons of England*, 103 (5), 324-331.

medicina

MDPI

Perspective

The Quality Improvement Challenge—How Nurses and Allied Health Professionals Can Solve the Knowing–Doing Gap in Enhanced Recovery after Surgery (ERAS)

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Abstract: The English National Health Service (NHS), and all health services around the world, will continue to face economic and capacity challenges. Quality improvement (QI) interventions, such as Enhanced Recovery after Surgery (ERAS), that are proven to improve patient care and deliver operational benefits are therefore needed. However, widespread implementation remains a challenge. Implementation of ERAS within the NHS over the last 10 years is reviewed, with a focus on total hip arthroplasty (THA) and total knee arthroplasty (TKA). Difficulties with implementation are highlighted, and a recommendation for the future is presented. This perspective is novel in the ERAS literature, and centres around increasing the understanding of perioperative care teams on the need for utilising a recognised QI method (e.g., plan–do–study–act cycles, Lean, and Six Sigma) to implement ERAS protocols (which are a QI intervention) successfully. The importance of differentiating between a QI method and a QI intervention has value across all other ERAS surgical procedures.

Keywords: enhanced recovery after surgery; quality improvement; surgery; orthopaedics

1. Introduction

Health services around the world, including the English National Health Service (NHS), have faced economic and capacity challenges over the last 10 years, and these will remain and increase following the global COVID-19 pandemic. The ongoing reduction in resources and increasing demand for services, will provide an immense challenge to NHS organisations and staff. Quality improvement (QI) approaches may be used to improve the quality of patient care and save money, but their success is both dependent on the local context and how they are implemented [1,2]. Enhanced Recovery after Surgery (ERAS) (or enhanced recovery/fast-track) protocols are a QI intervention and are a multi-modal approach to care which has been shown to reduce mortality, morbidity, and length of stay (LOS) across a range of elective surgical procedures [3].

2. The History of ERAS Implementation within the NHS

ERAS protocols optimise the peri-operative pathway by minimising the surgical stress response to surgery by using and combining techniques, such as minimally invasive surgery, regional anaesthetic techniques, multi-modal opioid sparing pain management, early nutrition, effective fluid management and early mobilisation. ERAS protocols have been detailed in procedure specific evidence-based

guidelines for a range of surgical procedures [3] and include recommendations for total hip arthroplasty (THA) and total knee arthroplasty (TKA) [4].

In England, the spread and adoption of ERAS was initially promoted over 10 years ago via a government led programme. The Department of Health (DOH) launched the Enhanced Recovery Partnership Programme (ERPP) in April 2009, which was a 2-year national improvement programme focused on surgical procedures involving the colorectal, urology, gynaecology, and orthopaedic (focusing on THA and TKA) specialties [5]. The ERPP aimed to reduce and address the wide variations in LOS found across common elective surgical procedures. ERAS protocols were an attractive intervention in order to improve clinical outcomes and increase the capacity required to meet the 18-week referral-to-treatment target. In year 1, the ERPP focussed on increasing awareness of ERAS through events, conferences, and producing supportive literature and online resources. In year 2, the ERPP focussed on spread, adoption and sustainability of ERAS, and amongst other activities produced a basic national ERAS database as well as encouraging regional support through the strategic health authorities.

There is a perception that ERAS strategies have been universally adopted in England; however, recently published data suggest that this is not a reality [6]. For some hospitals, ERAS protocols have become so embedded into practice it is now considered the standard care, yet for others, there has been a significant decline in compliance to ERAS protocols since the end of the national programme [7]. Following the programme, there has been no on-going formal national programme to support ERAS adoption, and so the effect of ERAS protocols on influencing outcomes at a national level is questionable.

Recent research has highlighted that the programme had no discernible independent effect on decreasing LOS nationally for both THA and TKA [6]. Despite the scientific evidence for ERAS, there is still a knowing–doing gap, and widespread implementation within the NHS has not occurred. Mean LOS remains over 4 days after THA and TKA compared with 2 days in large epidemiological studies in equivalent socialised health care systems [8,9]. It is important that the status of nationwide implementation is highlighted and addressed, because improving surgical outcomes for THA and TKA patients is of critical importance to the NHS. Given the current economic challenges within the NHS, the relative high volume of procedures performed compared to other surgeries (THA and TKA are the most common orthopaedic procedures in the United Kingdom [10]) means that a reduction in LOS for these patients could deliver significant capacity savings to the NHS. Given the homogeneity of the procedure and relative fitness of patients compared to other surgical procedures, it may also be argued that THA and TKA are procedures where pathway improvements should be easier to deliver.

3. Why Has ERAS Not been More Widely Adopted within the NHS?

Thus, why is clinical practice not reflecting evidence-based surgical care? When the motives for doing so, namely improved patient outcomes and economic savings are so attractive and needed. The question of ERAS implementation has attracted previous attention [11] and remains unresolved. It is not because the implementation of ERAS for THA and TKA in the NHS is not feasible. Pockets of excellence exist [12,13] and a high-quality service should be possible within all NHS hospitals.

The failure of widespread and complete adoption is multi-faceted, and there are contextual factors, similar to other QI interventions, that may limit the success of implementing ERAS. Whilst some staff may feel positive about the implementation of ERAS [14], previously identified and general barriers to implementing ERAS pathways have been reported to include frontline clinicians being resistant to change, not having enough resources for implementation; difficulties with collaboration and communication across the multidisciplinary team; and local or contextual factors, such as patient complexity or hospital location [14,15]. Conversely, facilitating factors in successful implementation sites are reported to be (1) adapting the programme to fit local contexts, (2) achieving and demonstrating early success, (3) gaining support from both clinicians and hospital leadership, (4) having a strong multidisciplinary ERAS team that regularly communicates and (5) recruitment of supporters and full time ERAS staff or champions [14,15].

These factors resonate with the wider quality improvement literature where context has been found to be a crucial determinant of whether quality improvement projects are successful. Kaplan et al. [16] concluded that strong clinical and managerial leadership at all levels, a supportive organisational culture with high staff motivation for change, the use of process and outcome data to monitor changes, and the use of a recognised QI method (such as a plan–do–study–act cycle) when introducing a QI intervention were all crucial to success.

4. Recommendations for the Future Implementation of ERAS

We must refocus our efforts and remember that even though ERAS has been shown to improve clinical outcomes, implementing ERAS itself is not the goal, but instead is an intervention by which patient care can be improved. Instead, it should be recognised that improving a clinical outcome is achieved by combining clinical decisions informed by evidence-based medicine (such as an ERAS protocol) with the needed process or system changes, that allow the right things to be delivered in the right way [17]. Understanding this concept is crucial if we are to understand that "wanting to improve is not the same as knowing how to do it" [18].

The need for perioperative care teams to increase their knowledge of QI approaches is therefore required, and this should include the understanding that QI approaches may involve both QI methods (including techniques such as plan–do–study–act cycles, Lean, and Six Sigma) and QI interventions (such as checklists, care-bundles, and clinical pathways) [19]. This nuance is important because an ERAS protocol should be classified as a QI intervention, and this has not previously been emphasised in the ERAS literature. ERAS protocols are QI interventions intended to improve a process, and the evidence for an ERAS protocol for THA and TKA is well established [4]. In the right context and environment, there is clear evidence for successful deployment and adaption. For example, outpatient surgery for THA and TKA is now possible when implementing ERAS informed peri-operative protocols [20]. However, as highlighted previously, the successful deployment of ERAS protocols across all hospitals has not been universal because of contextual factors, and the relationship between reduced compliance of ERAS components to poorer outcomes has been shown [21].

This is important because one of the key contextual factors identified by Kaplan et al. [16] to be associated with successful quality improvement efforts, that has received minimal attention to date within the ERAS literature, is the use of a specific QI method (such as plan–do–study–act cycle, Lean, and Six Sigma) when introducing an ERAS protocol to a specific hospital. A QI method is defined as a "systematic technique for identifying defects in clinical systems and making improvements, typically by involving process measurement and remeasurement" [19]. As such, it may be considered a vital factor in the successful adaptation and implementation of ERAS protocols in varying settings and contexts. This is alongside the more widely described and acknowledged factors such as clinical and managerial leadership, the role of an ERAS champion, a supportive organisational culture, effective multidisciplinary communication and collaboration, and the use of data and ongoing audit [22].

5. Conclusions

Implementing an ERAS protocol involves the introduction of a QI intervention into a dynamic environment, across multiple departments, with a varied network of multidisciplinary relationships, and it normally challenges existing working traditions. With such a complexity of factors and variables, it is extremely difficult to introduce an ERAS protocol without the use of a QI method to help understand current processes. It is therefore recommended that to improve the success of implementation, perioperative care teams must understand the role of utilising a QI method to adapt and implement ERAS protocols to their specific context. The future use and evaluation of the use of QI methods to implement ERAS should be encouraged, so that perioperative teams can transition from a will to improve, to an understanding of how to improve.

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Conflicts of Interest: The author declares no conflict of interest.

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A hospital-based mixed-methods observational study to evaluate a hip and knee replacement quality improvement project

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Abstract

Purpose – Health services continue to face economic and capacity challenges. Quality improvement (QI) methods that can improve clinical care processes are therefore needed. However, the successful use of current QI methods within hospital settings remains a challenge. There is considerable scope for improvement of elective clinical pathways, such as hip and knee replacement, and so the use and study of QI methods in such settings is warranted.
Design/methodology/approach – A model to manage variability was adapted for use as a QI method and deployed to improve a hip and knee replacement surgical pathway. A prospective observational study, with a mixed-methods sequential explanatory design (quantitative emphasised) that consisted of two distinct phases, was used to assess its effectiveness.
Findings – Following the use of the novel QI method and the subsequent changes to care processes, the length of hospital stay was reduced by 18%. However, the interventions to improve care process highlighted by the QI method were not fully implemented. The qualitative data revealed that staff thought the new QI method (the model to manage variability) was simple, effective, offered advantages over other QI methods and had highlighted the correct changes to make. However, they felt that contextual factors around leadership, staffing and organisational issues had prevented changes being implemented and a greater improvement being made.
Originality/value – The quality of QI reporting in surgery has previously been highlighted as poor and lacking in prospective and comprehensively reported mixed-methods evaluations. This study therefore not only describes and presents the results of using a novel QI method but also provides new insights in regard to important contextual factors that may influence the success of QI methods and efforts.

Keywords Health care, Quantitative methods, Quality improvement, Qualitative methods, Hospitals
Paper type Research paper

1. Introduction

1.1 Problem description

The orthopaedic service at the Golden Jubilee National Hospital (GJNH), in Glasgow, Scotland, is the recognised national centre for hip and knee replacement within Scotland. The service was set up in 2003, and the enhanced recovery pathway was initiated in 2007 following a visit by members of the inter-disciplinary team to Copenhagen in Denmark to observe a fast-track

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hip and knee replacement service (Husted and Holm, 2006). The GJNH team then developed a designated Enhanced Recovery Programme (ERP), which they named the CALEDonian® technique. Its implementation resulted in improvements to patient outcomes whilst reducing the length of stay following surgery (McDonald *et al.*, 2012).

From 2010, a national programme within Scotland to establish ERP as the normal pathway of care for all patients undergoing joint replacement was launched and strongly supported by the GJNH. This programme resulted in improved patient care throughout Scotland, including reductions in urinary catheterisation use, the need for blood transfusion and the mean post-operative length of stay for patients across Scotland (Scott *et al.*, 2013).

However, whilst the national ERP improved outcomes nationally, outcomes at the GJNH remained consistent but did not continue to improve. Therefore, with the ongoing national improvement work driving hospital boards across Scotland to improve, the outcomes at the GJNH became average when benchmarked nationally. Therefore, in order to sustain its position as a recognised national centre of excellence and to accommodate a change in referral sources and the continuing increasing demand on its services, it was vital that a review of the current enhanced recovery after surgery (ERAS) pathway was undertaken. This would help ascertain where further improvements could be made that would improve clinical outcomes and maximise capacity.

1.2 Available knowledge

In order to instigate change, it was recognised by local leadership that a systematic quality improvement (QI) effort was required in order to understand how to make improvements relevant to the GJNH current pathway. A clinical leader from the GJNH approached an external QI researcher to help with the QI effort after participating in a workshop at the 2012 ERAS UK Conference (ERAS UK Conference, 2012). In the workshop, a QI method used to advise the implementation and improvement of an ERAS pathway in hip and knee replacement was presented. The clinical leader identified that this QI method could be used at the GJNH, and so the QI researcher was invited to visit the GJNH hospital to meet with clinical leaders and hospital executives. The QI method, which was a model to manage variability (adapted from Litvak (2005) for use in clinical microsystems to improve care processes), was presented, and the GJNH leadership team agreed to engage the QI researcher to help them with the project.

The need for external help and the need to use a specific QI method to inform change were recognised by the GJNH team due to their work nationally to help other sites implement ERAS. They recognised that process changes were required, and these needed to be driven by the whole inter-disciplinary team, and this resonated with guidance from the National Health Service (NHS) Institute for Innovation and Improvement (Institute for Innovation and Improvement, 2006). The team also acknowledged how the fast-track hip and knee replacement service they had observed in Denmark had continued to improve. Patients were now being routinely discharged at a median of two days post-surgery (Husted *et al.*, 2011). The improvements to care achieved by the Danish team were achieved by carefully analysing the specific barriers to discharge within their clinical context (Husted *et al.*, 2011), and areas for improvement were highlighted as improvements to care processes.

Further, it was acknowledged that if the patient pathway was highly structured and standardised, and if the inter-disciplinary team were involved in the development and production of the pathway, then improvements to patient care were possible.

1.3 Rationale

Leadership at the GJNH identified that a specific QI method was required that would help to structure, analyse, implement and sustain improvements. The model to manage variability was chosen because it was identified by the project leads as a QI method that could help to

reorganise care process. It was felt to have the required sensitivity and format for managing variability that could be understood by the clinical team. This was supported by the fact it had been utilised in another orthopaedic clinical microsystem successfully, and the leaders were aware of the results and process (Wainwright and Middleton, 2010).

The model to manage variability works as a QI method by identifying sources of variability within the clinical microsystem that may affect the outcome measure seeking to be improved. Clinical microsystems are an appropriate organisational level at which QI efforts can be applied (Donaldson and Mohr, 2000; Nelson *et al.*, 2002) and defined as the "small, functional, front-line units that provide most health care to most people. They are the place where patients and providers meet, and 'the quality and value of care produced by a large health system can be no better than the services generated by the small systems of which it is composed" (Nelson *et al.*, 2002, p. 473). Sources of variability are identified by using a cause-and-effect diagram (or Ishikawa diagram), and then sources of variability are either classified as artificial or natural variability. This is a novel and distinguishing factor from other QI methods, such as Lean or Six Sigma. An outline of the approach is provided in Figure 1.

The model, adapted from Litvak (2005), proposes that the artificial variability of care processes is the most likely barrier to providing efficient and high quality healthcare. Natural variability is explained as being the intrinsic, normal and naturally occurring part of every system. Natural sources of variability are identified and then subdivided into "clinical, flow, and professional" categories. Natural "clinical variability" may represent the wide range of naturally occurring clinical presentations a patient may have, the level of their symptoms and their responses to treatment whereas natural "flow variability" may relate to the random arrival of patients for treatment and their consequential referral to hospital. Natural "professional variability" refers to the intrinsic differences in experience and technical skills that normally occur across healthcare professionals. If any variability is not easily classified into any of the "natural" subcategories, it is thought to be "artificial". The rationale for identifying artificial variability is that it usually arises in processes because of the decisions made by those managing the system. It does not naturally occur, and in most healthcare systems, it is almost always multi-factorial and frequently hidden. It is therefore difficult to understand and identify without a systematic approach or method. Artificial sources of variability should therefore be removed, and natural sources of variability should be managed.

The decision to adapt Litvak's (2005) model was underpinned by a recognition that all care processes within a clinical microsystem are subject to variability and that an improvement to quality would occur through understanding and reducing the unintended variability within this system (Wheeler, 1999). Adapting Litvak's (2005) model for use to improve care processes was further thought to be attractive to clinical teams because whilst it acknowledges the need to remove unintended artificial variations in practice as a central objective, it also provides consideration of the natural differences between individual patients. This was felt to be an advantageous feature over alternative QI methods by the clinical team.

Previously, research utilising this approach has focused on modelling improved patient flow in unplanned care areas, such as critical care, emergency departments and operating theatres (McManus *et al.* 2003, 2004; Litvak, 2005). This adaption of the model is a novel development, and utilising the model to manage variability as a QI method to improve care processes has not been previously proposed or studied. In this case, a QI method is defined as a "systematic technique for identifying defects in clinical systems and making improvements, typically involving process and remeasurement" (Jones *et al.*, 2016).

1.4 Specific aims

The objective of the project was to maximise capacity at the GJNH in order to help meet the increasing demand in Scotland for hip and knee replacement, whilst re-establishing the GJNH as the exemplar unit in Scotland for outcomes following hip and knee replacement. The

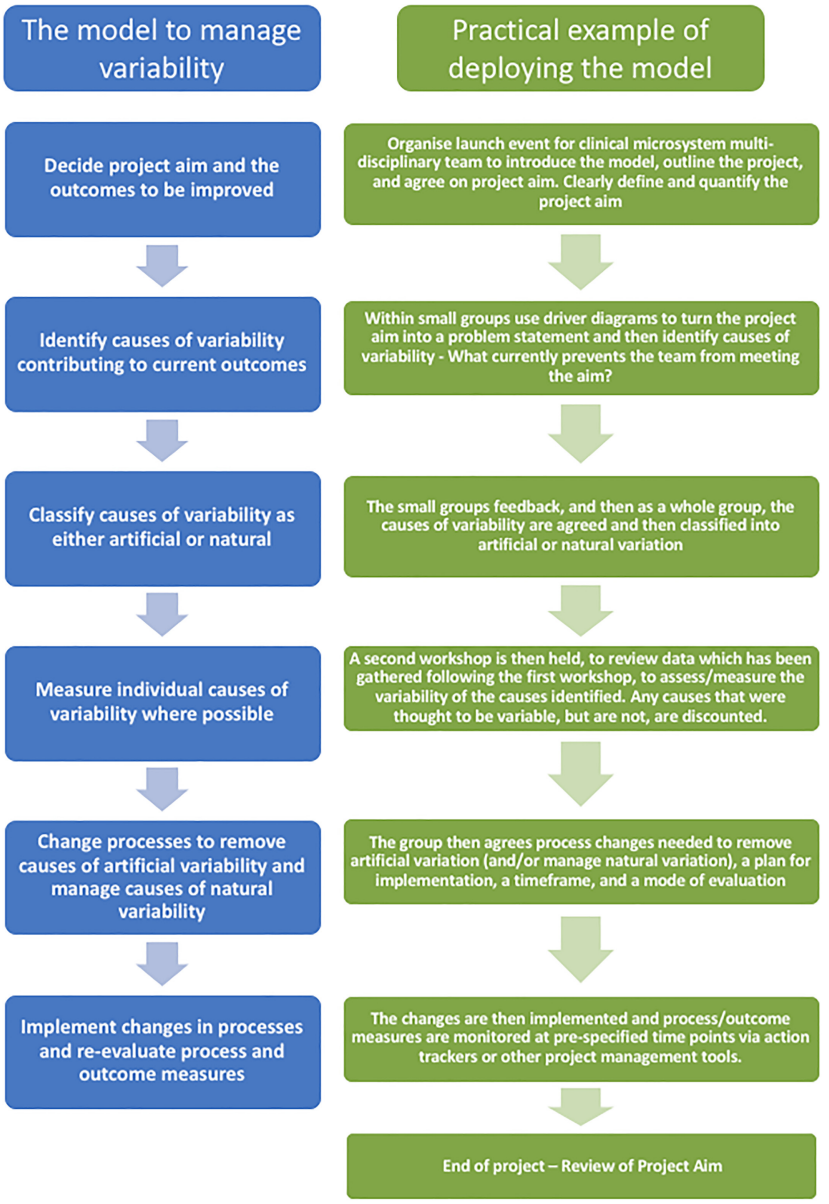

Figure 1.
Adapted model to manage variability for use to improve clinical care processes in a clinical microsystem

project utilised the model to manage variability as a QI method, in order to inform improvements to the ERAS pathway within the GJNH elective orthopaedic clinical microsystem.

The clinical microsystem team decided on two improvement aims.

(1) To ensure all patients are pre-assessed and fit for surgery two weeks prior to their operation (more specifically, to improve from the current rate of 65–100%)

(2) To reduce average length of stay (LOS) for hip and knee replacement by two days (more specifically, to reduce LOS from the average of 5.5–3.5 days)

The first aim was chosen as the team recognised a high number of patients were attending for pre-assessment less than two weeks prior to surgery. This would often lead to theatre slots not being filled, cancellations when patients were found to be "not fit for surgery" and preparing patients appropriately pre-operatively with the right education and information was difficult and often rushed. Appropriate discharge planning could also be a problem, as there was not enough time to make arrangements before admission. Reducing LOS was chosen by the team as the second improvement, as they felt LOS was an appropriate proxy indicator of quality, and it was the comparator outcome measure used in Scotland to nationally benchmark.

2. Methods

This study and the methods used are reported in accordance with the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines (Ogrinc *et al.*, 2016).

2.1 Context

The GJNH is Scotland's specialist hospital for reducing patient waiting times, and as such, as well as serving local patients, referrals are received from across the country. The hospital is a busy and large elective care centre, performing over 57,000 procedures per year, with over 1800 members of staff, more than 200 in-patient beds and 16 operating theatres. The GJNH is home to one of the largest elective (planned care) orthopaedic centres in Europe, performing over 3,500 hip and knee replacements each year. The orthopaedic clinical microsystem has an inter-disciplinary approach to care, with consultants, nurses, physiotherapists and occupational therapists all working together.

2.2 Intervention

The principles of Litvak's (Boston University Health Policy Institute, 2006) variability methodology were adapted to identify, classify and manage the intrinsic sources of variability contributing to the delays in the pre-assessment process (improvement aim 1) and the current patient LOS within the clinical microsystem (improvement aim 2). By employing this framework, the team was able to co-ordinate improvement efforts.

The first stage was to undertake an analysis of current processes and to identify sources of variability that were contributing factors to delays in the pre-assessment process and the current LOS experienced by patients. This was coordinated by the two clinical managers. A workshop facilitated by the external QI researcher involving leaders from across the inter-disciplinary team was held in order to identify and agree causes of variability within the clinical microsystem related to the improvement aims. Attendees at the workshop involved representation from the pre-op, intra-op and post-op care teams and included surgeons, anaesthetists, nurses, theatre staff, therapists, radiography staff, pharmacists and administrative staff.

This workshop was held in January 2013, and the outputs were summarised by the group into a cause-and-effect diagram for each improvement aim (Figures 2 and 3). The cause-and-effect tool (or Ishikawa diagram) is considered one of the seven basic tools of quality control (Ishikawa, 1985). It is also known as a fishbone diagram because of its shape. In this case, the "fish head" represented the improvement aim. The potential causes of variability that affected the two improvement aims identified within the workshop were indicated as the "fish bones" of the diagram. Once these variables or causes of variability were identified, they were

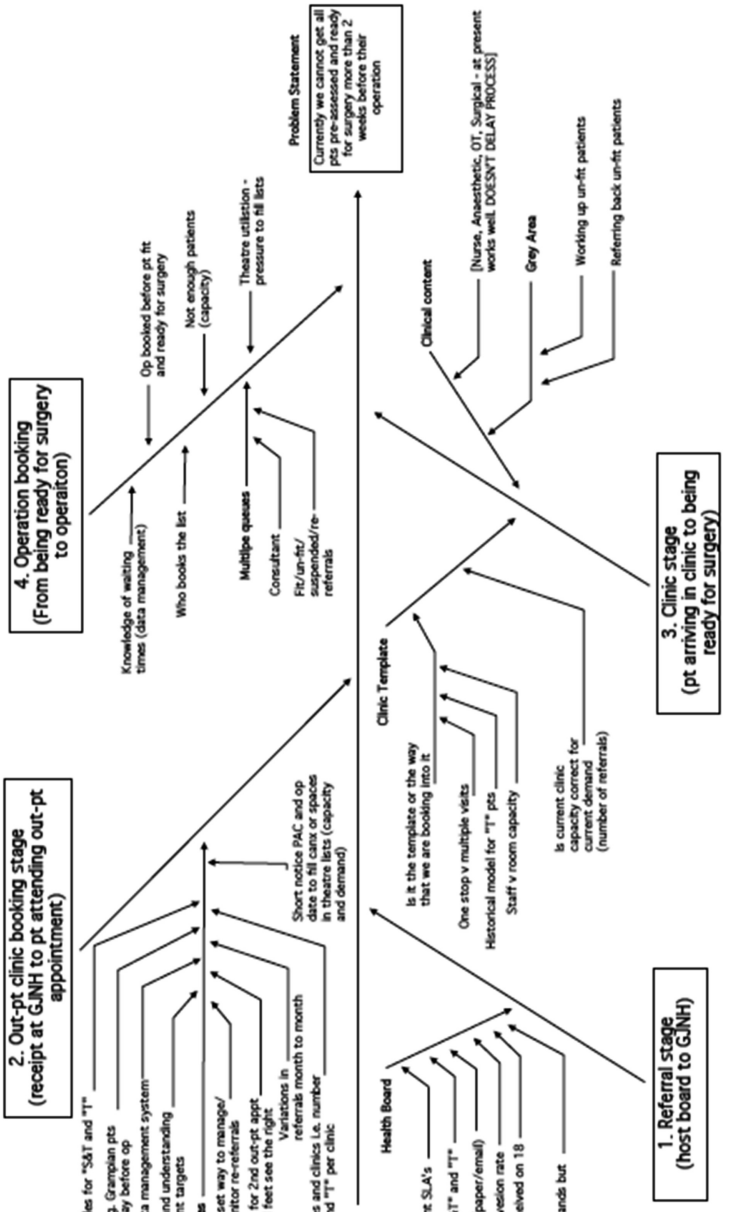

Figure 2.
Cause and effect aim for improvement aim 1

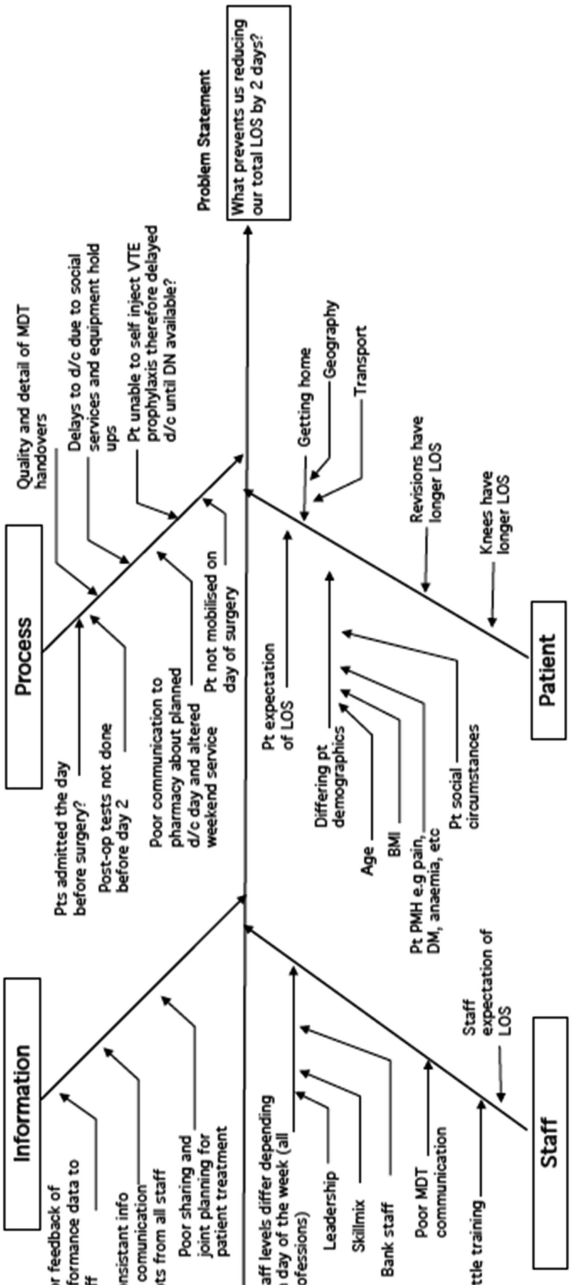

Figure 3.
Cause and effect aim for improvement aim 2

subsequently classified into either "natural" or "artificial" causes of variability according to the classification proposed by Litvak (2005).

Following the identification and classification of variability, the first active step was to eliminate the artificial variability from the care processes of the system. Litvak (Boston University Health Policy Institute, 2006) explains that artificial variability should not be accepted or worked around. Changes were therefore introduced to remove artificial variability from the delivery of care processes, and the details of what was changed, when and by whom can be seen in Table 1. Once artificial variability had been eliminated, and the causes of natural variability were managed where possible. Details of changes made to the care processes to manage natural variability are also provided in Table 1.

Once the methods to remove artificial variability and manage natural variability were identified, the new care processes were introduced. Following the initial workshop in January 2013, the change phase of the project was defined as being from January 2013 to June 2013, and this describes the period when the identified changes were prepared and introduced as they became ready. The intervention phase from July 2013 to December 2013 describes when all of the changes were implemented, and the post-intervention phase from January 2014 to December 2014 describes the period post-implementation, where there was no project activity, but outcomes were continually monitored to evaluate sustainability. This was to see whether the changes observed within the project were sustained, part of an external ongoing trend, or could be concluded to be a result of the intervention.

2.3 Study of the intervention

A before and after prospective observational cohort study design was used, with a mixed-methods sequential explanatory design (quantitative (QUAN) emphasised) that consisted of two distinct phases (Creswell *et al.*, 2003). A quantitative phase followed by qualitative phase was used to evaluate how successful the model to manage variability was as a QI method (Creswell, 2009). In this design, the quantitative data were collected and analysed first, and then the qualitative data were collected second in the sequence, in order to help explain the quantitative results achieved in the first phase. This is summarised in Figure 4. Creswell (2009) uses capital letters to emphasise the dominant approach.

The SQUIRE guidelines (Ogrinc *et al.*, 2016) were used as a framework to plan, structure and report the findings. Within this SQUIRE framework, the TiDier checklist (Hoffman *et al.*, 2014) is used to describe the intervention (Table 2).

2.3.1 Quantitative analysis. Quantitative data were collected and then analysed. It was a four-condition design: where the first condition was a baseline phase, the second condition was the change phase, the third condition was the intervention phase and then the fourth condition was a post-intervention phase. The effect of the process changes described in Table 1 were measured by collecting and analysing data for the time from pre-assessment to operation (improvement aim 1) and LOS (the outcome measure of improvement aim 2). Statistical process control (SPC) charts were used to evaluate process changes over time. At the end of this quantitative phase, the aim was to establish whether the intervention was successful or not at improving the desired outcomes within the clinical microsystem.

2.3.2 Mixing/connecting data. Following the quantitative analysis, there was a second qualitative phase of the evaluation that built on the initial quantitative phase and was connected by this intermediate stage of the study. In mixed-methods research, integration may occur via connecting, building, merging or embedding (Fetters *et al.*, 2013). Integration in this study occurred through building, where by the quantitative data collection informed the data collection approach of the qualitative, with the latter building on the former. The rationale for this approach was that the quantitative data that were collected and analysed established to what extent the project aims were met. Once it had been established

Table 1.
Identification, classification and management of variability

	Identification		Classification	Management	
	Factors from the cause and effect diagram that the MDT identified as influencing current LOS	Detail of cause and description of variability	Type of variability	Change to care process to be introduced (all changes introduced from when the intervention commenced)	Evidence for success of change to care process (data and evidence source provided where appropriate)
Improvement aim 1 – to increase the number of patients with more than 14 days between pre-assessment and admission					
(1)	Referral process from host board to GJNH	Different service level agreements (SLA), methods of referral and timing of referral	Artificial	Remove variability. Introduce a standardised SLA with all health boards and single waiting list management system	This was completed and implemented by July 2013
(2)	Clinic and theatre booking process	Patients not booked in order. Multiple booking systems	Artificial	Remove variability. Consolidate and introduce a single booking system for both clinic and theatre	This was completed and implemented by July 2013
(3)	Out-patient clinic capacity	Variable capacity depending on day and variable number of pre-assessment slots	Artificial	Remove variability. Change to increase clinic schedule and organisation of clinic capacity	This was achieved and the orthopaedic out-patient clinics were redesigned in June 2013
Improvement aim 2 – to decrease LOS by 2 days					
(1)	Time between admission and operation	All patients were admitted the day before surgery	Artificial	Remove variability. Increase day of surgery admissions by completing anaesthetic review at the pre-assessment stage	Changes to increase anaesthetic cover in the pre-assessment started in May 2013, however the increased cover for clinics remained hard to fulfill due to staff shortages, until physicians associate were recruited in September 2013 to assist
(2)	Time to first mobilisation	Physiotherapy staffing levels varied throughout the week and meant that the day of operation and time of return from theatre would affect the time to first mobilisation. Limited weekend service	Artificial	Remove variability. Re-education of Caledonian technique to increase focus of early mobilisation and increase staffing levels by introducing a 7-day service	Training and education was provided by clinical leaders at the start of the intervention period in July–August 2013. The new 7-day therapy service was not introduced until January 2014 (the start of post-intervention period)
(3)	Patient expectation of LOS	Patients had different expectations of how long they would stay in hospital	Natural	Manage variability. Updated patient information resources and conducted staff training	A new discharge criteria booklet was produced by the clinical team, and created with the hospital communications department. This was piloted and launched in July 2013 at the start of the intervention period
(4)	Staff understanding of the Caledonian technique and ERAS	Expectations of patient pathway varied amongst staff	Natural	Manage variability Regular training sessions instigated and organised. Regular feedback on current LOS and outcomes introduced	Training and education was provided by clinical leaders at the start of the intervention period in July–August 2013. A mechanism for weekly data analysis and feedback was developed with the IT department and started in July 2013

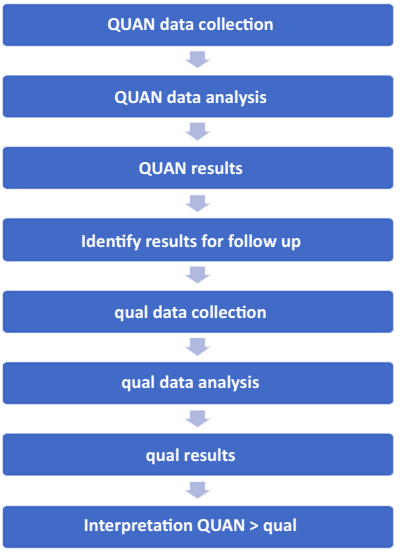

Figure 4.
A flow chart to illustrate the explanatory sequential design: Follow-up explanations model (QUAN emphasised) that will be used in the validation site

Intervention (TIDieR parameters)			QI method		
(1)	Brief name	✓	(1)	Name of QI method	✓
(2)	Why: Rationale for intervention	✓	(2)	Baseline measurement	✓
(3)	What: Materials used to apply intervention	✓	(3)	Data collection schedule	✓
(4)	What: Procedures undertaken	✓	(4)	Data analysis (e.g. driver diagrams)	✓
(5)	Who: Provided the intervention, including level of training	✓	(5)	Data volume/duration (e.g. length of PDSA cycle)	✓
(6)	How: The interventions were delivered	✓	(6)	Explicit description of prediction of change	✓
(7)	Where: Location	✓	(7)	Missing data (and reasons given)	✓
(8)	When and how much: duration, dose, intensity	✓	(8)	Description of generalisability	✓
(9)	Modifications: To intervention over the course of the study	✓	(9)	Named primary outcome	✓
(10)	How well (planned): Strategies to improve or maintain intervention compliance	✓			
(11)	How well (actual): The extent to which the intervention was delivered as designed	✓			

Table 2.
Table to report inclusion and location of information describing the intervention utilising the adapted TIDieR checklist and QI method checklist proposed by Jones *et al.* (2016)

quantitatively whether the intervention was successful or not, the qualitative data and analysis in the next phase was used to explore how and why the intervention was either successful or not, and the relative role of the model to manage variability as a QI method (Rossman and Wilson, 1985; Tashakkori and Teddlie, 1998; Creswell, 2009).

This explanatory sequential design is a two phase mixed-methods design and was chosen so that the qualitative data in the second phase could help to explain or build upon the initial quantitative results (Creswell, 2009). The design was well suited to this study because the qualitative data were used to explain the outcomes of the project (Morse, 1991). It also provided an understanding from the staff perspective of how easy the model was to implement, use and manage within the clinical setting. The information generated here

helped to refine conclusions regarding the model on its generalisability and subsequent potential use in other elective clinical microsystems.

2.3.3 Qualitative phase. In this second stage of the mixed-methods sequence, qualitative data were collected and analysed and used to help explain, and/or elaborate on, the quantitative results achieved in the first phase. This qualitative data were collected using interviews of the two clinical managers who led the implementation of the model. Interviews were conducted after completion of the intervention stage. These two individuals were tasked with leading the project and led the deployment of the model to manage variability as a QI method. They therefore had the greatest insight into its usability and success. Open-ended questions were used and informed by the mixing phase described previously. Contextual factors surrounding the implementation of the model and the project were explored. The contextual factors included in the model for understanding success in quality (MUSIQ) (Kaplan *et al.*, 2012) were used as a prompt to ensure that all relevant factors were considered. Data collection consisted of observational notes recorded by the interviewer in addition to a recorded transcript.

2.3.4 Synthesis and evaluation. The results of both the quantitative and qualitative stages were interpreted and synthesised in relation to each other and the wider evidence base. Then a summary of the most important successes and difficulties in implementing the model was made, and the main changes observed in care delivery and clinical outcomes because of the model were stated. A comparison and evaluation of the study results in light of the evidence base is made. Consideration was then given to possible sources of bias or imprecision in design, measurement and analysis that may have affected the study outcomes (internal validity). Factors affecting external validity such as the generalisability of the model were also considered. Consideration was also given in relation to the sustainability of any changes, i.e. the likelihood that any observed gains might weaken over time.

2.4 Measures

The outcome measures used to evaluate the outcome of the intervention in relation to each improvement aim are provided below.

(1) In relation to the first improvement aim, time from pre-assessment appointment to operation date was calculated (days were measured as the number of midnights between the pre-assessment appointment and day of admission to hospital).

(2) In relation to the second improvement aim, LOS in hospital was calculated (days were measured as the number of midnights between day of admission and discharge from hospital).

For both outcome measures, data were extracted from the hospital administrative data system and checked for accuracy and completeness against local (clinical microsystem level) audit data. LOS is commonly used as a proxy indicator of quality and is the widely used outcome measure for the implementation of ERAS. In regard to this project, both outcome measures were considered relevant, reliable and valid outcome measures that were feasible to obtain and had good usability.

2.5 Analysis

For the quantitative data, SPC was used to monitor the change in outcome measures for both improvement aims. Change was evaluated between each of the four project phases (baseline, change, intervention and post-intervention stage. For both outcome measures, the data were considered to be continuous data, and so the xmr chart was judged the appropriate SPC to use (Mohammed *et al.*, 2008). Both outcome measures were evaluated by calculating the mean on a monthly basis and then presenting as monthly data in consecutive points. Data for the six months prior to the project (July 2012–December 2012) is presented as the baseline phase,

along with data from the start of the project for the next two years (January 2013–December 2014), to cover the change, intervention and post-intervention phases as described previously. The data from the baseline and project phases are presented continuously, and the mean and control limits were re-calculated at the start of each phase.

For the qualitative data, the process of analysis started with familiarisation of the data, before organising and preparing the data for analysis. Thematic analysis was then undertaken through a process of coding themes from the interviews relating to the contextual factors included in the MUSIQ (Kaplan *et al.*, 2012). The data were then interpreted in light of both the quantitative and other qualitative findings.

Thematic analysis was chosen as a method because of its flexible approach that could be modified to the need of the study, whilst providing a rich and detailed account of the data (Nowell *et al.*, 2017). The aim of the analysis was to enable an understanding of how the intervention worked or failed to work from the perspective of the individuals involved in leading the project. There were six phases to the analysis, as recommended by Nowell *et al.* (2017). After familiarisation with the data, initial codes were then created (accompanied by reflexive journaling), and then themes were searched for. These themes were then reviewed and triangulated, before they were defined and named.

2.6 Ethical considerations

The project was presented to the Head of the Research Department at the GJNH in November 2012. It was defined as a QI activity; therefore, the need for submission to the hospital and local NHS Research Ethics Committee was confirmed as not being required. However, full ethical consideration was given to the project by utilising published guidance and policy templates from the Healthcare Quality Improvement Partnership (HQIP). This ensured that the patients' interests and rights were properly protected throughout the study. The HQIP template provided outlines for best practice structures and mechanisms that provided an ethical oversight and formed the basis of a thorough governance framework.

3. Results

Following the decision to improve the service, the external QI researcher was invited to facilitate an introductory workshop in January 2013. This was to meet staff, initiate the project and introduce the model to manage variability. It was also important for the external QI researcher to establish credibility with the local team and to start to build relationships with staff. Internally, the project was supported by an executive sponsor, two clinical managers with service improvement experience and lead clinicians from surgery, anaesthetics, nursing and therapies. The two clinical managers led the QI effort locally and coordinated the project team. This core team was supported externally by the QI researcher who over the course of the project made 12 site visits to the hospital (every 2–4 weeks) and also assisted remotely.

The initial workshop in January 2013 was followed by a change phase of the project, defined as being from January 2013 to June 2013, and this describes the period when the identified changes from the workshop were prepared and gradually introduced as soon as they ready. The intervention phase from July 2013 to December 2013 describes the period when all of the changes were implemented and regularly monitored by the project team, and the post-intervention phase from January 2014 to December 2014 describes the period post-implementation, where outcomes where monitored but the formal project had finished.

The two clinical managers leading the project both worked part-time on the project around their normal duties and led the local team through the use of the model to manage variability. Staff members from all professional groups attended the workshops and contributed to a

cause-and-effect diagram, which aimed to identify all of the causes of variability that contributed to the short period of time between pre-assessment and admission, and the current LOS which was felt could be reduced. The core team then pulled out the key themes and factors that they felt most strongly influenced the current outcome measures of the two project aims following this consultation process. Where data were required to analyse specific factors, they were extracted from the hospital patient record system.

Following the identification of factors that were influencing both improvement aim outcome measures, the team decided on the changes required to care processes in order to either remove artificial variability or manage natural variability. The results of this process are summarised in Table 1. The team then planned how the necessary changes would be implemented and agreed to initiate all of the changes as soon as they were able, within the change phase (January 2013–June 2013). It was decided that the new care processes that made up the intervention would all be in place by July 2013 and would be actively monitored by the project team from July 2013–December 2013. Once the change in care processes was introduced, regular review using SPC was undertaken by the project team to monitor performance.

3.1 Quantitative results

SPC charts are presented (Figures 5–8) for the outcome measures defined for both improvement aims. They show data for the baseline phase, change phase, intervention phase and post-intervention phases. The data are continuous and account for all patients operated on within that time period. There is no missing data. In order to present the data cleanly, and in accordance with routine outcome monitoring at the hospital, monthly means were calculated in order to produce the xmr chart. The xmr chart consists of two charts, the x-chart and the mr-chart. The x-chart is a control chart of the 30 observed values for each outcome, and the mr-chart is a control chart of the moving ranges of the data. At each phase, the control chart is recalculated, and the processes remain stable within each phase for both outcome measures.

3.2 Qualitative results

Following the quantitative analysis, the results were shared with the two clinical managers, and the second qualitative phase of the evaluation was conducted. Integration with the mixed methods design occurred through building, where by the quantitative data collection informed the data collection approach of the qualitative interviews. The qualitative data collection and analysis aimed to explore how and why the intervention was either successful or not and the experience of utilising the model to manage variability.

3.2.1 Project success. Both interviewees felt the project had been successful, in which the procedural elements of the QI method (the model to manage variability) had been executed as planned and that the outcomes had improved. However, there was acknowledgement that the team had not managed to change all of the care processes identified by the model and had not achieved their initial improvement aims entirely. Both interviewees judged success based on the relative improvement to the outcomes measures linked to the improvement aims. This was opposed to reviewing whether each change to care process had been achieved, or whether there had been any other wider benefits of the project.

> I would say it has been successful because we have achieved change and we have achieved a degree of change that has been sustained since it has been changed, and we have evidence to support that. (Clinical Manager 1)

> When we're looking at the data now, we've been partially successful, if we look at the two aims we've improved, but not fully achieved what we had planned. (Clinical Manager 2)

Consequently, the viewpoints of the two clinical managers leading the project were explored to understand why the project had not been more successful.

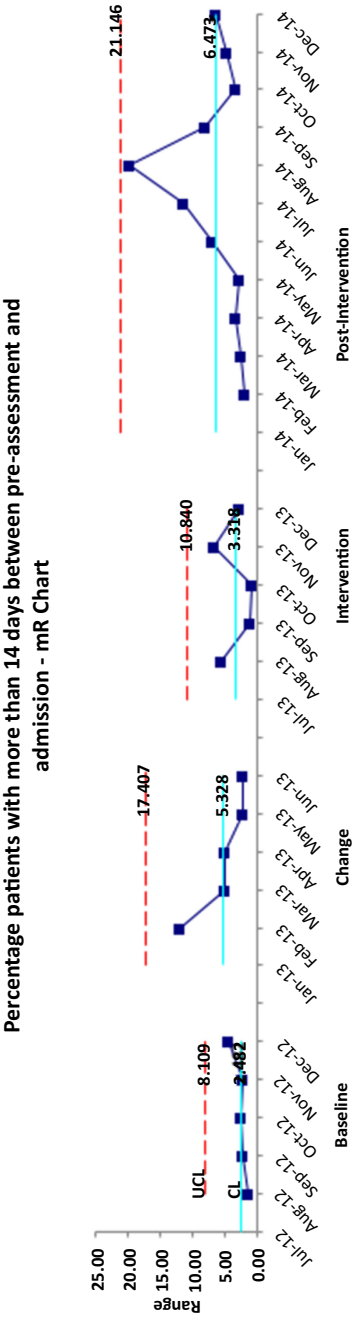

Figure 5.
SPC (mr-chart) for improvement aim 1

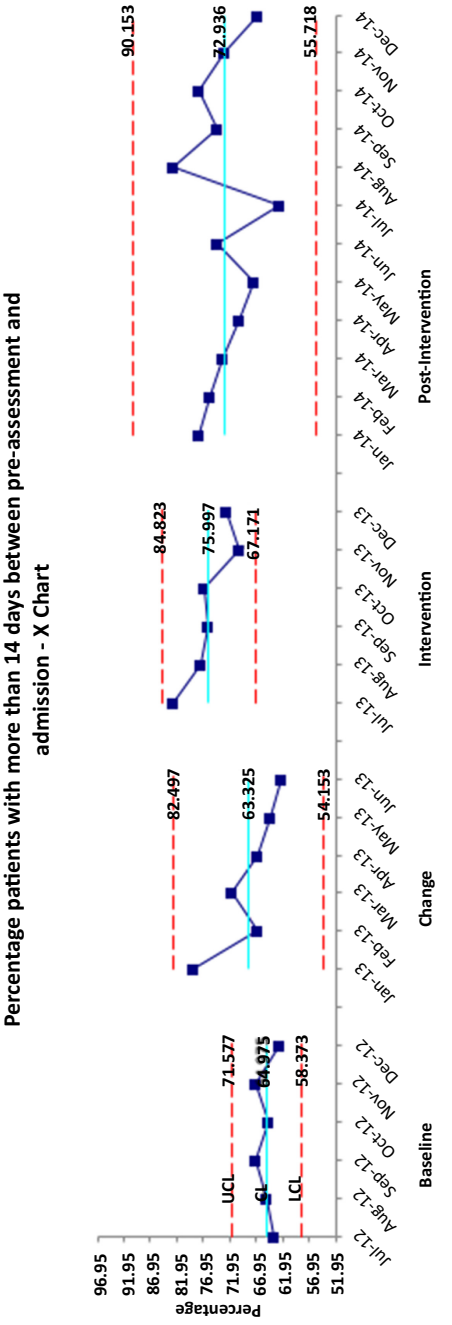

Figure 6.
SPC (xmr-chart) for improvement aim 1

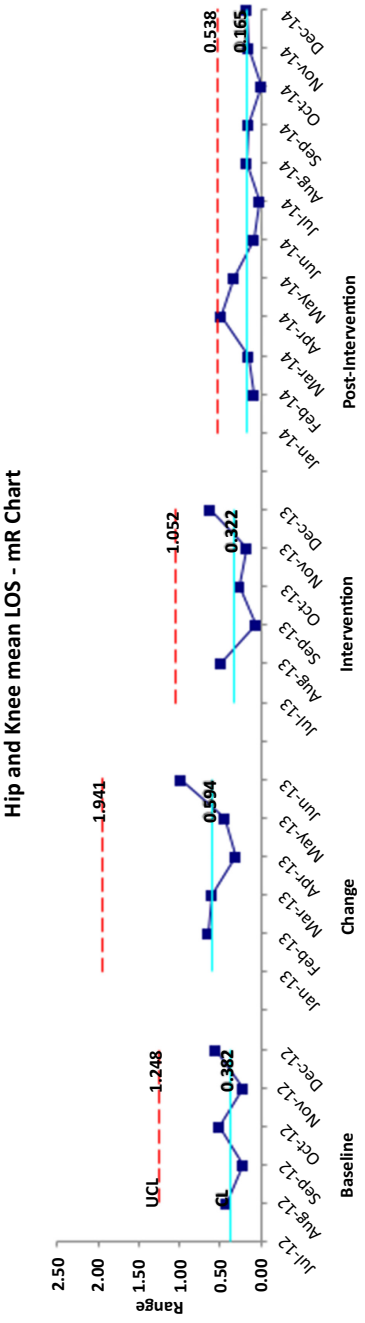

Figure 7.
SPC (mr-chart) for improvement aim 2

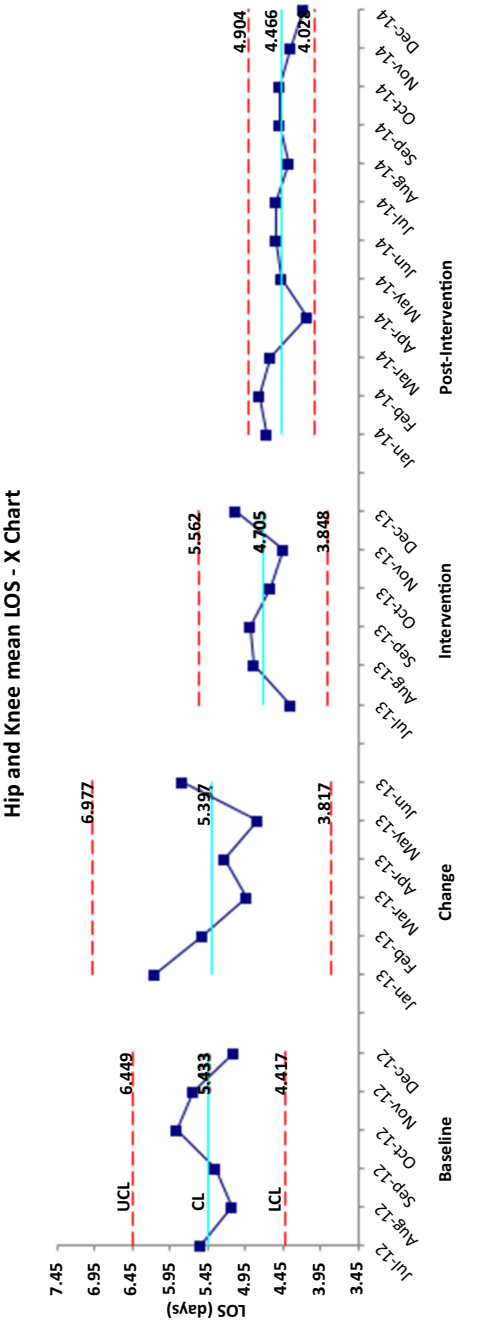

Figure 8.
SPC (xmr-chart) for improvement aim 2

3.2.2 Views on model to manage variability. The role of utilising the model to manage variability as the QI method used to inform the intervention was explored with the interviewees. Both interviewees viewed the model positively and did not think that the model was associated with why the improvement aims had not been fully achieved. Specifically, they both reported advantages of the model and found it intuitive to use.

> I just feel the model to manage variability pulls the group together, you get the information you need, you get the data to support it and you work through a process that's actually reasonably quick to do as well. (Clinical Manager 1)

> I firmly believe the model is an easy and simple method of getting improvement projects up and running and to get everybody looking at a problem in a much more holistic way. (Clinical Manager 2)

Advantages of the model over alternative QI methods that both interviewees had previously used were also highlighted.

> I had experience of using other models, LEAN and things like that and I've never warmed to them just because of the complexity of the language . . . I've found the model to manage variation much more simplistic and easy to explain to people, to utilise, and to make the improvements. I found it very useful. (Clinical Manager 2)

And both interviewees described how the model had impacted their other work in the hospital, either by reporting that they had used the model in other projects or by describing how the concepts within the model where now used routinely by other members of staff.

> And I think it's really funny now when you go into a meeting and the head of services will talk about artificial and natural variation and they use it quite routinely now and people know what they are talking about and nobody would have known that at the beginning. (Clinical Manager 1)

> I went on to utilise the model in another specialty in the hospital and being that external person and asking the questions was of benefit. I had no expertise in that surgical specialism whatsoever, but being able to use the model, stimulates them to think even harder about what they're doing and how they do it and look at the processes by which they're managing their patient's pathway. (Clinical Manager 2)

Both clinical managers felt that the model to manage variability was easy to use, had been implemented appropriately and had impacted the organisation more widely that just within this specific project. Therefore, the relative roles of other contributing factors to the projects outcomes were discussed. Contextual factors thought to both facilitate and limit the project were considered.

3.2.3 The role of an external agent. Both interviewees thought that the role of the external QI researcher and the credentials and expertise of that person played an important facilitative role within the project.

> I think a lot of the people around the table respected the fact that you had done similar work in other places using this model and had a successful outcome. And you were able to answer a lot of the questions right at the beginning that I could not have answered. I think that very much got us buy-in at an early stage with the consultants. I do not think I would have got that buy-in. (Clinical Manager 1)

3.2.4 The role of leadership and engagement. Conversely, when invited to discuss why the project had not been as successful as planned, both interviewees perceived that increased leadership and engagement from within the clinical microsystem would have improved outcomes. They reflected on the role of leadership from a personal perspective and also in relation to the participation and leadership of others involved in the project.

> I think using the model was good. However, I was part-time, and was not fully able to push and drive the changes as much as I would have liked. Would it be better if you had somebody who was full-time

> . . . It may just have meant we'd have got things done quicker and would have got better results and a bit more focus on it. (Clinical Manager 2)

> Responsibility, somebody taking responsibility to keep joining up the dots and I think that's what probably not happened for various reasons. (Clinical Manager 1)

In addition, there were other organisational factors that were highlighted by both interviewees in regard to staffing. They both noted frustration that it had been hard to adequately organise anaesthetic cover within the pre-assessment clinic in order to increase the number of day of surgery admissions. They explained that the human resource process to change to a seven-day therapy working model had also taken longer than anticipated. One of the clinical managers noted a frustration in regard to knowing what they wanted to implement but not being able to do it.

> What we identified using the model to manage variability to change was correct, and these are still the same issues that are preventing us from further improvement, however staffing constraints have not allowed us to make the change. (Clinical Manager 1)

4. Discussion

A successful QI effort is one in which the intended improvements are successfully achieved. In this project, the primary outcome measures associated with each improvement aim improved, although they did not meet their targeted improvement. For improvement aim one, the percentage of patients who had more than two weeks between their pre-assessment clinic visit and their operation increased from 65% in the baseline phase to 76% in the intervention stage. This 11% improvement then reduced by 3%–73% in the post-intervention monitoring period. All of the changes to the care processes identified as being required to increase the percentage of patients who had more than two weeks between pre-assessment clinic visit and their operation were made. However, the 100% aim was still not achieved. This outcome may have been due to the fact there were actually not enough patients on the waiting list at any one time, in order to plan operating lists more than two weeks in advance.

For improvement aim two, mean LOS decreased from 5.4 days in the baseline phase to 4.7 days in the intervention stage and 4.5 days in the post-intervention monitoring period, representing an 18% overall decrease in LOS. This reduction, is analogous with reductions reported in other implementation studies of ERAS in joint replacement. Saunders *et al.* (2016) reported a 17% reduction in LOS for primary joint replacement following the introduction of an ERAS pathway, and a reduction of 19% was reported by Ricciardi *et al.* (2020) in their report of utilising lean as a QI method when seeking to improve a knee replacement pathway. It should also be noted that in a recently published report from NHS England (GIRFT, 2020), the national average length of stay reduced for hip replacements by 19% and for knee replacements by 17.8% in the period 2014–2019. The improvement made by the team at the GJNH within the project could therefore be argued to be highly significant compared against the background trend LOS. It was also lower than the national average in 2014 for both hip (5.18 days) and knee (5.25 days) replacement in Scotland (Scottish Arthroplasty Project). There was also and importantly no statistical or clinically significant change to balancing measures, such as major complications after surgery (including dislocation, infection of the operated joint, deep vein thrombosis or pulmonary embolism (DVT/PE), death, acute myocardial infarction (AMI), acute renal failure and cerebrovascular accident (CVA) or stroke) throughout the periods of data collection. These remained within expected values as measured and reported by the Scottish Arthroplasty Project (2019).

The reasons for failing to achieve a greater reduction in LOS may be assumed to be because the proposed changes to clinical processes (informed by using the model to manage

variability as a QI method) that made up the intervention were not all implemented as planned. There were difficulties and delays to organising and changing the artificial variability of staffing levels. The seven-day therapy service took longer than anticipated to implement, and the provision of anaesthetic cover within the pre-assessment clinic was difficult due to inadequate staff numbers and difficulties with scheduling rotas. These were both changes to the care processes that aimed to decrease LOS by increasing the rate of day of surgery admission (as anaesthetic review would be undertaken in clinic rather than on admission) and to expedite early mobilisation and avoid delays to discharge (through earlier access to therapy). This difficulty to implement post-operative elements of an ERAS pathway is not uncommon, and it has been found in reviews of ERAS implementation that postoperative elements related to mobilization and rehabilitation often demonstrate much lower levels of compliance compared to other stages of the peri-operative pathway (Coxon *et al.*, 2017).

The mixed-methods approach to the evaluation, accompanied by the explicit reporting of the intervention through the utilisation of the TIDieR checklist, is a strength of the project. QI reporting in surgery is acknowledged to be generally poor (Jones *et al.*, 2016) and the explicit reporting of intervention and QI method used, along with context has been recommended (Jones *et al.*, 2019). Research evaluating QI success is strengthened by utilising approaches from the social sciences, such as mixed-methods (Kaplan *et al.*, 2010). In this case, the connecting component and qualitative interviews conducted with clinical managers provided experiential data from those involved in leading and facilitating the project to explain some of the specific contextual factors that influenced the outcomes of the project.

This qualitative data confirmed that the two clinical managers felt the project had been successful, although only partially. They thought that it had been leadership, staffing and organisational related issues that had prevented the outcomes improving further. Such issues are consistent with the wider QI literature (Kaplan *et al.*, 2010) and experience of teams working to implement ERAS pathways (Paton *et al.*, 2014). It may be argued that more qualitative data could have been collected from the wider team (including clinical staff), and this could have confirmed that saturation was achieved. However, due to the number of people involved across the peri-operative pathway, it was felt that if more value was to be gained, then at least one person from every department/profession would need to be interviewed, and time and resources did not allow for the additional 10–20 interviews. Additionally, as this research also sought to evaluate the use and deployment of a novel QI method (the model to manage variability) to guide the improvement effort, it was felt the feedback and views from the two clinical managers facilitating the use of the QI method would be most pertinent.

In regard to the QI method used, the two clinical managers highlighted that the model to manage variability had been received well by the inter-professional team. It had engaged them in the QI process and led to the technique being used in other projects within the hospital, and the terms natural and artificial variability had made their way into common usage amongst the team. More specifically in relation to the model to manage variability, both clinical managers thought it offered advantages over other QI methods they had used in the past, and both felt that the external input of the QI researcher to help introduce it was an important facilitating factor.

These findings confirm the evidence from the wider evidence base where it is acknowledged that the use of a QI method (in this case the model to manage variability) can be helpful to inform improvement efforts. However, it was other contextual factors that were highlighted by the two clinical managers as being key contributing factors to the project outcome. Context is well understood to be a critical factor in QI research (Stevens and Shojania, 2011), and despite the GJNH being a recognised national centre for hip and knee replacement, it was hard for the team to lead and manage change within the organisation, in order to make the required staffing changes and drive the project forward.

Knowing how to improve is not always the same as being able to improve. Successful implementation of ERAS pathways is known to be associated with an organisation having a

change agent to fully drive the implementation process (Roberts *et al.*, 2010; Coxon *et al.*, 2017). Given that both clinical managers acknowledged that they could only dedicate part of their time to the project, it may be judged that the absence of a full time change agent with overall responsibility for the project was a contributing factor to the only partial achievement of the project aims.

In closing, this novel QI method, similar to alternative QI methods (e.g. Lean and Six Sigma), has a strong theoretical theory to underpin its use. Further, this study provides supportive empirical evidence to illustrate that the model to manage variability may be an effective QI method to guide improvement efforts within an NHS clinical microsystem and may offer advantages over other QI methods. However, the study also provides an important insight on the connection between applying improvement science theory to a specific case scenario (or clinical microsystem) within the real world. The explanatory data from the interviews highlight the complex relationship between context, mechanisms and outcomes when conducting QI work. This is an important finding and confirms the future need for a greater use of behaviour change and organisational psychology theory to improve the design, adaptation and evaluation of QI methods in healthcare.

4.1 Limitations

In regard to the generalisability of the work, as with many QI reports, the failure to include a comparison group means that external causes for change cannot be ruled out. However, the attempts made to ensure transparency within the reporting and the mixed-methods explanatory design should be highlighted as efforts made on behalf of the reader to counteract this potential bias. This is important because consideration should always be given to possible sources of bias within the design and reporting of a study. It is therefore acknowledged that the role of the QI researcher as both an external change agent within the project and as the researcher evaluating the project is important to recognise. The need to acknowledge reflexivity is an accepted issue within the reporting of many QI studies, and so thorough reporting of the details of implementation and evaluation is very important. In the absence of external and independent evaluation (which of course may also introduce its own bias), transparent and thorough reporting allows the reader to make their own judgements.

4.2 Conclusions

This study sought to improve clinical processes within an orthopaedic clinical microsystem and to ascertain details of when, how and why the model to manage variability should be used as a QI method. The mixed-methods approach revealed in the first quantitative phase that the outcome measures for each project aim were improved, although only partially. The secondary qualitative phase which built on the initial quantitative phase provided insight on the generalisability of utilising the model, by helping to understand its implementation and other contextual factors. The model to manage variability was felt to be utilised successfully to inform the planned interventions; however, contextual factors relating to leadership, staffing levels and organisational factors meant that not all of the interventions were implemented. This provides further information in regard to the model to manage variability, in which it can be considered a useful QI method. However, as with other QI methods, it is not independent of contextual factors, which can influence the relative success or failure of the planned interventions following its use.

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BMJ Open Quality

Wanting to improve is not always the same as knowing how to improve—an example from a total knee arthroplasty pathway

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INTRODUCTION

Enhanced recovery after surgery (ERAS) (or enhanced recovery or fast-track) protocols for total knee arthroplasty (TKA) can be considered a quality improvement (QI) intervention, that is, their implementation may be defined as a purposeful effort to improve care processes that will result in improved patient outcomes.[1] ERAS protocols are a multimodal approach that improves the quality of patient care, including reducing length of stay (LOS) for TKA.[2] ERAS protocols seek to optimise the perioperative pathway by using and combining techniques such as minimally invasive surgery, regional anaesthetic techniques, multimodal opioid sparing pain management and early mobilisation. ERAS protocols have been detailed and include procedure-specific guidelines for TKA.[3]

This report evaluates efforts to improve an ERAS pathway for patients with TKA at a National Health Service district general hospital, where ERAS had previously been implemented.[4] Within the hospital, there was a desire to further reduce LOS. Local audit data were interpreted, and it was proposed that factors related to the anaesthetic (such as pain, motor block, symptoms of orthostatic intolerance) were delaying discharge. The anaesthetic protocol was changed five times in an attempt to reduce LOS and this process is retrospectively evaluated in this report. The stimulus to reflect on past improvement efforts was prompted in order to guide successful future QI efforts.

METHODS

This is a retrospective service evaluation of routinely collected data from the hospital's administrative and clinical record systems and in accordance with the Health Research Authority Decision tool (http://www.hra-decisiontools.org.uk), ethical approval was not required. A total of 652 patients undergoing TKA were evaluated between September 2008 and March 2015. Within this time, the type of anaesthetic was changed by the clinical team five times, in consecutive change cycles.

Each patient received the same standardised postoperative prescription including regular paracetamol, oxycontin, non-steroidal antiinflammatory drugs, omeprazole, ondansetron, Mg(OH)2, senna and as needed oramorph. In phase 1, the standard of care at that time was a regime of a spinal anaesthetic including intrathecal opiate (ITO) with a femoral nerve block (FNB) and a sciatic nerve block. In phase 2, a spinal anaesthetic with ITO, an FNB and local incision anaesthesia (LIA) were used; in phase 3, a spinal anaesthetic with ITO and LIA was used; in phase 4, a spinal anaesthetic with ITO, LIA and gabapentin were used and in phase 5, a spinal anaesthetic with ITO, LIA, gabapentin and an adductor canal block were used. No other elements of the pathway, including the physiotherapy and mobilisation protocol, were changed, and these have been previously described.[4]

The outcome measures evaluated were LOS (days), time until first walk (hours), pain on movement (10 point Visual Analogue Scale where 0 equated to 'no pain' and 10

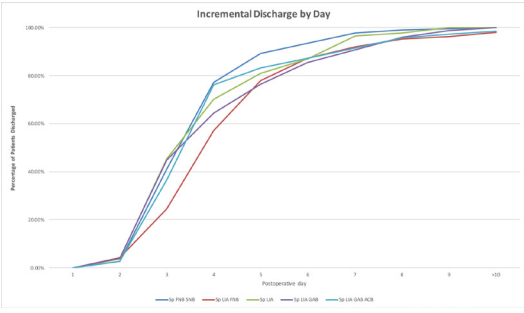

Figure 1 Incremental percentage discharge of patients by day for each of the different anaesthetic techniques.

Table 1 Impact of anaesthetic technique on LOS, pain on movement, time to first walk and oramorph consumption.

	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Anaesthetic technique	Sp FNB SNB	Sp LIA FNB	Sp LIA	Sp LIA GAB	Sp LIA GAB ACB
Data review period	01/09/08–28/02/09	01/08/12–30/09/12	01/12/12–31/01/13	01/04/13–31/05/13	01/11/14–01/03/15
Number of cases	185	236	84	76	71
LOS (days) *Mean (min–max, SD)*	4 (2–10, 1.3)	4.7 (2–18, 2.0)	4.2 (2–9, 1.6)	5.3 (2–10, 1.8)	4.3 (2–11, 1.8)
LOS (days) *Median*	4	4	4	4	4
Pain on movement (VAS 0–10)* *Mean (min–max, SD)*	4.88 (0–10, 2.7)	4.38 (0–10, 2.84)	5.24 (0–10, 2.71)	5.46 (0–10, 2.37)	5.69 (0–9, 2.4)
Time to first walk (hours) *Median (min–max)*	Not available†	31 (27–100)	29 (26–80)	29 (27–104)	29 (27–102)
Oramorph consumption before 1300 first postoperative day *Median (min–max)*	Not available†	10 (0–70)	10 (0–130)	20 (10–90)	15 (0–140)

*VAS—0 equated to 'no pain' and 10 equated to the worst pain a patient could imagine.
†Data were not available. Routine collection of these outcome measures was introduced after Phase 1 was completed.
ACB, adductor canal block; FNB, femoral nerve block; LIA, local incision anaesthesia; LOS, length of stay; SNB, sciatic nerve block; VAS, visual analogue scale.

equated to the 'worst pain a patient could imagine') and oramorph consumption before 1300 on the first postoperative day.

RESULTS

A total of 652 patients were included and outcomes for each phase are presented in table 1. There was no difference in median LOS (the primary outcome measure) across the five phases. (figure 1). The results of the secondary outcome measures are presented descriptively in table 1.

DISCUSSION

Optimising anaesthetic technique is a key factor to facilitate early mobilisation and therefore reduce LOS following TKA.[5] The aim of the team's improvement effort was therefore well directed. However, despite the team's endeavour, LOS failed to improve across the different techniques. There were some minor variations in the secondary outcome measures with each phase, which were not felt to be clinically significant or an indication that any of the changes should be reversed. Given that this was a rolling service evaluation and not research, and no clinically significant differences were judged to have been observed, a statistical analysis examining the difference in secondary outcome measures was not completed. In regards to the choice of anaesthetic, it is acknowledged that the evidence base for TKA is hard to interpret, however, in many centres, patients are discharged within 0–2 days and these anaesthetic protocols are available to replicate.[6]

When considering the success of this QI effort, the choice of anaesthetic technique is obviously important. However not considering the role of other contributing factors to delayed mobilisation is also significant. Patient (eg, expectation), organisation (eg, limited staff and time constraints) and cultural (eg, lack of staff 'buy in') factors have all been previously highlighted as barriers to early mobilisation[7] but were not considered in this project. This highlights the challenge for individual professional groups to improve care on their own within a multidisciplinary pathway, and that more objective and exhaustive methods to identify barriers to discharge should be used.[8] To move towards the goal of a 'pain and risk-free surgery', clinical evidence of individual techniques must be combined with a whole clinical microsystem QI effort in order to do 'the right things in the right way'.[9]

CONCLUSION

In this retrospective service evaluation, the type of anaesthetic was changed by the clinical team five times in consecutive change cycles. The aim was to reduce LOS, however, median LOS remained unchanged across all phases. Teams focused on QI efforts that seek to improve outcomes of multimodal ERAS pathways need to remember that outcomes are influenced by many inter-relating factors. To improve outcomes in a dynamic system, across multiple stakeholders, a whole clinical microsystem approach is needed. The future use of a specific QI method is recommended, so that the transition from a will to improve, to an understanding of how to improve can be made.

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Perspective

Enhanced Recovery after Surgery (ERAS) for Hip and Knee Replacement—Why and How It Should Be Implemented Following the COVID-19 Pandemic

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Abstract: The COVID-19 pandemic has led to a reduction in hip and knee replacement surgery across healthcare systems. When regular operating returns, there will be a large volume of patients and an emphasis on a short hospital stay. Patients will be keen to return home, and capacity will need to maximised. Strategies to reduce the associated risks of surgery and to accelerate recovery will be needed, and so Enhanced Recovery after Surgery (ERAS) should be promoted as the model of care. ERAS protocols are proven to reduce hospital stay safely; however, ERAS pathways may require adaption to ensure both patient and staff safety. The risk of exposure to possible sources of COVID-19 should be limited, and so hospital visits should be minimised. The use of technology such as smartphone apps to provide pre-operative education, wearable activity trackers to assist with rehabilitation, and the use of telemedicine to complete outpatient appointments may be utilised. Also, units should be reminded that ERAS protocols are multi-modal, and every component is vital to minimise the surgical stress response. The focus should be on providing better and not just faster care. Units should learn from the past in order to expedite the implementation of or adaption of existing ERAS protocols. Strong leadership will be required, along with a supportive organisational culture, an inter-professional approach, and a recognised QI method should be used to contextualize improvement efforts.

Keywords: enhanced recovery after surgery; hip replacement; knee replacement; COVID-19; outpatient surgery

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1. Introduction

The COVID-19 pandemic has and will continue to have a significant impact on healthcare systems across the world. Whilst the current focus is to deal with the acute effects of the pandemic, there will be subsequent pressures felt within our healthcare systems. These include the long-term rehabilitation of COVID-19 patients; the management of the sequelae of interrupted care for patients with long-term chronic conditions; and safely resuming elective surgery for an increased number of patients [1].

For the surgical specialities, a phased return to elective procedures will be seen. Within orthopaedic surgery, this will mean considerable challenges for patients with hip and knee osteoarthritis who require replacement surgery. Due to the non-life-threatening nature of osteoarthritis, the age of patients awaiting surgery (commonly over 65 years old), and the in-hospital stay usually required following the procedure, it will mean that hip and knee replacement surgeries will be some of the last surgical procedures recommended to return [2]. Therefore, when patients present for surgery, they are likely to have increased disability levels, be more de-conditioned (following reduced activity levels due to social isolation and also increased pain due to the prolonged wait for surgery), and there will be a large volume of patients to treat [3]. Strategies will be needed to reduce the associated risks of surgery and to accelerate recovery, at the same time as optimising capacity. Enhanced

Recovery after Surgery (ERAS) protocols can deliver these outcomes [4] and should, along with outpatient surgery (where suitable and safe), be promoted as the model of care [5].

2. Enhanced Recovery after Surgery (ERAS)

ERAS programs (or Rapid Recovery or Fast-track programs) have developed over the past 20 years. They have been demonstrated to reduce length of hospital stay (LOS), morbidity, and convalescence time, without an increase to readmission rates or complications [6]. ERAS protocols can be considered a Quality Improvement (QI) intervention, and are an inter-professional and multi-modal approach to care. ERAS protocols seek to optimise patient care before, during, and after surgery in order to minimise the surgical stress response. They are multi-modal and combine techniques such as pre-operative education, minimally invasive surgery, regional anaesthetic techniques, multimodal opioid-sparing pain management, and early mobilisation. ERAS protocols have been detailed and summarised for total hip replacement and total knee replacement [4]. ERAS protocols are being promoted as key strategies to be adopted by orthopaedic clinical microsystems when hip and knee replacement is restarted, and it is anticipated that there may be an increase in early discharge and day-case (or outpatient) surgery [3].

3. Nursing and Allied Health Professional (AHP) Adaptations to ERAS Protocols Following COVID-19

ERAS pathways will require some adaption as surgery returns following the COVID-19 pandemic in order to ensure both patient and staff safety. Whilst the actual surgery and anaesthetic will remain relatively unchanged (there may well be some changes to facilitate more outpatient surgery e.g., timing in the day of surgery, and shorter acting anaesthetics), nursing and AHP interventions pre- and post-operatively are likely to be significantly adapted. Clinical microsystems will be required to adhere to new evidence-based practices to risk-stratify patients before surgery, screen for COVID-19, and utilise strategies to minimise possible exposure whilst in hospital (e.g., Personal Protective Equipment (PPE) requirements for both patients and healthcare workers). Such changes to practice will be general principles applicable to all surgery. They should be made in accordance with the relevant local policy regarding the surgical management of patients post COVID-19 pandemic.

With specific relevance to ERAS protocols, in order to minimise risk, patients will need to be discharged from hospital back home as soon as it is safely possible to do so. Patients are likely to be strongly motivated to get home and distance themselves from exposure to COVID-19, but this should be done safely. Patients will still need to achieve the required medical, nursing, and therapy milestones in order to be discharged without a risk of increased complications and readmission. Caution is required because recent data has indicated that there may be an increased risk of complications for patients discharged on the day of surgery compared to those who stay in the hospital for 1–2 days [7]. Therefore, careful pre-operative discharge planning by nurses and therapists will be essential, with provisions made for self-isolating or shielding following surgery (if required by local policy). In addition, at the pre-operative stage, patients with substantial surgical risk factors should be optimised by ERAS protocols to reduce the chance of post-operative complications [4]. For those patients with non-modifiable risk factors in relation to surgery and also COVID-19, an informed decision making process should be undertaken in partnership with the patient, so that conservative treatment options and delayed surgery are considered as alternatives.

The potential role of utilising technology in ERAS pathways has previously been highlighted [8], and its use may offer advantages for nurses and AHPs at multiple stages of the pathway, post COVID-19. For example, the provision of pre-operative information and education is often delivered to patients before hip and knee replacement via a pre-operative class or "joint school". Alternative options can be made available via online resources or smartphone apps. If hospitals do not already have a smartphone app, generic apps are available and can be utilised [9]. Also, wearable devices and activity trackers may be utilised post-operatively for patients to manage their rehabilitation independently [10], and post-discharge follow up check-ups can be conducted via telephone or video follow up [11].

Whilst conducting remote follow up, patients and carer's must be informed of how to contact appropriate services if they are concerned about the development of complications in between appointments, and these communication channels should be integrated with community and primary care teams.

The need and importance of a consistent and seven-day provision of therapy has been previously highlighted within ERAS pathways [12] and must continue, or be established. Daily inter-professional ward rounds with senior nursing and AHP presence will be required, so that any barriers to discharge can be assessed and acted on quickly so that delays to discharge are minimised.

4. Ensuring the Successful Implementation and Adaptation of ERAS Pathways

The importance of highlighting the role of implementing ERAS when surgery returns following COVID-19 is two-fold. First, despite the evidence-base and published clinical guidelines [4], the widespread global implementation of ERAS is not complete. In many hospitals, ERAS is not yet the standard of care. For example, LOS is still around four days after hip and knee replacement in countries such as England and Spain [13,14], compared with 0–2 days in extensive epidemiological studies from Denmark and USA [7,15]. The restarting of services, therefore represents an opportunity to "reset" pathways at a time when limited capacity and increased demand may help to drive positive changes. Second, for those sites with ERAS already implemented, there will be a push to progress towards day-case or outpatient surgery in order to further maximise resources, and the need to adapt existing protocols to incorporate digital solutions (as described previously) will bring an additional quality improvement challenge.

In both cases, ERAS teams can learn from the past in order to expedite the implementation of or adaption of existing ERAS protocols, so that insights from previous implementation are taken advantage of. There may also be new opportunities following COVID-19 to make improvements. For example, the organisational need to maximise capacity and resources may provide economic levers to change as well as challenges depending on the context. Also, the response to the COVID-19 pandemic has required inter-professional and cross-departmental working in many hospitals, and these strengthened relationships have allowed our healthcare systems to change at speed. There may be an opportunity for surgical units to build on this inter-professional collaboration, an essential factor, given that the role of good teamwork and integrated working is a known element of high performing hip and knee ERAS units [16].

It should also be remembered that ERAS is a QI intervention, and so if the QI literature is looked at more broadly further insight and confirmation of critical contextual success factors can be found. Eight key contextual factors linked to the success of QI efforts have recently been proposed following a systematic realist review [17]. These factors are:

1. Active, supportive, and engaged leadership;
2. Multi-disciplinary collaboration;
3. A supportive organisational culture;
4. Staff with the right individual skills and capabilities;
5. Organisational capacity and capability for QI;
6. An infrastructure to collect and analyse outcome data;
7. A shared readiness and belief in change;
8. A change agent to drive and lead the change.

These factors resonate with the ERAS implementation literature [18,19] and present an "aide memoir" for health professionals tasked with implementing change to or the introduction of an ERAS pathway. For those leading the change, the concepts outlined by [17] should be used to enhance the planning of any QI effort.

Given this knowledge and context, orthopaedic teams seeking to implement or adapt their ERAS pathway should therefore ensure that their clinical and managerial leaders recognise that they will need to actively lead and take responsibility for the change at all levels. They should recruit a change agent, drive the improvement of organisational characteristics

if required (such as QI knowledge, skills and capability) and seek to create a supportive organisational culture, to ensure that staff recognise the benefits of changes for patients and are motivated to change. Support from administrators will also be needed to help with the data and technical infrastructure to support outcome monitoring and digital solutions.

With these components in place, the use of a recognised QI method to ensure the correct changes are made to the care process for the local context is also recommended. This is because even though ERAS pathways have been proven to improve clinical outcomes, their delivery is context-dependent, and as they are developed, changes need to be holistically informed. Improving a clinical outcome is achieved by combining clinical decisions informed by evidence-based medicine (such as an ERAS protocol) with the needed process or system changes, that allow the right things to be delivered in the right way [20]. Understanding this concept is crucial, and when combined with effective leadership, a supportive organisational culture, and an infrastructure to collect data, units will be able to understand how to improve their pathways.

5. Conclusions

Following the COVID-19 pandemic, there will be a large volume of hip and knee replacement patients and an emphasis on a short hospital stay. Therefore, ERAS should be promoted as the model of care. However, ERAS pathways may require adaption by orthopaedic teams at the pre and post-operative stages to ensure patient and staff safety. The use of technologies such as smartphone apps, wearable activity trackers, and telemedicine may be utilised so that the focus remains on providing better and not just faster care. When adapting pathways, inter-disciplinary teams should learn from the past, and recognised that strong leadership, a supportive organisational culture, and the use of a recognised QI method will be required to contextualise and ensure successful improvement efforts.

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