

A realist evaluation of patient involvement
in a safer surgery initiative

A thesis submitted in partial fulfilment of the requirements of
Cardiff University for the degree of Doctor of Philosophy

2016

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Acknowledgements

I would like to give sincere thanks to NISCHR (now Health and Social Research Wales) for providing me with the funding which enabled me to embark on this PhD.

I am also eternally indebted to my supervisors, Aled Jones and Davina Allen without whom I would not have completed this endeavour. Their seemingly endless supply of patience, guidance and wisdom was something that inspired me and I hope that I am able to show similar qualities to students in the future.

Lastly, but certainly by no means least, I would like to thank my wonderful wife Joanne, who has supported me through this process and endured my endless wobbles and complaints and I know that I couldn't have done it without her. Thank you JoJo xxxx

How is this thesis organised?

This thesis is divided into four distinct parts. In Part I: 'The background', I provide an introduction to the study and describe why it is relevant and important, where it sits in current policy debates, what I did, and how I did it. I then present an overview of the policy landscape in relation to patient involvement in patient safety and following this I provide a review of the empirical literature in relation to patient involvement in patient safety, with a focus on those studies which investigated direct patient involvement in their own care. I then describe the ERAS programme, considering how it relates to patient involvement in patient safety and where the programme sits in relation to the preceding literature and policy review.

In Part II: 'The study', I provide a methodological discussion, description of the research design and the methods used. It is my intention to provide a clear audit trail of what I have done and why, how data were generated, in what way this data related to the research aims and how I analysed these data. I then provide a chapter that considers the different approaches taken by each of the cases under study in relation to the implementation of ERAS, firstly considering the processes undertaken and resources engaged by each of the case studies to initially develop and then launch the ERAS programme on the respective units. Secondly, I give consideration to the processes undertaken and resources engaged to sustain the operation of the programme as part of the ongoing implementation process in the respective clinical areas.

In Part III: 'Patient involvement in ERAS – the interaction of context, mechanisms and outcomes', I first introduce the conjectured Context-Mechanism-Outcome configurations (The CMOs). I then present three further chapters, each of which presents an evaluation of one of the three conjectured CMOs, drawing on my empirical data to identify the contextual factors across the three case studies which influence the outcomes of each of these CMOs and present my 'remodelled' CMOs based on these findings.

In Part IV: 'Summary, Discussion and Conclusion', I provide a summary of my findings, and a discussion chapter which thematises my findings and considers these themes in the context

of the wider literature. I also present a section outlining the limitations of this study followed by my methodological reflections with a consideration of the learning I have achieved during my PhD candidature which I will take forward into my future research endeavours. I then provide a brief conclusion to complete the thesis, making consideration of this thesis as a foundation in relation to ideas for my future work.

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Part I: Background

This first part of the thesis is comprised of three chapters: In chapter one I provide an introduction to the study and describe why it is relevant and important, where it sits in current policy debates, what I did, and how I did it. In chapter two I present an overview of the policy landscape in relation to patient involvement in patient safety and following this I provide a review of the empirical literature in relation to patient involvement in patient safety, with a focus on those studies which investigated direct patient involvement in their own care. In chapter three I describe the ERAS programme and how it relates to patient involvement in patient safety, also considering where this programme sits in relation to the preceding literature and policy review.

Chapter 1: Policy Landscape

This research was undertaken in an area which is relatively new for researchers and policy makers and in this chapter I will contextualise my overall research by presenting an overview of the policy landscape in relation to patient safety and patient involvement. This approach will help contextualise the research question by providing a history of the subject, and review the ideas and theories that have brought us to this point in the debate (Waring et al 2010). It should be noted that this thesis focuses on patient involvement in patient safety, with patient safety being presented as an aspect of healthcare quality by the Institute of Medicine in its landmark work, *To Err is Human* (IOM 1999). However, a renewed focus on quality has seen an increasing tendency in the literature to separate the concepts of quality and safety (Wilkinson et al 2011). With this in mind, I use the terms safety and quality interchangeably during the course of this thesis, whilst recognising that safety is a dimension of quality. I begin this chapter by considering the policy and literature in relation to patient safety and patient involvement in patient safety, before considering patient involvement in more general terms.

1.1 Patient Safety

Research has shown that healthcare organisations can cause harm to patients, much of which is avoidable, and there is reliable evidence to suggest that this harm is a widespread and recurring phenomena (Institute of Medicine 1999; Department of Health 2000; Leape et al 2002; de Vries et al 2008; Longtin et al 2009; Jha et al 2010). An 'adverse event' is commonly defined as an unintended injury, accident, error or complication caused by healthcare treatment and / or management of a patient rather than the patient's underlying condition (Reason 2000; de Vries 2008). These adverse events represent a major source of morbidity and mortality and it is generally agreed that approximately 10% of hospital admissions result in one of these events (National Audit Office 2005; de Vries et al 2008; Jha et al 2010). For example, a systematic review of the literature on in-hospital adverse events was carried out by de Vries et al in 2008 in which eight studies including a total of 74,485 in-patient records were selected and the median overall incidence of adverse events was 9.2%. It should be noted the conclusions of the review by de Vries et al (2008) are based solely on

retrospective case review studies, and as such, most likely represent an underestimation of the problem.

Aside from the obvious harm and distress adverse events can cause to individuals (Department of Health 2000), they also present substantial economic implications to healthcare organisations in relation to additional treatment, extended hospital stays and in many cases financial recompense to the victims (National Audit Office 2005; de Vries et al 2008; Jha et al 2010). A review commissioned by the Department of Health to explore the costs of unsafe care in the NHS (Frontier Economics Europe 2014) suggests that the costs are likely to be in the range of £1bn per year to £2.5bn per year, with estimates in excess of the upper range of £2.5b not unreasonable.

Patient safety is a relatively new healthcare discipline that emphasises the reporting, analysis and prevention of these healthcare related errors (World Health Organisation 2009) and there is consensus of opinion that the publication of the Institute of Medicine report, *To Err is Human* in the US (IOM 1999) and the subsequent Department of Health Report in England, *An organisation with a memory* (Department of Health 2000) acted as a catalyst for the formation of the modern patient safety movement (Leape et al 2002; Stelfox et al 2006; Huehns et al 2010; Longtin et al 2010). This safety movement has gained impetus due to a number of high profile inquiries into failings in healthcare such as the Bristol Royal Infirmary Inquiry (2001) and more recently the Mid Staffordshire Inquiry (Francis 2013) which have highlighted the importance of addressing the prevention of harm to patients. However, commentators note that whilst efforts to improve patient safety have proliferated in the twenty first century, progress towards improvement has been frustratingly slow (Leape et al 2009; Department of Health 2009; Waring et al 2016).

Perrow (1984) and Reason (1997) have highlighted the importance of the role of systems and their design in causing error and there is evidence to suggest that a major contributor to adverse events in healthcare are breakdowns in these complex systems (Jha et al 2010). In response to this, the main thrust of the patient safety movement is that safety problems are primarily a systems problem (Reason 1997; Institute of Medicine 1999). The emergence of human factors engineering in healthcare as a science that attempts to better understand

which human vulnerabilities lead to mistakes and then engineer systems that reduce the likelihood of is also gaining prominence. The uptake of these ideas in healthcare has been partly justified by successful application in other industries, particularly aviation (Waring et al 2010). Many commentators believe that the systems approach has helped clear the way for thinking about solutions and creating systems with inbuilt defences (Reason 2000; Maillard et al 2005; de Vries et al 2008).

This approach to system interventions has been defined by Mesman (2007) as the 'deficiency model' of patient safety and this definition has proven highly consequential for the patient safety agenda in that it can lead to thinking that a deficiency can be addressed or 'plugged' by quality and safety improvement projects, or research findings. This new line of thinking also acknowledges that existing responses to quality and safety were insufficient and that organisation systems or cultures should be modified to enhance the safety of healthcare organisations and clinical teams (Waring et al 2016). However, in practice much of this work demonstrated an impoverished understanding of the fundamental concepts of 'culture' and 'system' (Waring 2013). This failure to effectively consider wider social, cultural and institutional factors may explain why quality improvement / safety initiatives are challenging to implement, or why success in one setting is difficult to replicate in another (Allen 2014).

Waring et al (2015) also comment that the 'deficit model' has a preoccupation with error and that little consideration is being made of the practices that make up the 90% of 'safe' care, including the rescue work of professionals. Similarly, recent work has also drawn attention to the everyday organising work of hospital nurses and their contribution to quality and patient safety through this work (Allen 2014). Other researchers have also begun to demonstrate how safety is produced collectively by frontline actors (Iedema et al 2011; Mesman 2011), challenging the deficit model and instead describing how safety is performed on an ongoing basis (Mesman 2011) by not only the professional skills of clinicians, but also others, including patients (Iedema et al 2011). As noted by Unruh and Pratt (2006), an effective approach to understanding and preventing adverse events should account for the roles and actions of all those involved in the system processes, and so it

stands to reason that the role of the patient should be examined in any efforts to reduce errors.

1.2 Patient involvement in patient safety

Encouraging patients to take an active role in their own healthcare was identified in the landmark patient safety publication 'To Err is Human' (Institute of Medicine 2000) as a vital factor in the quest to improve patient safety. It has since been contended that if patients were involved in their healthcare they could help to further reduce opportunities for accidents and errors during the course of their care (Vincent and Coulter 2002; Koutantji et al 2005; Weingart et al 2005; Davis et al 2007). More recently, there has been growing interest in the development and use of interventions to promote and support patients' roles in securing their own safety in healthcare contexts (Hall et al 2010; Longtin et al 2010; Peat et al 2010; Doherty and Stavropoulou 2012; Vaismoradi et al 2014).

As the patient is supposed to be at the centre of the treatment process, with the opportunity to observe the whole process of care, they may see things that healthcare workers do not and may observe inconsistencies and errors in care that would otherwise go unnoticed (Koutantji et al 2005; Weingart et al 2005; Donaldson 2008). This has led some commentators to suggest that patients are well positioned to be a potentially useful resource in relation to patient safety and the reduction and prevention of adverse events (Koutantji et al 2005; Weingart et al 2005; Johnston and Kanitsaki 2009; Ward et al 2011).

There has also been recognition in recent policy developments in the UK that have seen health policy makers and groups within the NHS contend that if patients were 'actively engaged' by healthcare providers as partners in healthcare delivery, they could help to reduce opportunities for accidents and errors during the delivery of patient care (Department of Health 2010; NHS Wales 2010, 2011). It has also been suggested that since patients are the only individuals physically present during every treatment and consultation, they carry with them important contextualized information as they move through a complex and distributed process of care and therefore may be a valuable resource for safe and effective treatment systems (Unruh & Pratt, 2006; Coulter, 2006).

1.3 Patient involvement: A policy context

Patient involvement as a desirable goal of health policy has longstanding antecedents at a broad level, with the period of the late 1970s and throughout the 1980s identified as particularly significant in the UK (Thompson 2007). These developments can be traced through community development initiatives of the 1970s, the World Health Organisation's declaration of Alma Ata (World Health Organisation 1978) and the consumer orientation of the 1980s (Keat et al 1994). Around this time, concerns were also highlighted about the potentially disabling effects of healthcare which drew focus on the dominant role and potential fallibility of professionals, leading to a loss in public confidence about their expertise (Ocloo and Fulop 2012). A landmark publication in this respect was Illich (1976), who attested that the medical profession had become a major threat to patients through the level of iatrogenic harm (harm resulting from the actions of a healthcare provider or illness caused by treatments) within healthcare systems (Waring et al 2016).

The work of Illich (1976) is also significant in the debate about the role of patients in patient safety because it contributed to emerging sociological debates about professional power (Waring et al 2016). The goal of patient-centeredness is to customize care to the specific needs and circumstances of each individual, that is, to modify the care to respond to the person, not the person to the care (Institute of Medicine 2001). Further to this, Hickey and Kipping (1998) highlight the demand to provide services that are responsive to the needs and wants of patients, and the patients' right to be involved in their own care. However, historically the relationship between the patient and the healthcare worker has followed a paternalistic model, where patients are regarded as passive recipients of care and decisions regarding their care are the domain of the medical profession (Emmanuel and Emmanuel 1992; Longtin et al 2010). Further to this, Anderson and Funnell (2005) describe an 'acute care paradigm', which has underpinned the approach to healthcare in hospitals and in which there is a tendency for patients to surrender control to healthcare professionals, who are then relied on to use their expert skills and knowledge to solve patients' health problems. This reflects the sick role described by Parsons (1951) of an acutely ill person, temporarily passive and acquiescent, being treated by an active doctor and other carers (Allen 2000). Clinicians have the powers to diagnose and provide treatments to determine the

classification of safety and harm (Hor et al 2013), while patients can be further disempowered by illnesses which can restrict their ability to do things (Kleinman 1988). Since this early conceptualisation of a hierarchy of professional control and patients' passivity, ideas of patient autonomy have come to the fore and there have been attempts to shift the emphasis from paternalism to recognition of the importance of an engaged and informed patient (Coulter 1999).

The drive to abandon medical paternalism in favour of a more patient-centred approach has also been identified as a key driver influencing attitudes about patient involvement in healthcare (Elwyn et al 2000; Entwistle and Watt 2006). At the individual level, taking the patient's perspective is an important step in the improvement of the healthcare process. So, rather than thinking of patients as subjects in the healthcare process, it has been suggested it would seem more appropriate to view them as co-producers (Tudor Hart 1998) with an active role in their care which needs to be recognised and enhanced (Coulter 2002). Patients know about their experiences of illness, their social circumstances, behaviours, attitudes to risk, values and preferences, and this type of knowledge is needed to manage illnesses successfully (Coulter 2002).

The recommendations of the public enquiry into failures of the performance of surgeons in the Bristol Royal Infirmary Inquiry (2001) was also critical to developments of patient involvement, when urging healthcare services to involve patients in decisions, keep them informed, elicit feedback and listen to their views (Coulter 2002). More recent failures in healthcare, particularly the events which took place in Mid Staffordshire NHS Trust (Francis 2013) have also been important drivers in calls for increased involvement of patients throughout the healthcare systems, and the UK government response (2014) to the Francis Report (2013) includes specific recommendations for improving patient involvement in their care. The Welsh Government also provided a formal response to Francis (2013) in the form of a policy document 'Delivering Safe Care, Compassionate Care' (Welsh Government 2013). A key outcome of this document was to ensure "patients and service users are at the centre of all that we do as equal partners" (WG 2013, p. 8), although it is not entirely clear in the document how the success of this aspiration would be monitored in relation to patient involvement in their direct care. The Welsh Government also urges healthcare providers in

Wales to understand the contribution that people can make to producing their own health, which has led to the Welsh Government prioritisation of co-production as an element of their 'prudent healthcare' approach in NHS Wales (Bradley et al 2014).

Despite these promising developments, the debate regarding patient safety has primarily been conducted at a professional and academic level (Coulter and Ellins 2006; National Audit Office 2007) and the problem of safety in healthcare has generally remained the responsibility of healthcare professionals, based on their claims to expert knowledge, clinical autonomy and self-regulation (Freidson 1970). In addition, what an adverse event is and how it is defined has been left exclusively to clinicians and researchers, yet commentators have argued that patients may have information and expertise of which healthcare staff are unaware (Vincent and Coulter 2002; Travaglia and Braithwaite 2009). However, even since the inception of the modern patient safety movement in the late 1990s, there has been little attention paid to the knowledge and experience of patients and their families on patient safety and the potential contribution they can make, whether individually or collectively (Vincent and Coulter 2002; Johnston and Kanitsaki 2010).

Patient groups have sought to influence both health policy and practice in relation to patient safety, and (Barnes and Coelho 2009) victims of adverse events and their families in the UK have been instrumental in campaigning for improvements in patient safety. For example, 'Cure the NHS' which was established by people who lost relatives or experienced poor care standards at the Mid Staffordshire NHS Foundation Trust. However, Ocloo (2010) examined patient safety from the viewpoint of harmed patients and argues that, although these experiences have acted as an important catalyst for the emergence of a patient safety movement, evidence suggests that these experiences have been largely excluded in the construction of patient safety reforms.

Historically, scientific rationalism has provided the dominant value structure in an NHS in which medical and associated clinical professions have prevailed and Harrison (2002) argues that the NHS is founded in "scientific-bureaucratic" values that privilege randomised control trials and independently observed measures, rather than patient experience measures (Callaghan and Wistow 2006). Critics of biomedicine argue it is vital to recognise that lay

people have their own valid interpretations of health and illness and that understanding these is essential to the process of healthcare (Ocloo 2010). This requires a discernible shift towards incorporating patients' perceptions, values and preferences into a more subjective medicine, moving healthcare goals towards quality of life and patient's perceptions of health (Thompson 2007). Ocloo (2010) contends that addressing the dominant perspectives in patient safety requires a major shift in tackling the imbalance of power which currently exists between patients and healthcare providers. In support of this, a recent review of the development of patient safety demonstrates that voices of patients are largely missing (Hor et al 2013). There has been suggestion that there is a need for a broader knowledge framework for the evaluation of patient safety which takes into account patients' perspectives (Ocloo 2010). Similarly, Sharpe and Fadden (2001) have also previously called for a much wider perspective when looking at processes that are seen to cause harm to patients, arguing that the process of defining harm tends to reflect a narrow, clinical interpretation that excludes non-clinical outcomes that the patient may consider harmful.

A further contributory factor in attempts to change the role of patients has been the shift from a focus on acute conditions to long term, or chronic, health problems requiring continuous and complex management (Holman and Lorig 2000). This has led to policy recognition in the form of the Expert Patient Programme (Department of Health 2001) of the contribution made by people with long term conditions to the management of their own health (Thompson 2007). However, it should be noted this model of patient involvement may not reflect the experiences of many hospitalised patients who experience isolated acute care episodes with the NHS.

Another issue to consider when discussing patient involvement in patient safety is what is realistic to expect patients to do. The nature of 'expert' and 'lay' knowledge, and the relationship between professional providers of health services and the public they serve can also create difficulties, as often the result is disputed practices of involvement which can result in a disjuncture between policy intentions and practice 'on the ground' (Martin 2009). Concerns have also been raised that involving patients in safety initiatives and behaviours could inadvertently shift responsibility from healthcare providers to patients (Entwistle 2004; Lyons 2007). Lyons argues that relying on patient engagement should not be seen as a

solution to the issues of patient safety, but should rather be viewed as an unexpected source of help (Lyons 2007). Entwistle (2004) supports this, noting that patients should not be burdened beyond their ability with concerns of patient safety. As Davis et al (2007) comment, patients can only function as a 'buffer' in addition to safety measures that are already in place and should not feel that if they do not wish to contribute, or indeed are unable to contribute to their own safety, they will not receive substandard care as a result.

Patients are gradually being seen as having a more active voice which needs to be heeded, for example through groups such as the Patients Association, and surveys of patient opinion and experience are now given greater prominence than previously (Wilkinson et al 2011). This approach to garnering patients' opinions in relation to quality and safety are a useful means of considering service improvement (Wilkinson et al 2011), but this is only one of many ways to measure the patient experience. It has also been noted that, although the need to involve patients is generally accepted, the capability of the patients in making judgements about quality of care is regarded with a degree of suspicion from some quarters, and Elwyn et al (2007) effectively capture this sentiment by asking "is what patients say they want the same as good quality care?" (p1021).

What we have seen in this chapter is that patient safety is clearly an important issue in healthcare, with many people affected by adverse events, which can cause harm to patients and also impede the efficiency and effectiveness of healthcare services. Several high profile failings in healthcare in the UK have brought further focus on patient safety issues. As part of the modern patient safety movement, there has been a reliance on a 'deficit' model of patient safety, and a 'systems' approach which has come under increasing scrutiny in recent years. Commentators have noted the power discrepancies between patients and healthcare providers, particularly in relation to the medical profession, and how patient safety has been defined and controlled by these professionals. It has been suggested that patients can play an important role in helping to improve patient safety, although as we have seen the issues of power and the traditional 'passive' role that is adopted by patients can be a hindrance to this.

Chapter 2: A Review of the Empirical Literature

The term *patient involvement* is used in different contexts to mean different things, therefore in this chapter I firstly present a conceptual analysis of patient involvement, drawing on contemporary evidence from the literature to provide background and context to the types of roles patients can take in their healthcare and to what extent this involvement takes place. Following this I provide a review of empirical literature relating to patient involvement in patient safety with a focus on studies that report on patient involvement in patient safety during acute healthcare.

2.1 A conceptual analysis of 'patient involvement'

Although there appears to be broad support of the idea that patients should be 'involved' in and 'take-part' in their healthcare, there is no clear consensus on what precisely this means and how far, and in what ways this involvement ought to extend (Johnstone and Kanitsaki 2009). The term 'patient involvement' is widely used in healthcare policy and literature, often interchangeably with other conceptually similar terms such as 'patient engagement' and 'patient participation' (Entwistle and Watt 2006). There is also a diversity of roles individuals may enact as patients, carers, or members of the public and similarly, patients can be involved in diverse areas of healthcare at a macro, meso or micro level. This can range from service design or improvement, policy development, research, or patients own individual care and treatment (Forbat et al 2009). Within these different levels of involvement, there is seen to be a spectrum ranging from passive input, through to active involvement and on to equal partnership (Sykes and Godwin 2007). Therefore, before examining the empirical evidence specifically in relation to patient involvement in patient safety, I will consider what 'involvement' means in relation to the variety of potential roles patients can take in healthcare and consider where patient involvement in patient safety is positioned in this continuum.

Snyder and Engstrom (2015) carried out a narrative review of the literature to provide an overview and synthesis of empirical research related to patient involvement at the micro-level of healthcare, specifically in relation to individuals and their interactions and practices.

Based on their selection criteria of peer reviewed, empirical studies which were published between 1995 and 2015 and with a main focus on 'patient involvement', 214 articles were included for review. A major form of patient involvement identified by Snyder and Engstrom (2015) in their review, and of most significance to this thesis, was patient involvement in healthcare delivery. This concerns ways in which to actively involve patients in the delivery of their own care; the three main ways identified are self-care; medication and; self-monitoring (Snyder and Engstrom 2015). In addition to this, Carman et al (2013) also proposed a model of patient involvement which describes patient involvement at the level of direct care as those activities or behaviours related to prevention, diagnosis and treatment. Patient involvement in patient safety would be an appropriate inclusion in this category as it represents an instance of the wider concept of patient involvement in healthcare delivery as defined by Snyder and Engstrom (2015) and Carman et al (2013).

Within each of the different forms of involvement described by Snyder and Engstrom (2015), multiple dimensions need to be considered, such as which patients could be involved, the extent of this involvement and the level of responsibility patients are assumed to take. In Snyder and Engstrom's (2015) review the degree of involvement ranged from situations in which the patient provided feedback, to those situations in which the patient assumed most of the responsibility. The model presented by Carman et al (2013) also presents the forms patient involvement can take in direct care as a continuum, which ranges from one end of the continuum as a patient simply receiving information, on to being an active partner in the care team, setting goals, making decisions and managing their own health. Involvement at the partnership end of the continuum can involve patients communicating with healthcare professionals about their health situation, asking questions and understanding risks and benefits associated with care choices (Carman et al 2013).

Another useful model to consider in the context of this thesis is that proposed by Grande et al (2014) in which they examine existing reviews of patient involvement methods to present a model where the focus is on involving patients in the clinical workflow. As part of this exercise, they also assessed the feasibility of advocated patient involvement methods. The authors' concentrated their efforts on methods to involve patients in clinical settings – what they refer to as the first level of engagement – direct care. Articles were extracted from

1977 to 2011 that matched these criteria and ten reviews were selected for inclusion. Based on this review, Grande et al (2014) categorised patient involvement methods based on information provision, patient activation and patient-provider collaboration. These methods were divided into low and high feasibility, which was predicted on the extent of work required by the patient or the healthcare system (Grande et al 2014). The authors conclude that methods which have a good fit with existing workflows, require little (if any) additional human resources, and that require proportional amounts of work by patients are likely to be most feasible. In contrast, methods of engagement which were defined as low feasibility were characterised by a significant patient burden, a poor fit with complex clinical workflows and additional time and work separate from the hospital. Furthermore, attempts to engage patients in their healthcare need to ensure the patients' learning burden does not overwhelm their capacity to absorb new information and adopt more active roles (Grande et al 2014).

Grande et al (2014) also produced a classification model presented in a series of steps, where methods are based on a progressive structure, which has relevance to this thesis. This classification begins with those methods designed primarily to provide patients with information, to those methods designed to activate specific behaviours, on to those which are intended to catalyse patient and provider collaboration (Grande et al 2014). 'Passive information provision' describes methods based on the provision of information to patients in passive ways and is characterised by the unidirectional transmission of the information. In Grande et al's model, 'Information + activation' focuses on skills and motivation to enact particular communication behaviour with a provider and describes methods which target patient engagement through encouraging, prompting, coaching, help and support to perform specific behaviour(s) in the clinical encounter. The final step is described as 'Information + activation + collaboration' adds collaboration to the grouping of methods, which Grande et al (2014) describe as a two-way process that supports engagement.

In conclusion to this consideration of conceptualisation, it is clear that patient involvement at the direct level of care can take a variety of forms and should also be considered along a continuum. However, describing patient involvement in terms of a continuum does not suggest that the goal always for patients to be at the higher end of the continuum. Indeed,

this type of involvement may not always be appropriate for every patient in every setting. The level of patient involvement is best determined by the topic at hand in consultation with the individual patient and so the same patient may occupy different positions on a continuum of involvement, even during an individual care encounter (Carman et al 2013). Grande et al (2014) also draw attention to the fact that the level of need and interest in involvement will vary between patients', as well as within individual patients, depending on particular circumstances, which highlights the need for messages and methods tailored for individual patients (Grande et al 2014). The next section of this chapter reviews empirical studies which have examined different approaches for involving patients in the safety of their own care, as this is the central concern of the thesis.

2.2 An empirical perspective on patient involvement in patient safety

I will now present a review of the empirical literature relating to patient involvement in patient safety, starting with details of my search strategy.

2.2.1 Search Phase

The first phase of the review was the search phase which began with a scoping search of databases where test searches were run to establish which combinations of search terms bring the most successful sets of results. The search terms (keywords) define the limits and nature of a literature search, so they should be established in such a way that permits selection of all related articles, whilst eliminating those which are not relevant. Initially I was interested in primary research that considered patient involvement in patient safety. I used a variety of key search terms in combination including "patient safety", "adverse events", "medical error", "healthcare error", "involvement", "participation", "engagement", "empowerment". I used different combinations of these keywords and also considered further synonyms, plurals, different spellings, use of hyphens and use of abbreviations and used Boolean operators to support my searches. I restricted my searches to studies that were published in English as no translation services were available to me and I set my date parameters to include studies published since 1999, as this coincides with the publication of

the landmark Institute of Medicine patient safety report 'To Err is Human', which many experts agree was the catalyst for the modern patient safety movement.

Based on the scoping search, I then carried out comprehensive searches of the databases that were relevant to patient involvement in patient safety, supported by the key search terms and combinations I had identified. These databases were Medline, CINAHL, British Nursing Index, and PubMed. I also used other exploratory methods which consisted of hand searching on key journals identified through the scoping exercise and snowballing (searching references of references) to identify key sources. Further to this, I set up library alerts with key search terms to stay up to date with current literature.

2.2.2 Inclusion / exclusion criteria

Defining the inclusion and exclusion criteria can help focus on the relevance of the studies to the research aim. I was interested in primary research studies that reported on adult patient involvement in patient safety in acute healthcare therefore I excluded studies which involved children and family centred care, people with long-term conditions, shared decision making (and its synonyms) and community based studies.

Collectively, the search strategy yielded 397 articles. From the initial searches, articles were excluded where the title and the abstract made it clear the paper did not fulfil the inclusion criteria. There were many duplicates which were also removed. Initially I also chose to exclude systematic reviews and literature reviews. Following this initial evaluation process, 22 primary studies were selected for inclusion comprising of 12 studies published in the UK, 9 published in the US and one published in Australia.

I then further evaluated each of the research articles selected using the relevant qualitative and quantitative critical appraisal tools available from the Critical Appraisal Skills Programme (CASP). Using these critical appraisal tools helped me to research the evidence I had identified in an explicit and transparent way and reach judgements about this evidence. Specifically, use of these tools this supported me in consideration of the validity of each study and also enabled me to make consideration of the results and think about how these

results related to my own research aims. I read and re-read each article and produced a summary document describing the specific context and justification for the research, what (if any) theory was used to inform the research design and analysis, the methodological approach taken in the study and the results and recommendations. I also established the main empirical findings and what the implications of these findings were in relation to my research aims. I then extracted and collated the key results, grouping methodologically comparable studies together.

During my review I had become aware of a consensus in the academic literature that there is a paucity of empirical evidence available on patient involvement in patient safety. This was supported by the findings of a large scale scoping review of over 20,000 documents by Peat et al (2010) and more recent reviews of patient involvement in patient safety have also concluded that the evidence base for this subject is not growing at a pace and that there is generally a lack of high quality evidence in this area (Doherty and Stavropoulou 2012; Vaismoradi et al 2014). As a consequence of this, and in light of the relatively small amount of empirical evidence unearthed by my own search strategy, I chose to adapt my inclusion / exclusion criteria for my own review to include systematic reviews and literature reviews. To support this, I also extended my database searches to include the Cochrane Library and the Joanna Briggs Institute (although these did not glean any additional studies). Although original articles are preferable, these reviews provided a broader perspective on patient involvement in patient safety than that which had been reflected in my initial search. In total there were 16 reviews included, comprising of 12 literature / narrative reviews and four systematic reviews. As with the primary research articles, these were predominately made up of UK based publications, along with some publications from the US.

2.2.3 Summary of database searches

Database	Total no of 'hits'	Primary Research	Reviews
British Nursing Index	119	4	3
CINAHL	93	9	7
Medline	83	11	5
PubMed	102	3	5
Total articles included (excl. duplicates)		22	16

As a result of the adaptations to my search strategy, the review papers included in this literature review form the cornerstone of this chapter, through which I intend to distil the landscape of patient involvement in patient safety at different levels and in different contexts. I will also synthesise findings from the primary research papers revealed during my searches which I deemed relevant to the aims of my research through a process of critical evaluation. In doing so, I provide critical engagement with and synthesis of the different ways in which patients can be involved in their own care, and specifically in safety, which will help to frame my subsequent analysis of patient involvement in patient safety through an ERAS programme.

Although this narrative type of approach to literature reviews is sometimes seen as less rigorous and open to interpretive bias, it does offer a more inclusive and holistic approach for reviewing studies that are drawn from heterogeneous sources (Greenhalgh et al 2005; Waring et al 2010). The narrative approach also allows for qualitative descriptions, interpretations and synthesis which leads to the identification of common and emerging themes, as opposed to evaluating specific study findings or testing existing theory (Waring

et al 2010). Based on this, the purpose of the review was to try and map, interpret and critique a range of evidence on patient involvement. However, it was not my intention to produce an encyclopaedic inventory of every paper published. As Greenhalgh et al (2005) put it, I favoured sense making over cataloguing.

The results from a narrative review such as this can be presented as a 'conceptual frame' and to support this literature review and to assist in the sense-making and cataloguing of a diffuse evidence base, I preface the review with a series of frameworks outlining the key findings from the literature in relation to the distinct themes identified from my review of the evidence base. Following this, I will provide more insight into each of the particular frameworks, highlighting primary research of particular relevance to patient involvement in patient safety in acute care.

This begins with a review of interventions reported in the literature which are designed to involve patients in patient safety. I then go on to consider the various factors which have been reported as influencing patients' willingness and ability for involvement in patient safety behaviours and activities. Following this, I consider the influence of healthcare professionals in efforts to involve patients in patient safety, before finally reviewing the literature in relation to patients' perceptions and understanding of patient safety, providing insight into how patients view their safety when using healthcare services and what they perceive their role might be in relation to patient safety.

2.2.4 Organising framework for interventions intended to involve patients in patient safety

1. Informing the management plan. Patients might help to make sure that their treatment is appropriate for them, helping to ensure the appropriate treatment plans are formulated by:
➤ Patient choice of care provider, making appropriate information available for patients on infection rates, complications and other safety-related information
➤ Ensuring informed consent is gained, ensuring patients understanding of the illness and treatment, associated risks and opportunity for choices and involvement
➤ Sharing relevant information with the health professionals involved in formulating plans, for example by making sure that healthcare professionals know about any allergies or adverse reactions to medication, whether any advance directives are in place
➤ Making sure that a proposed plan is appropriate, exploring treatment options, for example by asking if there are any alternatives to the treatment recommended
➤ Ensuring patient advocacy arrangements in place, when required

2. Monitoring and ensuring safe delivery of treatment. Patients might help to make sure that treatment is given correctly as planned and according to appropriate protocol:
➤ Helping to ensure safe delivery of planned treatment by health professionals, for example by checking on a therapies calendar that the correct dose of medication is given at the right time
➤ Reducing medication errors. Patients should be given full information about the purposes of their medicines and their likely side effects. Patients should be encouraged to speak up when they notice unexplained changes in their medication
➤ Helping to ensure safe delivery of treatment by self, for example by monitoring blood INR levels and modifying self-administered anticoagulant medication dosage in response to this
➤ Acting to minimise any potential problems of treatment and responding appropriately if they occur, for example by following instructions for self care after surgery and alerting the surgical team if any notifiable symptoms occur
➤ Reducing hospital acquired infections. Patients should be encouraged to ask staff if they have washed their hands and patients should also be encouraged to practice good hand hygiene
➤ Monitoring adverse events. Patients should be encouraged to report concerns and adverse events
➤ Helping to maintain continuity of care, coordinating treatment tasks
➤ Monitoring own health status
➤ Detecting underperformance / deviations from policy or standards; detecting errors and near misses

3. Informing systems improvement. Patients might help to make sure that problems and risks within healthcare systems are identified and reduced by:
➤ Providing feedback about experiences of healthcare safety, for example by completing a post discharge survey
➤ Acting as a patient representative, for example serving on a patient and family advisory council to identify and appraise possible safety improvements; involvement in post-event explanations or investigations
➤ Retrospectively reporting concerns, adverse events or near misses
➤ Making formal complaints and where necessary, litigating

2.2.5 Organising framework for factors which can influence patients' willingness and ability for involvement in patient safety

1. Patient related factors
➤ The patient's existing knowledge and beliefs about safety and medical error and the patient's experiences relating to medical error and healthcare. Patients expectations
➤ Prior experience of patient safety incidents
➤ Existing knowledge of the healthcare system and level of health literacy
➤ Emotional experiences
➤ Coping styles
➤ The varied personal characteristics of individual patients, including assertiveness, preference for active or passive involvement; patient preference for collaborative, rather than confrontational behaviour and confidence in own capacities
➤ Socio-demographic and biographical details
➤ Patients feelings of physical or emotional vulnerability and level of anxiety

2. Illness related factors
➤ The point on the illness trajectory, the stage and severity of the patient's illness
➤ The type of illness and any comorbidity
➤ The nature of illness. For example, the association of certain health problems with moral judgements or stigma (e.g. mental health problems) may influence a patient's involvement in the health care they receive.
➤ How the illness symptoms manifest themselves and how such symptoms affect functional status including physical, consciousness level, and the ability to receive and process information
➤ The type of treatment plan for the illness and how much opportunity for patient involvement this allows
➤ The likely impact that patient involvement will have on the patients' health outcomes
➤ The patient's prior experience of illness
➤ The patient's knowledge of his or her own condition

3. Health care setting related factors

- The extent to which patients can be involved in their healthcare will vary according to the different type of healthcare setting, that is, primary, secondary or tertiary care setting and whether the admission process is scheduled or unscheduled
- The patient's perceived 'busyness' of the healthcare environment

4. Task related factors

- The specific patient actions and behaviours that are required for improvement in safety. The type of safety related behaviours.
- Whether or not decisions require medical, clinical or specialist knowledge
- The type of decision to be made, for example 'problem solving situations' or 'decision making situations',
- The perceived value of potential outcomes to the patient
- Does the patient deem it major decision making or minor decision making?
- The perceived immediacy and gravity of threat to safety and perceived threat to wellbeing of the patient
- The patient's perceived level of challenge associated with the proposed action
- Patients' willingness to participate may differ depending on whether they alone or accompanied by a friend, carer or relatives
- The likelihood of involvement differs depending on whether the patient is acting for his or her self or on behalf of someone else, or whether it is a relative, carer or friend acting on behalf of a patient
- The extent to which the patient is sure of grounds for action
- Fear of repercussions can affect patients' willingness for involvement

5. Health care professional related factors
➤ Healthcare professionals' knowledge and beliefs about safety and patients' involvement in safety
➤ The way in which healthcare professionals interact with patients
➤ Whether staff recognise the benefits of involving patients in enhancing safety
➤ Whether staff actively encourage participation in safety related behaviour
➤ Prior experience, perception of nature of relationship with healthcare professionals
➤ The anticipated and actual response of healthcare professionals to patient's efforts to contribute to their own care and safety
➤ Health care workers' personal beliefs, attitudes and behaviour
➤ Healthcare workers' receptiveness to patients attempts to participate
➤ Health care workers professional group can affect attitudes towards participation
➤ Level of training for staff in patient involvement
➤ The type of illness / patient being treated
➤ Perceived availability of time, including the time required to educate and respond to the patient
➤ Healthcare workers desired level of control
➤ Healthcare workers' willingness to delegate / share safety tasks

2.3 In what ways can patients be involved in patient safety?

As early as 2002, Vincent and Coulter identified that at most stages of patient care there is the potential for patient involvement in patient safety related activities and behaviours. Therefore, in this concluding section of the chapter I will undertake a review of the empirical literature, considering papers which present evidence relating to the various ways in which patients may be involved in their safety during hospital care.

Vincent and Coulter (2002) describe how patient involvement could be through the provision of diagnostic information, which may help reach an accurate diagnosis, or through involvement in treatment decisions, deciding on an appropriate treatment or management strategy. They also note that patients can be involved in the management of treatments and conditions, the monitoring of adverse events and also helping to ensure treatment is appropriately administered, monitored and adhered to. Since Vincent and Coulter's paper (2002) several researchers have produced frameworks outlining the potential role of patients' in patient safety (Koutantji et al 2005; Unruh and Pratt 2006; Howe 2006; Watt et al 2009), which has culminated in the efforts of Peat et al (2010) who have produced an organising framework for interventions intended to involve patients in patient safety. To achieve this, Peat et al (2010) undertook a broad scoping review to identify and critique the various roles and methods by which patients might act to enhance their own, or others, safety when they use health services. The authors' identified 437 publications which described one or more interventions intended to promote patient involvement in patient safety, but report that very few of these provided an explicit rationale for their approach and few of the interventions have been formally evaluated for effectiveness or acceptability.

Peat et al (2010) also describe how many of the interventions included in their review appear to be spontaneous reactions to adverse events and there appears to have been little consideration of the mechanism of effect and of what conditions and circumstances are required for patients to adopt safety-orientated roles or behaviour, including their willingness and ability to do so. In conclusion to their exercise Peat et al (2010) identify three broad routes by which patients' might contribute to their safety. Firstly, by helping to make sure their treatment is appropriate for them (informing the management plan); secondly by helping to make sure their treatment is given as planned and according to the

appropriate protocol (monitoring and ensuring safe delivery of treatment) and; thirdly helping to make sure that problems and risks within healthcare systems are identified, and where possible reduced (informing systems improvement).

The findings of Peat et al (2010) are supported by the work of Hall et al (2010) who carried out a systematic review to evaluate the effectiveness of interventions that have been used with the explicit intention of promoting patient involvement in patient safety. Hall et al (2010) report improved patient safety incident outcomes for the intervention groups compared with control groups when interventions are aimed at encouraging patient involvement in 'monitoring and ensuring safe delivery of treatment by self' and 'informing the management plan'. In their review Hall et al (2010) identify 14 individual experimental and quasi-experimental studies, plus one systematic review, but were unable to draw any clear conclusions as to the effectiveness of the interventions due to concerns about the methodological quality of the studies. In light of this, the authors conclude there is limited evidence for the effectiveness of interventions designed to promote patient involvement in patient safety, as in general the evidence is poor quality and confined to the promotion of self-management of medication, most notably oral anti-coagulants.

In support of these findings, an earlier review by Coulter and Ellins (2006) set out to examine the effectiveness of patient involvement strategies, examining over 150 systematic reviews in an attempt to draw together the best objective evidence of outcomes of interventions that recognise the role of patients as active participants in attempts to improve healthcare quality and safety. During this exercise, Coulter and Ellins (2006) evaluated 20 systematic reviews of trials involving strategies for patients to contribute to safe medication use and adherence to treatment regimes. Of these strategies, simplifying dosing regimens was found to be the most effective, whereas interventions that involved education and information provision produced less conclusive and less robust results and are unlikely to be effective on their own.

As part of their wider review, Coulter and Ellins (2006) also evaluated a number of individual studies and one systematic review that reported on the effectiveness of patient involvement in hospital infection campaigns and describe these initiatives as one of the few areas in their review in which patients' potential contribution to improving patient safety

has been recognised and is being actively promoted. These initiatives were generally associated with encouraging patients to ask healthcare workers if they had washed their hands, in combination with increased provision of handwashing facilities, and this led to improvements in hand hygiene compliance among healthcare workers (Coulter and Ellins 2006). Also in relation to hand hygiene, McGuckin and Govednik (2012) undertook a review of the literature between 1997 and 2012 relating to patients' willingness to be 'empowered' in relation to hand hygiene (that is, asking healthcare workers if they have undertaken hand hygiene), and what the barriers to this 'empowerment' might be, exploring hand hygiene improvement programmes that include attempts at patient 'empowerment'. Although several studies show that, in principle patients are willing to be empowered in the sense that they would ask healthcare professionals about their hand hygiene practices, McGuckin and Govednik (2012) report a variation in the number of patients that are prepared to practice empowerment for hand hygiene, ranging from 5% to 80%, noting that the actual willingness of patients' to question healthcare workers can be increased when a patient is given explicit permission by a healthcare worker. Based on their findings, McGuckin and Govednik (2012) question whether there is enough information to determine if, and under what conditions, patients will be able to play an immediate role in healthcare workers' hand hygiene behaviour.

A common belief among policy makers and healthcare providers is that the most effective way to involve patients in attempts to improve patient safety is to provide them with relevant information and guidance (Entwistle et al 2005; Koutantji et al 2005; Waterman 2006). In keeping with this belief, patient safety models have tended to presume that making patients' safer via education is simply a matter of giving them information (Spath 2007). Behaviours relating to these forms of contribution are encouraged by the array of patient literature that has been developed, especially in the US, to advise people what they can and should do to avoid harm when they use healthcare services (Peat et al 2010).

Entwistle et al (2005) point to the lack of evidence on the effectiveness of these strategies and the possibility that advice may do more harm than good, also commenting that there was a lack of attention to patients' perspectives during the development of advisories such as these. In their study, Entwistle et al (2005) examined several major campaigns in the US

that advised patients about safety, analysing the content of five leading safety advisories for patients. A critique of their development, content and impact of these advisories was devised, drawing on published literature and 40 interviews with a diverse sample of key informants with expertise and interest in patient involvement and safety issues. Entwistle et al (2005) report that patients are given little practical support to carry out the recommended actions, and healthcare professionals' responses may render patients' attempts to secure their own safety ineffective. Some messages in the advisories suggest an inappropriate shifting of responsibility onto patients and advice that involves checking on, or challenging, healthcare professionals' actions appears to be particularly problematic for patients. Entwistle et al (2005) conclude that such behaviours conflict with the expectations many people, including healthcare professionals and patients', have of patients' roles.

In the UK prominent safety organisations such as the National Patient Safety Association (NPSA) have previously implicitly endorsed the aim to facilitate patients' involvement in safety and have produced advisories that encourage patients to 'speak up' and ask questions of staff (NPSA 2004; NPSA 2006). In relation to encouraging patients' to 'speak up', Davis et al (2008) explored a convenience sample of surgical patients' (n=80) willingness to question healthcare staff about their treatment, using questions derived in accordance with contemporary patient safety initiatives aimed at encouraging patients to ask healthcare staff specific safety related questions about their healthcare. The survey included factual questions, for example 'when can I return to my normal activities?' and challenging questions, for example 'have you washed your hands?' Davis et al (2008) found that patients were significantly more willing to ask doctors and nurses factual, rather than challenging questions. They also found that doctors' instruction to patients' to ask questions increase patients' willingness to ask challenging questions of both doctors and nurses (Davis et al 2008).

Patients would seem well positioned to contribute to the safety of healthcare systems by feeding information about safety issues they have identified or experienced into local or national reporting systems (Hall et al 2010; Ward et al 2010). For example, Guijarro et al (2010) found in their systematic review that patient reporting is a reliable way to identify adverse events and empirical studies demonstrate the feasibility and value of patient

reporting (Weingart et al 2007; Weissman et al 2008). The reliability of patient reporting of adverse events has also been established as trustworthy through a systematic review carried out by King et al (2010) who reviewed methods to solicit patients' reports of adverse events. However, as patient reporting is a relatively new addition to patient safety reporting systems, the techniques that have most utility have not yet been identified and King et al (2010) report those studies conducted into this matter are too diverse to compare statistically.

As discussed previously in this review, terms used by healthcare professionals, such as adverse event, are often not recognised by patients (Burroughs et al 2007) and so reports solicited from patients are likely to increase if a common language is used in relation to patient safety (King et al 2010). Results from a study carried out in Swiss hospitals by Agoristas et al (2005) with the aim of estimating the frequency of undesirable events reported by recently discharged patients (n=1518) suggest that errors detected by patients are not easily identified by other means. This particular study is noteworthy as Agoristas et al (2005) compiled a list of 'undesirable events' for patients to report on, which was based on the literature and review of common patients concerns and complaints. This list comprised consisted of items related to medical complications, interpersonal problems and incidents relating to the healthcare process, the intention being to develop a list of undesirable events which were noticeable to patients. There was a response rate of 94.4% (n=1433) and over half of respondents (50.6%) reported at least one undesirable event, with two of the most frequently reported events being the unavailability of medical records (9.5%) and failure to respect confidentiality (8.4%). This lends further support to the notion that patients' perception of error is broader than that determined by healthcare organisations and professionals and is also closely aligned to communication and interpersonal relationships. It should also be noted that the two other highest reported undesirable events from this study were phlebitis (11%) and hospital acquired infections (8.2%), which supports the claim that patients can also reliably report on 'medical' adverse events or complications (Agoristas et al 2005).

In summary, several strategies to involve patients in the safety of their care have been reported in the literature, however there is little theory to support these interventions and few reports of outcome measures for this type of intervention.

2.4 Factors that can influence patients' willingness and ability for involvement in patient safety

The degree of patient involvement in patient safety will depend on the extent to which patients are able and willing to take a part in their healthcare and this will vary from person to person and can be influenced by a wide range of factors. During the course of this review I have already considered the relevance of patients' perceptions and understanding of patient safety, along with the importance of the role of healthcare workers and the interpersonal relationships between patients' and these healthcare workers. In this section I will now consider other factors that can influence patients' willingness and ability for involvement in patient safety and there have been several attempts published in the literature that attempt to capture and evaluate the empirical evidence relating to these factors. This has been in the form of two literature reviews (Davis et al 2007; Watt et al 2009), a scoping review (Peat et al 2010) and more recently, two systematic reviews (Doherty and Stavropoulou 2012; Vaismoradi et al 2014) and for the purposes of my literature review, rather than attempt to represent the literature here, I have chosen to summarise the broader findings of the aforementioned publications.

A literature review carried out by Davis et al (2007) set out to present factors that could affect the involvement of patients in safety issues in their care, drawing on direct evidence specifically related to safety contexts. Due to the paucity of evidence available at the time, the authors' also considered indirect evidence which was extrapolated from the literature relating to wider aspects of patient involvement in healthcare. This comprehensive review resulted in a grouping of five broad categories which explained factors that are likely to affect patient involvement in patient safety and which provide a useful conceptual framework for organising and understanding the likely determinants of patient involvement in patient safety (Davis et al 2007). The categories are: patient related; illness related; healthcare setting related and; healthcare professional related and Davis et al (2007)

conclude that a complex interplay between these factors appears to be influential in patients' willingness and ability to take action in relation to patient safety.

The studies by Watt et al (2009) and Peat et al (2010) build on the work of Davis et al (2007), again exploring and categorising the factors that can influence patient involvement in patient safety. There were four broad findings, three of which appear to map directly onto elements of the conceptual framework devised by Davis et al (2007), namely; the varied characteristics of individual patients', including knowledge and health status; patients' experience of and beliefs relating to medical error and; the actual and anticipated response of healthcare professionals to patients' efforts to contribute to their own safety. Further to these reviews, Doherty and Stavropoulou (2012) undertook a systemic review of the literature to identify factors that support and deter patients from being willing and able to become actively involved in reducing errors in their healthcare, with a total of 68 studies included in the review, of which 49 involved hospital patients. Studies included for review either investigated initiatives involving patients in safety, or studies of patients' perspectives of being involved in the safety of their care and the authors' conclude that the main factors for involving patients' in their own safety can be summarised into four categories. These are: illness; individual cognitive characteristics; organisational factors and; the clinician-patient relationship (Doherty and Stavropoulou 2012). Again, these factors can be mapped onto the framework presented by Davis et al (2007).

In addition to this, and most recently of all, Vaismoradi et al (2014) carried out a systematic review with the aim of synthesising the existing research on how patients are involved in patient safety initiatives, with a particular focus on nursing involvement. They identified 17 empirical research papers consisting of qualitative, quantitative and mixed methods studies and their findings area again similar to those presented by previous researchers, including Davis et al (2007), with the addition of a theme that considers the infrastructure and resources of the healthcare organisation in relation to attempts to involve patients in safety related activities (Vaismoradi et al 2014).

Based on analysis of the literature presented thus far, it is reasonable to suggest that the factors that affect patients' willingness and ability for involvement in safety can be categorised into five broad themes, namely, patient related, illness related, task related,

healthcare setting related and healthcare professional related. I have already considered the role of the healthcare professional in some detail, along with certain aspects of patients' characteristics and beliefs and I will now present some of the specific issues relating to the other themes. There is also evidence to suggest that individual patients' socio-demographic and biographical details can influence patient involvement in patient safety, including patients' 'health literacy' (Davis et al 2007; Watt et al 2009). Other important factors include patients' feelings of emotional and / or physical vulnerability, along with the patient's level of anxiety (Watt et al 2009). Patients' level of involvement is also related to their previous experiences relating to healthcare in general and patient safety (Davis et al 2007; Watt et al 2009) and patients' who are familiar with their own care and treatment plans are more likely to become involved in patient safety initiatives (Schwappach and Wernli 2010b).

Another important factor affecting the willingness and ability of patients to become involved in patient safety that patients need to be aware of any requirements for involvement and what this will entail for them in terms of any specific actions and behaviours that may be required (Davis et al 2007; Vaismoradi et al 2014). Patients health status is also a key requirement for their involvement in patient safety, as their ability for involvement is reduced by illness (Watt et al 2009; Vaismoradi et al 2014). This can be related to the point on the illness trajectory, the stages and severity of the patient's illness, how the illness manifests itself and how symptoms affect functional status (Davis et al 2007; Peat et al 2010; Doherty and Stavropoulou 2012; Vaismoradi et al 2014). The type of treatment plan and how much opportunity for involvement this allows is also a factor to be considered, along with the likely (or perceived) impact involvement may have on the patient's health outcomes (Davis et al 2007).

The type of healthcare setting, that is primary secondary or tertiary, can also influence patients' willingness and ability for involvement in patient safety, as well as the admission pathway – that is, whether it was unscheduled (for example emergency care), or scheduled (for example, elective surgery) (Davis et al 2007; Watt et al 2009). It has also been noted that attempts to involve patients in patient safety are likely to be more successful in environments where patient involvement is both valued and supported (Davis et al 2007; Watt et al 2007; Vaismoradi et al 2014).

To summarise, the evidence from the empirical literature demonstrates that there is a complex array of interrelated factors that can influence patients' willingness and ability for involvement in patient safety, including, importantly, the varied characteristics, experiences, beliefs and knowledge of individual patients.

2.5 The role of healthcare professionals' in patient involvement in patient safety

Interrelationships and communication with healthcare professionals have been shown to be an important factor in patients' perceptions of patient safety. This is related to healthcare professionals' knowledge and beliefs about patient involvement in safety orientated activities and also the way in which healthcare professionals interact with patients (Davis et al 2007). The anticipated or actual response of healthcare workers to patients' efforts to contribute to their own care and safety is an important factor (Watt et al 2009), with some patients' wary of causing offence by raising concerns or complaining about errors (Davis et al 2013). Studies have also shown that the encouragement and approval of healthcare staff is crucial in preparing patients for involvement in promoting the safety of their own care, with clinical staffs' positive attitudes, encouragement, support and education being identified as central to patient involvement in patient safety practices (Schwappach and Wernli 2010; Davis et al 2011; Davis et al 2012).

Watt et al (2009) analysed strategies which were designed to promote patient involvement in patient safety, reviewing literature that specifically explored patients' willingness and ability to adopt recommended safety promoting behaviours. A major conclusion from their review is that many patients would be willing to play a role in their safety if the context and nature of the relationship with healthcare providers were appropriate. Watt et al (2009) also conclude that attempts to engage patients in their safety places requirements on healthcare organisations to support healthcare professionals in this, for example by ensuring their workload demands are reasonable, thus helping staff to develop better relationships with patients (Watt et al 2009). This is supported by the findings of the systematic analysis of factors that influence patients' response to attempts to actively involve patients in strategies to reduce clinical errors undertaken by Doherty and Stavropoulou (2012). Overall, the findings of the review demonstrate that clinicians have an important influence at an interpersonal level on patients' willingness and ability to engage in

attempts to reduce errors and one of the main factors for involving patients in their own safety is what they refer to as the clinician-patient relationship.

Doherty and Stavropoulou (2012) also conclude from their review that patients' perceptions of their role and status as subordinate to that of clinicians is the most significant barrier to patient involvement in error prevention, resulting in patients' adopting a deferential attitude towards clinicians. This was closely related to patients' fear of being labelled 'difficult' by healthcare staff, which can lead to patients enacting a more passive role. An important factor in this was the perceived power of healthcare professionals, particularly the medical profession, and many patients' do not challenge clinicians because they feel it is not their role to do so (Doherty and Stavropoulou 2012). However, this reluctance can be tempered if patients receive direct instructions to do so from clinicians as described, for example, in the study by Davis et al (2011) in which doctors and nurses' encouragement appeared to increase patient-reported (n=80) willingness to ask challenging questions.

There is more evidence to support the relevance of the role of the healthcare professional in patient involvement in patient safety, for example Davis et al (2012) report on an exploratory study which used a cross-sectional survey to investigate doctors (n=40) and nurses' (n=40) attitudes towards patient involvement in safety-related behaviours. All participants from the relatively small sample were from an inner city London teaching hospital and the survey was comprised of: factual questions; challenging questions and; notifying healthcare professionals of problems or errors in care. Overall, the authors' conclude that both doctors and nurses indicated they would support patient involvement in safety related actions or behaviours, although in general nurses' seemed to support patients' more strongly, particularly in asking challenging questions.

Similarly, Schwappach et al (2012) examined healthcare professionals' attitudes towards patient involvement in error prevention. Using vignettes that described two error scenarios (missed hand hygiene and medication error), this study took place across 12 Swiss hospitals with a total of 1,141 participants (response rate 45%), comprised of 80% nurses and 15% doctors (5% other professions). This study provides insights into predictors of healthcare professionals' attitudes toward patient involvement in patient safety and found that approval of patients' safety related interventions was generally high and was largely

affected by patients' behaviour and correct identification of errors (Schwappach et al 2012). Overall, findings from the study indicate there are several factors which appear to be particularly pertinent in determining healthcare professionals' responses to hypothetical error scenarios: whether an error actually occurred; how both the patient and the healthcare professional responded to the error; whether the healthcare professional in the scenario was a doctor or a nurse (Schwappach et al 2012). In all of the scenarios, the healthcare professional approved of the patient intervening, interestingly this was the case even if they felt the situation could have negative effects on the healthcare professional-patient relationship and irrespective of how the situation would make them feel personally. There are some limitations to this study that should be noted in relation to the sample which is biased towards nursing staff. In addition, the authors' could not include all factors that may influence healthcare professionals' responses to patients in reality, for example workload demands, time constraints and the level of stress a worker may be under. There are also recognised disadvantages with the use of vignettes in relation to establishing reliability and validity (Gould 1996).

Schwappach and Wernli (2010a) also carried out a review of predictors of chemotherapy patients' intentions to engage in medical error and prevention and found that doctors and nurses play a crucial role in supporting and enabling patients' in their efforts to detect errors. Data from the study confirm it was not uncommon for patients to identify deviations from routines and then act to intercept potentially errant administration of medication. However, it was also observed that patients' recognised their limited capabilities for error detection and attached central importance to instruction by nurses regarding error prevention. Schwappach and Wernli (2010b) further explored oncology nurses' perceptions and experiences of patients' involvement in chemotherapy error prevention through a qualitative study in which nurses overwhelmingly reported positive experiences when involving patients in safety behaviour. In this study, patients' involvement was perceived to be compatible with trusting relationships, although it was also described by nurses as challenging (Schwappach and Wernli 2010b). The authors' of the paper conclude that nurses in the study acknowledged the diverse needs of patients' and thus used different strategies to accommodate patient involvement. It should be noted the authors of these studies acknowledge that chemotherapy patients often experience long and intense relationships

with the same staff and perceived approval of error prevention by staff is likely to be of vital importance to patients in these circumstances.

In their study, Hor et al (2013) also address the discourse of safety research and policy that has highlighted the role of clinical staff in patient safety and present evidence that points to the importance of healthcare staff engaging with patients' efforts in the (co)production of safety. In their conceptualisation Hor et al (2013) describe patient safety as a co-accomplishment in which patients and providers collaborate in the (co)production of safety. They draw on three interrelated but separate studies to argue that safety is an ongoing achievement of not only healthcare staff, but that patients are already involved in safety, particularly in interaction with healthcare staff. It should be noted the participants in the three studies were drawn primarily from patient populations dealing with what the authors describe as serious and long-term conditions, for whom risks of harm through healthcare are particularly crucial and potentially recurring (Hor et al 2013).

What emerged as significant in patients' accounts was the extent to which they were reliant on the cooperation of healthcare staff to enable or advance any attempts at self-initiated safety behaviour. Patient participants also distinguished between clinicians who were unfamiliar to them and those with whom they deemed to have a relationship and the positive benefits associated with having relationships with healthcare staff came through strongly in participants' accounts (Hor et al 2013). The authors' also report that another facet of patients having positive relationships with healthcare staff was that the maintenance of these relationships became a kind of 'safety work' for patients, with some describing actively avoiding conflict to prevent antagonising the clinicians in charge of their care, reminiscent of the literature on 'difficult patients' (Hor et al 2013).

Other factors identified in the literature in relation to the role of healthcare workers in attempts to involve patients in their safety include healthcare workers perceived availability of time, desired level of control and willingness to delegate or share safety related tasks with patients (Longtin et al 2010). Healthcare staff also need to be aware that individual patients' will want different levels of involvement, or none at all, however this may change over time and with context (Schwappach and Wernli 2010c). Patients may willingly become involved if they perceive this as normal and acceptable behaviour and within their control

(Davis et al 2012). However, it may also be the case that some patients' reject involvement because they feel this is not their role (Vaismoradi et al 2014), with some patients preferring to cede control to healthcare professionals, adopting a passive role (Rathert et al 2012; Vaismoradi et al 2014). To summarise, it is clear from the evidence presented here that healthcare professionals play a critical role in any attempt to involve patients in patient safety.

2.6 Patients' perceptions and understanding of patient safety

It has been suggested that there is a need for a broader knowledge framework for the evaluation of patient safety which takes into account patients' perspectives. In support of this, there is empirical evidence to suggest that patients' perspectives of patient safety differ from that of healthcare professionals and researchers, for example Blendon et al (2002) telephone surveyed 1,207 members of the public in the US (a response rate of 67%) for their views of medical errors. In Blendon et al's study (2002), before being given the researchers' definition of the term "medical error", 68% of the respondents reported they did not know what the term meant. This is not to say that patients are unaware that they are exposed to risks during hospitalisation. For example, one of the specific objectives of a systematic review carried out by Guijarro et al (2010) was to attempt to answer the question 'Do patients feel safe in hospital?' Studies reported on showed that between 25% and 40% of patients reported having felt some degree of concern at some point in their hospital stay (Thomas et al 2000; Burroughs et al 2005; Evans et al 2006).

However, patients' perceptions of what constitutes patient safety often differs from that described by healthcare staff, researchers and policy makers. For example, in a study carried out by Burroughs et al (2007) which surveyed patients discharged from 12 Midwestern hospitals in the US to investigate their concerns about medical errors during hospitalisation, the authors' report that what patients' thought about patient safety and medical errors expanded beyond "traditional" clinical medical definitions. This includes communication, care coordination, responsiveness of staff, and how patients were treated "as people" (Burroughs et al 2007). This wider definition of patients' perspectives of patient safety is supported by the findings of a systematic review carried out by Guijarro et al (2010), in which one of the aims was to analyse and compare studies about patients' perceptions of

safety of care in hospitals. Guijarro et al (2010) reported on 18 studies published between 1989 and 2006 and found that patients' concepts of patient safety events were different to those of healthcare professionals, with patients' placing emphasis on the emotional consequences of adverse events, citing psychological trauma and social, labour and economic troubles as the most important. This was in contrast to the medical perspectives which focused on death, physical harm, readmission or delays to hospital discharge and extended hospital stays, which patients were usually unaware were related to patient safety, or were risk factors for adverse events (Guijarro et al 2010).

The findings of the review by Guijarro et al (2010) are further supported by a more recent relatively small scale qualitative study carried out by Rathert et al (2011) which explored acute care patients' perceptions of safety using focus group methods with 39 patients from US hospitals. Using an interpretative analytical approach to identify patients' experiences of safety in hospital care, Rathert et al (2011) conclude that overall, patients often interpreted quality lapses as safety incidents, focusing mostly on issues relating to processes of care and interpersonal dynamics with caregivers. Communication was also identified by the authors' as a prominent theme, with participants indicating that to feel safe they required open, timely and accurate communication from healthcare professionals (although patients reported that often this did not occur). Overall, care processes and continuity of care seemed to be the biggest concern to patients and there was consensus among respondents that there was rarely one healthcare professional who gave the impression of having a complete picture about an individual's care plan, which was particularly concerning to participants (Rathert et al 2011).

There is also evidence to suggest that patients' experiences of care are linked to their perceptions of quality and safety. Doyle et al (2013) undertook a systematic review to explore evidence of the links between patient experience and patient safety and effectiveness outcomes, drawing on research from 55 studies covering a wide range of settings within primary and secondary care. The authors' summary of evidence indicates consistent positive associations between patient experience, patient safety and clinical effectiveness for a wide range of clinical areas, conditions, outcome measures and study designs. Overall, Doyle et al (2013) conclude there is some evidence of positive associations

between patients' experiences and measure of technical quality of care and adverse events, and it was more common to find positive associations than no associations.

The studies reported here suggest that patients are in a position to judge the safety of their care, but also that patients tend to associate safety with the quality of the interactions that determine their care and these criteria may diverge from those of clinicians and researchers. For patients, the concept of risk is mostly associated with a loss of control and feelings of fear or threats, rather than the more technical and objective perceptions of healthcare professionals (Peters et al 2006). Although there is a dearth of studies in this area it is clear these differences between patients and clinicians have been known about for a while. While these studies give some insight into patients' safety concerns, currently no specific measures of organisational safety appear to exist that ask for the views of patients. An important conclusion from this section of the review is that healthcare professional should consider the subjective experience in alignment with the more objective work of measuring patient safety.

2.7 Summary of chapter

In this chapter we have seen that patient involvement can take place across a continuum, from what is defined as a 'passive' roles, which tends to involve the provision of information, to more 'active' and partnership type roles, in which there is an expectation that patients will enact a certain type of behaviour or activity in relation to their care. It has also been contended that patient involvement in patient safety can be viewed as part of general involvement in their direct care which is associated with activities relating to prevention, diagnosis and treatment, rather than isolated as a discrete activity, as patients are unlikely to separate safety issues from other issues relating to their care. An important factor that has been identified in relation to patient involvement is the feasibility of the expectations of the patient, where this activity fits into the clinical workflow, and what resource impact this may have on the healthcare organisation. We have also seen that patients' perceptions of safety in healthcare often differ from the views of healthcare professionals, researchers and policy makers, where patients tend to view communication and relationships as more important than the more 'technical' aspects of healthcare and safety and patients also cited the emotional consequences of adverse events. There was

also evidence that patients' made positive associations between good experiences and effective outcomes and patient safety. It was concluded that patients are in position to judge safety aspects of their care, but that their interpretation of safety often differs from clinicians and is often associated with quality of interactions. Healthcare workers should consider safety issues from patients' perspectives.

The review of the empirical literature has demonstrated that the role of healthcare professionals is crucial in any attempts to involve patients in patient safety and patients' value the approval and encouragement of healthcare workers in any attempts at involvement. Many patients would be willing to take a role in their safety if the context of their relationship with healthcare professionals providing their care was appropriate. There was evidence that some patients are reluctant to adopt any sort of active, safety role due to their deference to healthcare professionals. There was evidence that patients who develop long-term relationships with healthcare providers are more likely to become involved in efforts to improve their patient safety. We are also introduced to the notion of co-production of safety, through healthcare staff and patients working together, although paradoxically, this co-production seemed to rely on the healthcare workers to instigate any action in this regard and patients were more willing for attempts at co-production when they believed they had a 'relationship' with their healthcare professional(s). It was also noted that not all patients would want involvement in their safety or care and that healthcare workers should be alert to this and be able to judge the level of involvement each patient may want. We have also seen that the degree to which patients are involved in patient safety can be influenced to varying degrees by a variety of other factors which can be generally categorised into five broad themes, namely patient related, illness related and healthcare setting, and as discussed, healthcare professional related, and that there is often a complex interplay between these factors.

We have also seen that there are variety of ways in which patients' may be involved in patient safety during hospital care, and several frameworks have been developed in the literature which can be broadly summarised with the categories of 'informing the management plan', 'monitoring and ensuring safe treatment' and 'informing systems improvement'. In general, there is a consensus in the literature that there is a lack of theory

behind the reported attempts to involve patients' in patient safety and systematic reviews also report low quality evidence for attempts to involve patients in their safety. There are also reports of attempts to encourage patients to 'speak up' about safety in their care, including questioning and challenging healthcare professionals about hand hygiene practices, but it is evident these strategies rely on the cooperation of healthcare staff for their success, with patients more likely to involve themselves if they are encouraged and supported to do so by staff. Another strategy reported in the literature is providing patients with information about what they can do to improve their safety, but again there is an apparent lack of theory to support this and the evidence suggests that again, patients would need cooperative from healthcare workers in such strategies. Patients have also been encouraged to report safety incidents into organisational reporting systems, although the evidence for this appears equivocal, with some suggesting that considering patient safety from patients' perspectives may improve the success of this type of initiative. One notable finding from this review of the empirical evidence is that the studies tend not to have any underpinning programme theory, which provides further rationale for the use of realist evaluation in my study, which I will discuss in more detail in the next chapter.

Chapter 3: What is Enhanced Recovery after Surgery (ERAS)?

In this chapter I provide critical insight into an enhanced recovery after surgery programme (ERAS) and consider where this programme fits in the wider context of patient involvement in patient safety, with reference to the debates and policies I have presented thus far in this section. It should be noted that although an ERAS programme is multifaceted with a range of interventions for each stage of the patient journey, it is not within the remit of this thesis to explore all these elements. In keeping with the IOM definition of quality in healthcare, patient safety can be identified as just one element of an ERAS programme and, as discussed, this thesis seeks to explore the specific elements of ERAS that are designed to encourage patients to take a role in enhancing their own safety during their surgical care. In this chapter I focus on elements of the programme which relate patient involvement in patient safety, drawing on the Department of Health (England) and the NHS Wales ERAS policy documentation, along with the published ERAS Society recommendations (Gustafsson et al 2013), which present a consensus for optimal perioperative care in colonic surgery in relation to an ERAS programme.

Enhanced recovery after surgery (ERAS) is an evidence based approach to improving the quality of patient care after major surgery that consists of a selected number of individual interventions which demonstrate an improvement in patient outcomes when implemented together, rather than when implemented as isolated interventions (Department of Health 2010; NHS Wales 2010, 2011; Gustafsson et al 2013). This multi-modal care pathway is designed to achieve optimal recovery for patients' using what is commonly referred to as a 'care bundle' approach, which is defined by the Institute of Healthcare Improvement (IHI) as *"a small set of evidence-based interventions for a defined patient segment / population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually"* (Resar et al 2012).

The All Wales Enhanced Recovery after Surgery Programme was launched in 2010 in the University Health Board (UHB) under study in this thesis, supported by the national improvement programme in Wales at the time, 1000 Lives Plus (Barlow and Fairlie 2013). As part of the Programme NHS Wales, in conjunction with 1000 Lives Plus, developed,

published and disseminated ERAS ‘improvement guides’, referred to as ‘How to Guides’ (HTG) for elective colorectal surgery (NHS Wales 2010) and elective orthopaedic (total knee replacement) surgery (NHS Wales 2011). These guides were intended to reflect the latest developments and “*better practice*” in Wales at the time (1000 Lives Plus website) and each guide was developed from “*clinical evidence and is supported by consensus opinion from [...] experiences in the delivery of ERAS in Wales and elsewhere*” (NHS Wales 2010, p2; NHS Wales 2011, p2). The main aim of these HTGs is described as being to “*disseminate the knowledge gained from experience with ERAS thus far and to provide a primary resource to support the implementation of ERAS across Wales*” (NHS Wales 2010, p6; NHS Wales 2011, p6). I will draw on these guides as a primary source of evidence for my attempts to build the programme theory in relation to patient involvement in patient safety through an ERAS programme.

The HTGs describe the fundamental principles of ERAS as ensuring each patient is in the best possible condition for surgery and that each patients will have the best possible management before, during and after his or her operation (NHS Wales 2010, 2011). This will also require that each patient “*experiences the best possible rehabilitation, enabling early recovery and discharge from hospital*” (NHS Wales 2010, p9; NHS Wales 2011, p7). The HTGs go on to refer to ERAS as a “*patient centred method of optimising surgical outcome by improving both patient experience and clinical outcomes*” (NHS Wales 2010, p6; NHS Wales 2011, p5) and further elaborate on the underlying principles of ERAS thus:

“It means [...] reducing harm by reducing length of stay in hospitals, and reducing variation by making sure that all surgical patients everywhere receive the same high level of care and make faster recoveries as a result. By improving the quality in care, and reducing harm it is also assumed that hospital stay will become more efficient, thereby allowing hospital services to realise the benefits of the programme, through savings in bed days.”
(NHS Wales 2010, p6; NHS Wales 2011, p5).

This demonstrates the focus of ERAS to improve the quality of care to patients who undergo major surgery, whilst also highlighting that reductions in exposure to harm can be achieved

by reduced length of hospital stay. The desired outcomes of an ERAS programme are therefore positioned by policy makers as reducing patients' exposure to harm by reducing the length of hospital stay, which also results in an improvement in the efficiency of hospital based services. There is research evidence to support this claim, for example a meta-analysis of seven RCTs based on patients' (n=852) undergoing colorectal surgery as part of an ERAS programme concluded that length of stay and morbidity rates were reduced for patients on the programme, without compromising patient safety (Lv et al 2012). A further meta-analysis which reviewed 13 RCTs (1910 patients) that compared ERAS programmes with 'traditional' care in elective colorectal surgery concluded that ERAS programmes were associated with significantly decreased hospital stay (Zhuang et al 2013). The results of these studies can be seen as an indication of the positive impact of ERAS on patient safety, framing its main contribution as primarily being to reduce patients' exposure to potential adverse events by way of a reduced length of hospital stay.

From an efficiency perspective, a report evaluating the ERAS programme in Wales commissioned by NHS Wales and co-authored by the national lead for ERAS (Barlow and Fairlie 2013) declared it was initially anticipated the implementation of ERAS for colorectal patients in Wales would result in an estimated annual bed saving of 8,395 days across the county, based on a reduction in length of stay of 50%. However, the authors of the report state it is unclear whether this level of saving was achieved as, rather surprisingly, no pre-programme baseline measurements of average length of stay were taken in any of the units that implemented ERAS in Wales (Barlow and Fairlie 2013). In relation to the patient involvement dimensions of an ERAS programme, the HTGs state that the aspirations of the programme can be supported through what is referred to as a "*patient centred*" approach to care (NHS Wales 2011, p5). Patient centred care is an often used phrase in healthcare policy documentation and a formative definition of this concept was provided by the IOM in 2001: "*Health care that establishes a partnership among practitioners, patients and their families to ensure that [...] patients have the education and support they need to make decisions and participate in their own care*" (IOM 2001, p41).

The patient centred approach described in the ERAS HTGs (NHS Wales 2011, 2012) supports the notion that patient involvement is an aspiration of the programme in Wales and to

further support this, the Welsh Government (2012) has cited ERAS in its flagship policy document for quality in NHS Wales, as an example of how surgical care can be improved if patients are involved.

“The enhanced recovery after surgery programme is one example of how care can be dramatically improved through better user involvement in their own care [...] This should become the norm in our efforts to improve surgical care”

(NHS Wales 2012, p7).

The University Health Board under study has also made a clear public commitment to involving patients in their own care through the Chair’s ‘Statement of Intent’ at the inaugural board meeting in 2009, and at subsequent board meetings. This statement of intent includes a commitment to ensure that patients are *“involved meaningfully in their care and that their views are listened to”* (UHB Website, 2011). Of course, ERAS does not exist in isolation in the UHB under study, and is part of an overall programme of improvement aligned to the aforementioned NHS Wales Quality Plan (NHS Wales 2012). ERAS belongs to the surgical care element of this improvement plan, which also encompasses different work-streams, for example the WHO Checklist (WHO 2008) and, as Benning et al (2011) discuss, such quality improvement and patient safety programmes do not exist in a vacuum, but instead have porous boundaries which leave them open to the influence of a range of possible factors outside of the programme originators original intentions.

In this next section I will discuss four specific ERAS programme interventions relating to patient safety that are reliant on patient involvement for their success. These interventions are ‘prehabilitation’, ‘diet’, ‘discharge planning’ and ‘early and continuing postoperative mobilisation’, with each of these separate but interconnected interventions designed to help to meet the overall objectives of an ERAS programme in relation to reducing length of hospital stay and thus reducing patients’ exposure to avoidable harm.

3.1 Prehabilitation

“For patients to achieve the best results post-operatively it is vital that assessment and preparation of the patient [...] starts in Primary Care. This maximises the time that the intervention can benefit post-operative outcomes”

(NHS Wales 2010, p13; NHS Wales 2011, p10).

Preoperative optimisation or ‘prehabilitation’ is intended to help ensure that patients’ are in the best possible physical condition for surgery, thus facilitating recovery and reducing postoperative risks (Department of Health 2010; NHS Wales 2010, 2011; Gustafsson et al 2013). The ERAS HTGs recommend that clinicians should provide health improvement advice to patients during prehabilitation relating to weight loss, smoking cessation and optimisation of fitness (NSH Wales 2010, 2011). Diet is also an integral part of an ERAS programme and as part of the prehabilitation process patients should be encouraged by clinicians to eat a healthy diet to help build up for their operation (NHS Wales 2010). To achieve the best results from prehabilitation, it is recommended that these strategies are instigated in primary care.

In support of this particular ERAS intervention a primary care bundle was developed and discussed with the directors of primary care across Wales prior to the launch of ERAS, with the intention that this particular element be evaluated independently to determine the impact. However, it is reported by NHS Wales (Barlow and Fairlie 2013) that there is little evidence of active primary care engagement in Wales and the ERAS ‘Final Report’ goes on to remark that healthcare organisations in Wales are not routinely demonstrating a *“joined up and standardised approach to improving surgical care”* (Barlow and Fairlie 2013, p4). This being the case, the first opportunity for healthcare professionals to present patients with information about prehabilitation is at a pre-admission (pre-operative assessment) appointment in secondary care.

“This ‘optimisation’ continues in secondary care [...] the pre-operative assessment should [...] optimally prepare patients [...] the optimal time is considered to be 2-3 weeks between preoperative assessment and day of surgery. This allows adequate time to maximise the benefits of the intervention required”
(NHS Wales 2010, p17; NHS Wales 2011, p15).

3.2 Dietary advice: postoperative early oral nutrition

The ERAS Society guidelines strongly recommend patients should be encouraged to take ‘normal’ food as soon as possible after surgery (Gustafsson et al 2013) and echoing this, the HTGs refer to nutrition as an integral component of an ERAS programme (NHS Wales 2010, 2011). Specifically, the HTGs state that the goal is for patients to accomplish *“early oral and enteral nutrition within 12 hours of leaving the operation theatre”* (NHS Wales 2010, p29; NHS Wales 2011, p26). The advantages of this are described in national guidelines as enabling IV access to be removed, thus making it easier for patients to mobilise and have their urinary catheters removed, which are safety enhancing actions to reduce the risks of hospital acquired infection and thrombosis (Department of Health 2010; NHS Wales 2010, 2011). In addition to normal diets, oral nutritional supplements have been used successfully in ERAS programmes to help patients achieve the recommended intakes of energy and protein to support postoperative recovery (Gustafsson et al 2013) and the ERAS HTGs promote the use of these drinks for patients.

3.3 Discharge planning

The HTGs state that although discharge criteria may vary between hospital sites, in general it is expected that patients prior to discharge would be able to: tolerate diet and oral fluids; mobilise; open their bowels (or pass flatus) and; be confident and agree to go home (NHS Wales 2010, 2011). The HTGs also state that patients should be aware of the planned date for their discharge, if the surgery was *“uncomplicated”* (NHS Wales 2010, p33). It is recommended that patients’ share in the discharge decisions, as detailed in the ERAS HTG:

“Adherence to patient-focused discharge criteria shared with the patient prior to surgery should facilitate discharge [...] it is essential the patient shared in the decision for discharge and is only discharged when ready”

(NHS Wales 2010, p.33; NHS Wales 2011, p30).

3.4 Early and continuing postoperative mobilisation

Prolonged immobilisation following surgery increases the risk of adverse patient outcomes such as pneumonia, insulin resistance and muscle weakness and therefore mobilisation on postoperative days one to three is a factor significantly associated with successful ERAS outcomes and a reduction in adverse events (Gustafsson et al 2013). In support of this the ERAS HTGs (NHS Wales 2010, 2011) state that bed rest is not recommended for patients' postoperatively and describe how the programme attempts to achieve mobilisation within six hours of patients' leaving the operating theatre, if practical. This mobilisation is much earlier than that associated with 'traditional' surgical care can promote gut function and is also linked to a reduction in adverse events such as chest infections and deep vein thrombosis (DVT), which are a cause of morbidity after major surgery (DH 2010; NHS Wales 2010, 2011; Gustafsson et al 2013). ERAS guidelines note that a patient's inability to achieve early postoperative mobilisation can be due to inadequate control of pain (Gustafsson et al 2013) and so the ERAS HTGs emphasise the importance of effective analgesia for patients taking part in an ERAS programme (NHS Wales 2010, 2011). (It should be noted that other interventions designed to reduce the risk of postoperative DVT are also associated with an ERAS programme in the form of pharmacological prophylaxis, usually with low-molecular-weight-heparin and mechanical prophylaxis in the form of compression stockings (NHS Wales 2010, 2011; Gustafsson et al 2013)).

3.5 ERAS and patient involvement in patient safety

The conceptual analysis of patient involvement presented in the literature review chapter has demonstrated the array of roles patients may take in healthcare and shows that any patient involvement in patient safety will take place on a continuum, depending on a variety

of circumstances relating to, for example, each individual patient and healthcare worker. In this respect, patient involvement in patient safety through an ERAS programme can be seen as an aspect of patient involvement in healthcare delivery at the direct level of care. This is in relation to behaviours and activities aligned to the prevention of adverse events and also aspects of patients' treatment and care pathway. As described with the specific ERAS interventions I have highlighted, this can be through involving patients in certain aspects of self-care and self-monitoring which, in relation to patient safety, can also take the form of monitoring and ensuring safe delivery of treatment by helping to ensure treatment is given as planned and according to the appropriate care protocol.

Patient involvement in patient safety through an ERAS programme can also be viewed in the context of the continuum of involvement described by Carman et al (2013), with patients' receiving information about what actions they can take to reduce their risks in hospital, and making decisions about this information in respect of managing their own health and postoperative recovery, and communicating with healthcare professionals and understanding the risks and benefits associated with their expected actions. (Of course, there are important aspects of this information which should be delivered in primary care, but as discussed these particular interventions were not taking place at the time of this study.)

The expectations of patients enrolled on an ERAS programme can also be related to the work of Grande et al (2014), in which they propose a model where the focus is on involving patients' in the clinical workflow in direct care. They conclude that those methods which have a good fit with existing workflows and required little additional human resources and that required proportional amounts of work by patients are likely to be most feasible in terms of achieving patient involvement (Grande et al 2014), which is a reasonable assessment of how an ERAS programme operates within the healthcare systems under study. Their conceptualisation of 'Information + activation' describes methods which target patient involvement through encouraging, prompting, help and support to perform specific behaviours in the clinical encounter. This approach would seem to lend itself to the particular interventions I have described relating to ERAS. Patient involvement elements of ERAS also appear to represent an attempt to encourage a form of 'co-production' between

patients and clinicians, with clinicians' expertise guiding the patient experience to help improve patient safety. In this sense, an enhanced recovery programme tackles what can be realistically expected for many patients to do in relation to their own care, whilst avoiding a complete shift of responsibility onto patients, although ERAS does encourage patients to take responsibility for their own health and wellbeing during their healthcare journey.

ERAS provides patients with an opportunity for some degree of involvement with their own healthcare services at a direct-care level. As always, the patient experience will be influenced by the quality of interactions between themselves and the clinicians who deliver the direct care in the NHS. In this respect, healthcare workers have an important role to play in an ERAS programme as they will be responsible for delivering the relevant information to patients and supporting and encouraging patients during their attempts at involvement in elements of ERAS. And, of course, it is essential that patients' willingness and ability to take part in these elements is explored and considered and there are a variety of factors which can influence this, including the varied characteristics of each patient such as their physical state and wellness. It is also of relevance what type of task or activity patients are expected to carry out. Patients' are also more likely to become involved in their care if the context and nature of their relationship with the healthcare professionals is appropriate for this and that the necessary support is provided to patients.

It has also been demonstrated through the literature review that patient involvement in patient safety related activities is more likely if patients receive direct instructions to do so from a clinician. In this sense, an ERAS programme is designed to alert patients to certain aspects of their care in which they are exposed to risks, although, as discussed, it is often the quality of the interaction with healthcare providers that is most important to patients. Overall, this chapter demonstrates there are patient safety elements within an ERAS programme and in terms of patient involvement, ERAS is focused on the level of direct care with individual patients.

Conclusion to Part I of the thesis

In conclusion to part one of my thesis, 'background', I have considered the policy context in relation to patient involvement in patient safety and also engaged with the empirical literature for wider patient involvement and involvement in patient safety. I have presented an overview of the problem of patient safety and why patient involvement in this is deemed appropriate and necessary. I have considered the factors which affect patients' willingness and ability for involvement in their safety and also presented literature relating to the various roles patients may take to achieve this involvement. I have also introduced the ERAS programme and consider this programme in the context of my research aims and the policy and literature debates and discussions. I now move on to Part two of this thesis, in which I provide details about my study.

Part II: The study

This part of the thesis is comprised of two chapters: In chapter four I provide a methodological description of the research design and the methods used, to provide a clear audit trail of what I have done and why. In chapter five I consider the different approaches taken by each of the three studies in relation to the implementation of an ERAS programme and also consider the processes undertaken and resources engaged in attempts to establish and sustain the operation of ERAS in the respective clinical areas. It was clear that these factors were influential on the subsequent attempts to involve patients in patient safety in the three case studies.

Chapter 4: The Research Methods and Methodology

This chapter provides a methodological discussion, description of the research design and the methods used. It is my intention to provide a clear audit trail of what I have done and why, how data were generated, in what way this data related to the research aims and how I analysed these data.

The broad aim of this study is to explore the extent to which patients are involved in attempts to improve their own healthcare safety through enrolment in an enhanced recovery after surgery (ERAS) programme. Recognising that patient safety is just one aspect of the ERAS programme theory, this research evaluates those elements of the programme that see patients taking a role in their own healthcare safety. This is achieved by considering in realist terms the mechanisms of effect by which patients might contribute to their healthcare safety and investigating the conditions and circumstances (contexts) that are required to enable this involvement.

The overall aim of this research is to seek out regularities in the patterns of these contexts and mechanisms which result in patient involvement in patient safety. The emerging theory will explain implementation variations, and the experiences of the programme participants in the different cases will provide an opportunity to make comparisons with initial programme theories, the objective being to better understand when and why patient involvement in patient safety works in an ERAS programme.

4.1 What is realist evaluation?

The theoretical framework guiding this research was realist evaluation which helps to explore what it is about an intervention that works, for who, in what circumstances and why (Pawson and Tilley 1997). The review of the literature supported my decision to adopt realist evaluation as a methodological approach as it was apparent there were a complex array of intertwined factors that could influence any attempts to involve patients in their healthcare safety and very little theoretical underpinning to the approaches designed to encourage patient involvement in safety. The theory-led nature of realist evaluation suited

my aims as I was interested in identifying the rationale of those ERAS programme interventions which were intended to involve patients in improving their safety during their healthcare.

'Realistic evaluation' rose to prominence following the publication of the eponymous book (Pawson and Tilley 1997), although it has since become more commonly known as 'realist evaluation'. The authors' of this book, Ray Pawson and Nick Tilley, had spent several years in the research fields of policing and prisons prior to publication and Tilley's first realist evaluation looked at close circuit television (CCTV) in car parks as a measure to try to reduce car crime (Tilley 1993). In this publication he demonstrated that research into CCTV is effectively blind without a theory of why CCTV might be effective and a theory of the conditions that promote this potential (Tilley 1993). The realist evaluation approach subsequently gained prominence in health services research largely due to the NHS Service and Delivery (SDO) report 'How to Spread Good Ideas' (Greenhalgh et al 2004) in which the authors' recommended a realist evaluation approach to whole systems research, encouraging the use of such theory driven research with a focus on identifying contextual factors that may affect programme implementation and outcomes. The years since the publication of Realistic Evaluation (Pawson and Tilley 1997) have seen more than one hundred papers published purporting to be realist evaluations, or a variation on this method, including prominent studies such as the realist evaluation of a whole-scale multi-million pound NHS moderation programme (Greenhalgh et al 2009).

Pawson and Tilley (1997) provide a set of realist evaluation principles, rather than methodological rules or steps to follow, reflecting that realist evaluation is about a logic of inquiry, not a set of prescriptions of how to do a study of this kind (Rycroft-Malone et al 2010). A logic of inquiry describes the practices that researchers use when they move from a research design to data generation, and also connects the research to specific methods of analysing the data generated (Denzin and Lincoln 2005). It has also been stressed that realist evaluation is a general research strategy, rather than a strict technical procedure (Pawson and Tilley 1997; Pawson 2013) and that innovation in realist research design will be required to tackle a widening array of policies and programmes (Pawson 2006; Pawson 2013).

Different contextual constraints can exist for programmes and the interrelationships, institutions and structures in which the programme is embedded will have a strong shaping influence. A realist approach to analysing patient involvement within a service delivery innovation programme such as ERAS seeks to provide a detailed description and explanation for the success or otherwise of programmes interventions in these different contexts (Pawson and Tilley 1997; Pawson 2006). Realist evaluation is based on a generative theory of causation which moves beyond merely associating interventions and outcomes to question how the outcomes came about. Realist evaluation is also theory driven, wherein the elicited theories behind the programme are examined by the researcher.

The intention of my research was to identify the various programme interventions by which patients enrolled on an ERAS programme might contribute to their safety, the conditions under which these contributions are likely to be successful and an examination of the extent to which those conditions are filled in particular contexts (Pawson and Tilley 1997; Pawson 2006). In this sense, the analytical challenge of my research was not only to determine whether patient involvement has 'worked' or not, but also to find out how attempts at patient involvement are shaped, enabled and constrained by interaction between the context of the programme and the identified mechanisms of change (Greenhalgh et al 2009). Using realist evaluation therefore can help to draw useful lessons about how particular preconditions make particular outcomes more likely, even though it cannot produce predictive guidance or a simple recipe for success (Greenhalgh et al 2009). To provide some background to realist evaluation approach I will firstly provide some insight into important concepts in relation to this approach to research, namely 'realism', 'contexts' and 'mechanisms'.

4.2 What is realism?

Realism is a broad logic of inquiry that is grounded in the philosophy of science and social science (Bhaskar 2005). What makes a body of work realist is a common understanding of some basic building blocks of social science, such as the nature of causation, the constitution of the social world and the stratification of social reality (Pawson 2006). Realism stands behind the generative theory of causation and its distinctive feature is to

look for causal powers within the objects, agents or structures under investigation (Pawson 2006). Whilst positivist accounts of scientific explanation enable us to predict the occurrence of particular events, they do not necessarily tell us why that event did or will occur (Keat and Urry 1982) but for realists, causation is not understood on the model of the regular success of events (Sayer 2000; Pawson 2006). Instead, generative theory holds that there is a real connection between events which we understand to be connected causally - one happening may well trigger another, but only if it is in the right conditions in the right circumstances (Pawson and Tilley 1997).

Policy makers and practitioners develop programmes for implementation into practice areas, often with the assumption that these work as they are evidence based and appeal to common sense. So, for example, in the case of ERAS there is an assumption from the programme authors' / developers that simply delivering patient education and information to patients at a pre-admission stage of their healthcare journey will ensure that all patients are equipped with the required knowledge at their time of admission. Realists do not conceive that programmes 'work' in this way, rather it is the action of stakeholders that makes them work, and the causal potential of an initiative takes the form of providing reasons and resources to enable programme participants to change. The capacity for change is only triggered in conducive circumstances and the researcher needs to gain an understanding of the conditions required for the programmes' causal potential to be released and whether this has been released in practice and this is the fundamental basis for realist evaluation (Pawson and Tilley 1997).

Realism refers to the embeddedness of all human actors within a wider range of social processes as the stratified nature of social reality (Sayer 1992). Based on this, actions only make sense because they contain in-built assumptions about a wider set of social rules and institutions which means that causal powers reside not in particular objects or individuals but in the social relations and organisational structures which they form. One action leads to another because of their accepted place in the whole, so, whatever the intervention, it can only work as intended if the subjects go along with the programme theory, so in abstract terms one can say that programmes work only if people choose to make them work (Pawson and Tilley 1997; Pawson 2006). That interventions are theories is the most

fundamental realist claim about them in the sense that interventions should be based on a hypothesis that postulates 'If we deliver a programme in this way, then it will bring about some improved outcome' and these interventions are always inserted into existing social systems (Pawson and Tilley 1997). It is supposed that from this changes in patterns of behaviour, events or conditions are then generated by bringing fresh inputs to that system (Pawson 2006). A particular programme intervention will only 'work' if the contextual conditions into which it is inserted are conducive to its operation and what the realist evaluator needs to find out is what it is about a programme that makes it work (Pawson and Tilley 1997). To help clarify how the realist approach works in practice, I shall explain the concepts of mechanism and context in more detail and how they relate to this research project.

4.3 What are Mechanisms?

Mechanisms are what Pawson (2006) refers to as the engines of explanation in realist evaluation and identifying these mechanisms involves an attempt to investigate how a programme actually tries to change behaviour. It is through the notion of programme mechanisms that the researchers can take the step from asking whether a programme works, to understanding what it is about a programme which makes things happen (Pawson and Tilley 1997; Pawson 2006). Identifying the mechanisms associated with patient involvement in patient safety through an ERAS programme involved developing propositions about what it is within the programme which triggers a reaction from its subjects; in this sense, a mechanism is a theory which spells out the potential of human resources and reasoning (Pawson and Tilley 1997). It became clear to me through analysis of the ERAS policy documents and guidelines that this particular programme presents several potential mechanisms for patient involvement in patient safety. Based on this analysis I assembled a range of these potential mechanisms, for example encouraging patients to take part in early and continuing postoperative mobilisation to reduce the risk of adverse events such as chest infection and deep vein thrombosis.

4.4 What do I mean by Context?

Programmes such as ERAS are always introduced into pre-existing social contexts and the interrelationships of the institutions and structures into which the ERAS programme is embedded will have a shaping influence (Pawson and Tilley 1997; Pawson 2006). Just as programmes involve multiple mechanisms, they will characteristically also exist within multiple contexts and the operation of the programme mechanisms is always contingent on these contexts; subjects will only act upon the resources and choices offered by a programme if they are in conducive settings and therefore the success of such programmes are influenced by these prevailing contextual conditions (Pawson and Tilley 1997; Pawson 2006; Pawson 2013). It should be noted that context does not refer simply to the geographical or institutional location into which programmes are introduced, it is also the prior set of social rules, norms, values and interrelationships gathered in these places which can influence the efficacy of programme mechanisms (Pawson and Tilley 1997).

A standard requirement of realist evaluation is to take heed of this context, and in the case of programmes such as ERAS this means unravelling the different layers of social reality that make up and surround them (Pawson 2006). In general, realist evaluation recognises the shaping influence of at least four contextual layers which Pawson refers to as “the four I’s”: The individual capacities of the key actors; the interpersonal relationships supporting the intervention; the institutional setting; the wider infra-structural system (Pawson 2006; Pawson 2013). I needed to understand the contexts in which the programme mechanisms I had identified as attempts to involve patients in patient safety could be successfully ‘fired’ – that is, what conditions are necessary to achieve the desired effects (in line with the realist principle of generative causation). My initial consideration of the potential contexts for this study from ERAS was based on related policy documents and guidelines and the academic literature on patient involvement.

A realist evaluation requires that the researcher brings together the identified contexts and mechanisms in Context-Mechanism-Outcomes (CMO) configurations. These are firstly ‘conjectured’ CMOs, which are then tested and further refined using empirical data which will identify the conducive conditions for the effectiveness of these CMOs.

4.4.1 The application of realist evaluation in health services research

To recap, the principles of realist evaluation methodology conceptualise interventions as social systems which comprise the interplay of human and non-human actors, agency and structure and micro, macro and meso processes. This is underpinned by a generative theory of causation concerned with the interplay between contexts, mechanisms and outcomes. The overall aim of realist evaluation is not to identify variables which associate with one another, but rather to explain how the association came about (Allen et al 2010).

Studies framed as realist evaluation appear to be increasing rapidly across a wide array of domains and although the body of literature is relatively young and small, realist evaluation has been applied in a variety of fields within healthcare research (Jagosh et al 2016). Commentators have identified that recent developments and use of realist evaluation in health-related research are particularly notable (Jagosh et al 2016; Williams et al 2016) and that this body of work covers a wide range of healthcare interventions including clinical practice, healthcare management and the evaluation of health programmes and policies (Marchal et al 2012). This includes realist evaluation of healthcare interventions aimed at individual patient / practitioner behaviours (Fairhurst et al 2005; Tolson et al 2007; Rycroft-Malone et al 2010). There have also been realist evaluations of large scale programmes of health service change (Evans and Killoran 2000; Greenhalgh et al 2009) and realist evaluations of local level changes to health care delivery (Byng et al 2005; Marchal et al 2010; Manzano-Santaella 2011; Wand et al 2011).

This literature is clearly developing into a broad body of work and along with those examples already cited there have also been realist evaluation studies published relating to breastfeeding support groups (Hoddinott et al 2010), the role of communities in practice in changing healthcare (Ranmuthugala et al 2011) and the impact of robotic surgery on team working and decision making in the operating theatre (Randall et al 2014).

4.4.2 Inherent strengths of realist evaluation in health services research

4.4.2.1 Tackling complexity

Many of the problems facing today's healthcare researchers are complex and one of the main strengths of realist evaluation is its suitability to investigating the complexity associated with contemporary healthcare services and systems. As Greenhalgh et al (2015) comment, the interventions and programmes associated with the health needs of today's society are themselves complex, with multiple, interconnected components which are either delivered individually or targeted at communities or populations. The success of these interventions and programmes depends on the response of individuals and the wider contexts in which these interactions take place (Greenhalgh et al 2015; Wong et al 2015). Evaluating these types of complex interventions is challenging as they require complex delivery programmes with multiple, intertwined components that engage with the particulars of contexts; what works in hospital A, or community A, may not work in hospital B or community B (Greenhalgh et al 2015).

Quasi-experimental research designs are most often associated with effectiveness studies, where analytical techniques such as linear regression and cluster analysis to help the researcher isolate the effect of each variable on outcomes (Marchal et al 2012). Randomised control trials that make comparisons between intervention 'on' and intervention 'off' may also produce statistically accurate findings, but fail to provide detail on where resources should be targeted to maximise impact (Greenhalgh et al 2015). So, although these types of research designs are very useful in assessing the effectiveness of healthcare interventions, they fail to provide the information required for complex and dynamic systems such as healthcare (Marchal et al 2012). The results of these types of studies do not identify in which conditions and through which configurations an outcome is achieved and this has limited the ability to provide context-sensitive solutions, with these limitations recognised in healthcare research for some time (Marchal et al 2012). The increased use of realist evaluation in the assessment and evaluation of healthcare services has been linked to the realisation by researchers and commissioners that coming up with solutions to these

problems is challenging and will require more insight into the nature of programmes and their implementation contexts (Wong et al 2015).

The issues faced by healthcare providers and commissioners have multiple causes operating at individual, interpersonal, institutional and infrastructural levels and the interventions or programmes designed to tackle these problems are also complex with multiple, interconnected components (Wong et al 2015). An effective evaluation needs to be able to consider how, why, for who and in what context these complex interventions work. Realist evaluation can help in addressing these challenges as this approach focuses on explaining what is working under specific conditions, recognising the complex nature of these programmes (Wong et al 2015; Williams et al 2016).

Ontologically, realist evaluation has implications for causality and explanation in research as, unlike the more conventional approaches that attempt to isolate systems from any extraneous influence in order to identify causal relationships, realist evaluation attempts to account for the interaction of the various causal tendencies within complex social systems such as healthcare (Kazi 2003). Therefore, the realist evaluation approach is well suited for examining multiple components of an intervention or programme individually to help understand who and why a programme works. In this sense, realist evaluation has potential for unpacking the 'black box' of the increasing range of complex interventions being used in healthcare (Greenhalgh et al 2015).

As mentioned, recently there have been several topics in health services research which have been investigated using a realist evaluation approach, with researchers support the claim that this approach is well suited to investigating complexity (Byng et al 2008; Pommier et al 2010; Wand et al 2010; Maluka et al 2011 and Manzano-Santaella 2011). Additionally, other researchers have commented on the utility of realist evaluation when investigating complex-causal pathways (Rycroft-Malone et al 2010). Other researchers have reported that realist evaluation also provides a sound framework to examine how context and mechanism influence the outcomes of healthcare programmes or interventions (Clark et al 2005; Tolson et al 2007; Greenhalgh et al 2009).

4.4.2.2 Explanatory Theory

Rycroft-Malone et al (2010) comment that there has been a lack of attention to theory in implementation research, with theory use to date relying mainly on a positivist approach, whereas there have been fewer examples of an interpretivist approach. Another perceived strength of the realist evaluation approach is that has potential for developing explanatory theory which shifts the unit of analysis from programmes to programme theories, thus eliminating the notion of programmes or interventions as treatments or dosages which have effects that can be averaged (Pawson 2006). The main aim of developing programme theory is to refine understanding of how and why interventions operate through the development of a more nuanced explanation – that is, the implicit or explicit hypotheses about anticipated outcomes on which interventions are based (Herepath et al 2015). As Rycroft-Malone et al (2010) explain, the researcher engages with theory at the start of the evaluation process by developing conjectured CMO configurations and these CMOs are the theories that are tested and refined throughout the evaluation process. There is also potential to develop middle range theory about why some interventions or approaches may work, not in an x causes y fashion, but as generative causation between the constituent parts of the theory through use of the CMO configurations (Rycroft-Malone et al 2010).

4.4.2.3 Outcome patterns

Programmes fire multiple mechanisms, having different effects on different participants, thus producing multiple outcomes. In order to understand causal connections, the realist researcher will need to examine and understand these outcome patterns, rather than seek out regularities (Pawson and Tilley 1997). As Pawson (2006) explains, it is the totality of these outcomes that will act as an initial empirical guide for optimal future locations for programmes. Realist evaluation does not provide a pass or fail verdict, rather the underlying rationale for the approach is that if we know and understand how different intervention or programmes produce variations in impact, depending on circumstances, we will be better able to support decisions about what healthcare policies and services to implement and in what conditions (Allen et al 2010). This focus on generative mechanisms provides an insight to health service design which is responsive to local operating conditions and constraints,

rather than adopting a one size fits all approach (Allen et al 2010). Whilst this means that programmes cannot simply be replicated from one context to another and automatically achieve the same results, the theory-based understandings about 'what works for who in what circumstances and why' are transferrable (Greenhalgh et al 2015).

This said, there is recognition that there is a limit on what realist evaluation can deliver. As Pawson (2006) comments, the researcher will never be able to completely grasp the totality of constraints of effectiveness of programmes or interventions, nor can the researcher anticipate the circumstances in which any subsequent scheme might be implemented. What realist researchers can provide is an account of the workings of a complex intervention and a better understanding of how theory might be improved (Pawson 2006). Pragmatically, the best evaluators, and subsequently policy makers, can hope for is partial and conditional explanations of programmes or interventions, but often this evidence is strong enough to support policy action (Astbury 2013).

4.4.2.4 Cycles of evaluation

It is often impossible to attend to everything in a single evaluation and Pawson and Tilley (1997) explain that realist evaluation is conventional in the sense that it utilises the 'research cycle' of hypothesis testing and refinement on an ongoing basis. The process, as Pawson and Tilley (1997) see it, realist evaluation is intended to be an ever repeating cycle, with further analysis on the same programme within the same evaluation, or by addressing the same theories in other evaluations of the same family of programmes. Pawson has repeatedly urged evaluators to avoid starting their inquiry from scratch and build on what is already known (Pawson and Tilley 1997; Pawson 2001; 2006; 2013).

This approach is acknowledged as a strength by some of those who have undertaken realist evaluations, with Tolson and Schofield (2012) stating that they see a strength of this approach lying in the generation of an evidence base which can lead to the accumulation of insights into what makes a programme work, and what can be done to improve outcomes in different contexts. Pawson and Tilley agree that replication is inappropriate for evaluating complex interventions as, given that realist evaluation focuses on uncovering the

relationship between context and mechanism, exact replications are unlikely to be achieved. As Rycroft-Malone et al (2010) comment, the idea of culmination is offered by Pawson and Tilley as a way of building ideas and insights across cases to enable theory development, rather than attempts at empirical generalisation.

From a practical point of view, examples in the literature show that the cycle of data collection is commonly confined to one cycle. For example, Rycroft-Malone et al (2013) reported that due to the availability of resources, the testing of their conjectured CMOs ended after only one examination and lament the fact that further cycles may have provided the research team with the opportunity to resolve some of the challenges experienced during the original cycle. Tolson and Schofield (2012) also recognised that further testing and refinement was required for their own realist evaluation study, but report that this was not achieved. They comment that their attempts to inform ongoing refinement of their findings was made difficult by the fact that project leads were more focused on expediting the completion of the evaluation, than on achieving a responsive iterative process. Tolson and Schofield (2012) put this down to naivety on their part that they thought they would be able to complete several rounds of evaluation. However, according to Astbury (2013), there are often such challenges to any attempts to carry out a long term, cumulative approach to evaluation. He goes on to comment that institutional arrangements make it difficult for researchers to conduct these types of studies in an arena which is largely governed by market demands and contractual obligations and where evaluation agendas are driven by sponsors who want specific answers about their particular programme (Astbury 2013).

4.4.3 Methodological Challenges for Realist Evaluation

Realist evaluation is an increasingly popular methodological approach to health services research and as Greenhalgh et al (2015) point out, as with all primary research approaches, guidance on quality assurance and uniform reporting is an important step in ensuring consistency of quality for realist evaluation studies. However, Greenhalgh and her colleagues express a note of caution in respect to the quality of realist evaluations to date. They note a number of common challenges facing those engaging with realist evaluation,

either as researchers, reviewers, or awarding bodies. The focus on this is on how to judge the quality of a realist evaluation (or proposal for such), including credibility and robustness of findings, along with how to undertake realist evaluations (Greenhalgh et al 2015). This is supported by Astbury (2013) who notes that many studies that are branded realist evaluation fail to consistently adhere to the cored principles of the approach, and Pawson (2013) comments that realist evaluation is sometimes used as an expedient methodological label.

Two recent reviews of studies purporting to be realist evaluations support these claims, demonstrating that some of these studies were not appropriately applying the concepts of realist evaluation, which had resulted in misleading findings and recommendations (Greenhalgh et al 2015). The first of these reviews was undertaken by Marchal et al (2012) who present a literature review with the overall aim of mapping how the concepts of realist evaluation are applied in health services research and identifying the methodological problems encountered in practice. Marchal et al (2012) identified 18 realist evaluations for their review and highlight the considerable diversity in the way in which the principles of realist evaluation were applied. They report a range of challenges that arose for researchers, with lack of methodological guidance a recurring issue, for example Byng et al (2008) and Rycroft-Malone et al (2010).

Pawson and Manzano-Santaella (2012) published a paper entitled 'A realist diagnostic workshop' to present what they considered flawed examples of realist evaluations, highlighting common errors in such studies. In alignment with Marchal et al (2012) they also point out that more guidance is needed for those who adopt realist evaluation as a methodological approach to alleviate misunderstandings about the purpose, concepts and processes associated with realist evaluation (Pawson and Manzano-Santaella 2012). As Rycroft-Malone et al (2010) have observed, Pawson and Tilley (1997) made clear they are resistant to the idea of laying down fixed rules of realist evaluation and stress that methodological progress will only be made if realist evaluations are tried out in practice. They also comment that whilst this affords the researcher an amount of flexibility, it can also feel like being part of a natural experiment (Rycroft-Malone et al 2010).

The literature shows that there are certain methodological and conceptual issues that have consistently challenged researchers who have chosen to undertake realist evaluations, including confusion about the precise meaning of realist concepts. These are concentrated on the conceptualisation and identification of mechanisms and contexts; the relationship between context, mechanism and outcomes; the use of theory; the role of interventions; and the philosophical basis of realism and realist evaluation (Marchal et al 2012; Pawson and Manzano-Santaella 2012; Astbury 2013; Herepath et al 2015; Greenhalgh et al 2015). As noted by Greenhalgh et al (2015), these are important issues to consider as where misunderstandings occur in relation to the methodology, rigour of the realist evaluation undertaken can often suffer. Limited conceptualisation of the key realist terms context and mechanism can also inhibit rigorous analysis of their boundaries (Herepath et al 2015). In light of these issues, I will consider each of these in turn, starting with mechanisms.

4.4.3.1 Mechanisms

Mechanisms present a particular challenge in realist evaluation. There is a lack of explanatory focus in the literature on mechanisms of change and the question of what constitutes a mechanism remains a challenge to realist evaluators, with different researchers conceptualising mechanism differently (Marchal et al 2012). Along with this, researchers have reported that identification of the mechanism is an evaluation process is not easy (Williams et al 2013) and Greenhalgh et al (2009) describe how they found identifying mechanisms in different activities in a large-scale modernisation effort far more difficult than is implied by Pawson and Tilley (1997). Barnes et al (2003) and Ranmuthugala et al (2011) also report difficulty in identifying mechanisms during their realist evaluations and describe contestation between researchers in their respective teams in regard to this, which required lengthy discussions and iterations.

Dalkin et al (2015) refer back to the influential work of Pawson and Tilley (1997), commenting that although these authors' made a distinction between resources and reasoning, the relative importance in understanding mechanisms as part of a realist evaluation is often understated. A consequence of this is that researchers often emphasise one at the expense of the other, under the banner of mechanism (Pawson and Manzano-

Santaella 2012). Further to this, Marchal et al (2012) report that some authors do adhere to the Pawson and Tilley (1997) definition of a mechanism being an account of the behaviour and interrelationships of the processes that are responsible for change – a theory. However, further scrutiny of the literature shows variations to this approach. For example, Evans and Killoran (2000) defined mechanisms as including interventions, whilst Greenhalgh et al (2009) define mechanisms as the stakeholders' ideas about how change can be achieved, where the mechanisms they found includes descriptions of the actual intervention. Marchal et al (2012) report that this was also the case with Tolson et al (2007) and Maluka et al (2011), although Tolson et al (2007) appeared to conflate activities and modes of implementation with mechanisms.

A tentative conclusion reached by Greenhalgh and colleagues following their evaluation of a large-scale modernisation project was that researchers should anticipate and learn to tolerate the inconsistencies between the assumption that a set of more or less well-defined mechanisms can be articulated and tested, versus the empirical reality in which these mechanisms may prove far more challenging to identify and articulate (Greenhalgh et al 2015).

4.4.3.2 Contexts

The relationship of identified mechanisms to the context of their implementation is key to a realist evaluation of complex healthcare programmes or interventions (Greenhalgh et al 2009; Dalkin et al 2015). As noted by Herepath et al (2015) there has been a lack of consistency in realist evaluations to date in agreeing on how context should be conceptualised and what elements of context are most important.

Further to the challenges associate with identifying mechanisms, the issues relating to the conceptualisation of context appear to be predominately related to distinguishing mechanism from context in a realist evaluation. Dalkin et al (2015) describe these attempts to distinguish which aspects within an intervention implementation process contribute mechanistically and contextually to the overall explanatory attempts as the realist researcher's quandary. In support of this statement, Tolson and Schofield (2012) report this

as being problematic during their study, with Byng and Redfern (2005) commenting that the ambiguity in attempting to make this distinction caused them problems when attempt to depict their CMO configurations. Dalkin et al (2015) also encountered this challenge during the course of their attempts to evaluate an integrated care pathway, as did Rycroft-Malone et al (2010), who also remark that further testing and refinement over additional cycles of data collection may have helped their attempts to resolve the challenges faced in identifying between mechanism and context.

4.4.3.3 CMO configurations

Further to the issues associated with identifying contexts and mechanisms, researchers have also described difficulties in disentangling the relationship between contexts, mechanisms and outcomes (Astbury 2013). For example, as part of their 'realistic diagnostic workshop' Pawson and Manzano-Santaella (2012) observed how some realist evaluations had produced detailed lists of contexts, mechanisms and outcomes, but had failed to produce any coherent explanation of the relationship between these elements.

Byng and Redfern (2005) describe how there are many potential ways of constructing these CMOs, with a multiplicity of contexts and mechanisms potentially involved in bringing about an outcome. They report their experiences of this as being very different from the diagrams dominant in the Pawson and Tilley (1997) text. As Astbury (2013) states, there are potential risks in adhering strictly to the CMO formula as this can be misread as implying that the relationship between the different elements is easy to identify, simple and linear. Dalkin et al (2015) caution that oversimplification of this approach can discourage efforts to identify more complex, multi-mechanisms interactions and linked chains and hierarchies of CMO configurations. Dalkin et al (2015) also note how it is not always a straightforward process to map the complexities of a healthcare intervention and the multiple systems within which it operates onto the CMO formula.

4.4.3.4 Programme theory / interventions

The most fundamental realist claim about interventions is that they are theories (Pawson 2006). A realist perspective sees interventions as being based on a hypothesis that if a programme is delivered in such a way, it will bring about some improved outcome – the intervention is introduced into a social system (such as healthcare), with a view to bringing about improvements in patterns of behaviour, events or conditions (Pawson 2006). In this sense, realist evaluation is designed to use theoretical explanations to make sense of the observed data (Greenhalgh et al 2015). This type of theory-driven inquiry presents a number of challenges for researchers, a significant one being that in some cases there may be little (or no) theory that applies to the programme or intervention under study (Marchal et al 2012). Astbury (2013) also comments on the inadequate specification of CMO hypotheses and in support of this Pawson and Manzano-Santaella (2012) call for a greater emphasis from researchers to elucidate the programme theory and express this as CMO configurations, describing what a programme or intervention is expected to do and, in some cases, how it is expected to work. Astbury (2013) also comments that the CMO table has a tendency to obscure the programme, hence causing confusion between mechanisms and programme mechanisms, a point reiterated by Dalkin et al (2015) who also note they were alert to conflating the mechanism with programme interventions.

Herepath et al (2015) argued that previous realist inquiries have applied the concept of intervention inconsistently, claiming it is regularly underspecified and often conflated with context. To address this problem in their study Herepath et al (2015) treated intervention as a separate analytical category. In their realist analysis of hospital patient safety in Wales, Herepath and her colleagues (2015) explicitly defined the intervention 'I' and added this to Pawson and Tilley's (1997) original CMO formula to produce intervention-context-mechanism-agency-outcome (I-CMAO) configurations. They report that this supported their understanding of precisely 'what' is working in a situated context, for who, and how (Herepath et al 2015).

4.4.3.5 Philosophical basis of realist evaluation

Realist evaluation is based on a realist philosophy of science which informs its underlying methodological assumptions and consideration of quality (Greenhalgh et al 2015). However, there is criticism in the literature that sufficient attention is not always paid to these philosophical roots by realist researchers (Marchal et al 2012; Greenhalgh et al 2015; Williams et al 2016). Greenhalgh et al (2015) cite this as one of the most common misapplications of the methodology, noting that most authors only fleetingly refer to the philosophical foundations of realist evaluation, even though this is arguably its most distinctive feature, providing much of its explanatory power. Porter (2015) goes so far as to say that the issue is one of the misinterpretation of abstruse philosophy by empirical researchers. Greenhalgh et al (2015) have identified that a major implication of this misapplication and misinterpretation is that some realist researchers have based their evaluations, either explicitly or implicitly, on fundamentally different philosophical assumptions. The most common being the positivist notion that interventions in and of themselves cause outcomes (Greenhalgh et al 2015). Attention has been drawn to this issue previously by Greenhalgh et al (2009) who caution that there will be conflict if stakeholders embrace 'realist' evaluations, but continue to be fixated on positive criteria when assessing the rigour and utility of such work.

4.4.4 Summary of section

To summarise, there are clear benefits associated with adopting a realist evaluation approach to healthcare research in the sense that it is well placed to explore and unravel some of the complexities associated with complex healthcare systems. It also allows researchers to move away from a linear cause and effect relationship in healthcare interventions to make consideration of causality, with a view to providing context-sensitive solutions. Realist evaluation also draws attention to explanatory programme theory, which again will support a more nuanced explanation of how interventions operate in complex systems such as healthcare. The use of outcome patterns further support this, providing insight into local operating conditions, rather than a one-size fits all approach. There is also potentially further strength in realist evaluation by undertaking cycles of evaluation to help

build and refine programme theories, although practical examples of this demonstrate there are challenges associated with this approach. The weaknesses and challenges associated with realist evaluation in healthcare research are predominately associated with methodological issues, with some researchers failing to adhere to the core principles of the approach, but nonetheless branding their studies 'realist evaluation'. Commentators have noted a lack of methodological guidance as a weakness, along with confusion about the terminology of realist evaluation, particularly 'context' and 'mechanism' and how one should go about developing CMO configurations. There is also criticism in the literature that researchers are undertaking realist approaches to their work without giving due consideration to the philosophical basis of realist evaluation and realism.

4.5 Study Design and Methods

A seemingly obvious but profound working principle of good science is that it should utilise methods that are suitable for, and compatible with, the subject matter under investigation (Pawson 2006). How we think the social world is constituted, or what we think it is (our ontology), shapes how we think we can know about it, but conversely how we look at it (the epistemology and the methods we use) shapes what we can see. An awareness of the logic of my approach and of the ontological and epistemological assumptions I was making, helped ensure that these assumptions will be available for scrutiny by myself and others, and therefore open to debate, modification and improvement. Equally important is that there is a consistent and coherent relationship between ontology and epistemology from a methodological perspective. In my research, the epistemological perspective begins with a theory of causal explanation based on generative principles. This ontologically supposes that the outcomes of the ERAS programme interventions are brought about by people's reasoning and the resources they are able to summon (the mechanisms) in a particular context. The overall aim of this research is to seek out regularities in the patterns of these contexts and mechanisms which result in patient involvement in patient safety. In this respect I am confident there was a good fit between my research aims and the methodology and methods I have chosen to explore this phenomenon.

I chose to use a qualitative approach to this research as it is a method of inquiry which is grounded in a philosophical position which is broadly interpretivist, in the sense that it is concerned with how the social world is interpreted, understood, experienced and constituted (Mason 2002). Using a qualitative approach helped me explore the understandings and experiences of research participants, the ways that social processes, institutions and relationships work in real world practices, and the significance of the meanings that they generate (Mason 2002). Qualitative research is based on methods of analysis, explanation and argument building which involve understandings of complexity, detail and context, which aim to produce rounded and contextual understandings on the basis of rich, nuanced and detailed data, which I have factored into my analyses and explanations. This has helped me in my attempts to provide explanations about how patient involvement in patient safety works in particular contexts (Mason 2002).

4.6 Why Qualitative Case Studies?

A realist evaluation should utilise multiple data sources and methods in a pragmatic and reflexive manner to build a picture of the case, which calls for making sense of various data sets to develop coherent and plausible accounts of the phenomena under investigation, in this case patient involvement in patient safety (Greenhalgh et al 2009; Rycroft-Malone et al 2010). In view of this I chose a qualitative case study approach for this study, which is methodologically complementary to realistic evaluation, advocating the use of multiple methods for data generation and recognising the importance of context (Yin 2009). I chose three cases that I thought would most likely provide data for my research aims (Stake 2005; Yin 2009), which were separate surgical units within the University Health Board (UHB) that were actively involved in the ERAS programme at the time of this study. Generally speaking, the more settings studied, the less time can be spent in each and a trade-off has to be made here between breadth and depth of investigation (Hammersley and Atkinson 2007), however I felt that these three case studies would provide sufficient variation in contexts to enable me to make useful cross case comparisons (Mason 2002).

4.7 The Case Studies: An overview

4.7.1 'Bishop'

Bishop was a surgical unit specialising in the care of patients undergoing lower gastrointestinal (colorectal) cancer surgery and patients with other conditions of the lower gastrointestinal tract, for example diverticulitis. Most of these procedures were associated with the ERAS programme, the most common of which were large bowel resections (colectomy), which is surgery to remove all or part of the large bowel, which was a procedure carried out under general anaesthetic using minimally invasive laparoscopic techniques. The majority of patients admitted to Bishop Ward were planned admissions and it was rare that the ward admitted non-surgical patients and during my observations it was evident that the nursing manager was involved in daily negotiations with the hospital management to try and ensure this remained the case. The ward had capacity for twenty patients, which comprised of four 'four bedded' rooms and four single rooms and during my observations the ward was usually running at full capacity. The designated nursing staff allocation for each day shift of four registered nurses and two healthcare support workers, which was reduced during a night shift.

4.7.2 'Albany'

Albany was a surgical unit specialising in the care of patients undergoing upper gastrointestinal, hepatobiliary and pancreatic surgery. The procedures associated with the ERAS programme were oesophagectomy, which is the removal of all or part of the oesophagus, and gastrectomy, where all or part of the stomach is removed. These procedures were carried out under general anaesthetic using an open surgery technique, in which a large incision is made in the patient's abdomen or chest. The ward also provided care for urology patients, trauma and orthopaedic patients and 'general medical' patients, commonly referred to as 'outliers' which resulted in an unpredictability of patient admissions to the ward. The ward had capacity for 38 patients and was equally divided into a 'North' side and a 'South' side and each side of the ward comprised of a nine bedded ward, two four bedded rooms and two single cubicles. During my observations the ward

was usually running at close to full capacity. The designated staff level for each day shift was eight registered nurses and four healthcare support workers, or six registered nurses and six support workers, which was reduced during a night shift.

4.7.3 'Columbus'

Columbus was a 27 bedded surgical unit used exclusively for elective orthopaedic patients. Due to infection control risks, it was the policy of the ward that no patients were admitted prior to screening for infection and there was a strict policy that no 'medical outliers' were admitted to this ward. Although patients were admitted for a range of orthopaedic procedures, the only one associated with the ERAS programme was a total knee replacement (TKR), which is surgery most commonly associated with osteoarthritis in which the knee is replaced by an artificial joint. This operation was carried out either under general anaesthetic, or more commonly under spinal or epidural anaesthetic, in which the patient is awake. Columbus was split into two separate bays of 13 beds, which were usually allocated to male and female patients, and one single cubicle. During my observations there was a wide variation in the bed occupancy levels, ranging from fully occupied some days, to less than half occupancy on other days. The nursing staffing complement for the day shift was six registered nurses and two healthcare support workers, which was reduced for the night shift.

4.8 What was my data generation strategy?

Most qualitative perspectives would reject the idea that a researcher can be a neutral collector of information about the social world (Mason 2002; Baker 2003) and in this sense, researchers do not simply work out where to find data which already exist in a collectable state, instead they work out how best to generate data from their chosen data sources (Mason 2002). During the course of data generation for this research I used a combination of methods, which comprised of; documentary analysis of ERAS policy guidelines and protocols and pathway documentation; observation of healthcare activities in hospital wards, pre-admission appointments and patient education sessions; semi-structured interviews with patients and semi-structured interviews with nursing staff. My data

generation strategy was designed to take place in two discrete stages, the first of which was intended to help establish the programme theories in relation to patient involvement in patient safety in ERAS and these would be presented in the form of conjectured conjectured-context-mechanism-outcomes (CMOs). The second stage was intended to 'test' these conjectured CMOs using empirical data generated in the three case studies and I will now describe each of these stages in more detail.

4.9 Data Generation Stage 1: Developing the theories (the conjectured CMOs)

In accordance with the realist evaluation logic of inquiry, the first stage of my data generation involved me developing theories about which ERAS programme interventions were designed for patient involvement in patient safety, and which contextual factors were amenable for these programme interventions. This stage of the inquiry involved considering potential mechanisms for patient involvement in patient safety (M) and generating ideas about which contextual factors (C) were likely to be important in 'firing' these mechanisms (generative causation), enabling me to articulate the programme theory in CMO terms. For the purposes of producing these conjectured CMOs, outcomes (O) are defined as instances where patients are involved in patient safety related activity in relation to their direct care.

Analysis of the ERAS policy guidelines and protocols along with consideration of the academic literature helped me to articulate the programme theory as I perceived it in the form of an array of conjectured CMOs. This was based on the main elements of an ERAS programme which lend themselves to patient involvement (as described previously). Specifically, 'prehabilitation' in relation to optimisation of fitness; dietary advice in the form of pre-operative build up and postoperative early nutrition; discharge and discharge planning; and early and continuing postoperative mobilisation. As I have discussed, primary care services in NHS Wales were not engaged with the ERAS programme at the time of the study and so primary care elements of the ERAS programme were disregarded in my development of the conjectured CMOs.

In line with the approach to realist evaluation as described by Pawson and Tilley (1997), there is also an expectation that the researcher will engage with policy makers and / or

programme designers and developers at this stage, in an effort to discuss and refine these conjectured CMOs. In view of this, my research had been designed so that the development of my conjectured CMOs would be supported by data from semi-structured interviews with ERAS programme authors and national programme leads, to illicit their ideas and assumptions about how the programme works and what is necessary to support its success in involving patients in patient safety. Here I present a brief account of my engagement with some of the key programme designers and leads for ERAS in NHS Wales in an attempt to discuss some of the ERAS programme theories relating to patient involvement in patient safety.

4.10 Meetings with programme authors / programme leads

I first met with one of the 'content specialists' of the national improvement service who described to me how the evidence base for the How to Guides (HTG) was perhaps not as strong as it could be in relation to the patient involvement elements. It was made clear to me that the time-frames for production of these guides could be very short and thus elements of the HTG were untested and innovative, which may entail an element of trial and error. It is interesting to note that the ERAS HTGs are seemingly based on the Department of Health (2010) document which serves a similar purpose in NHS England. So although there may be innovative aspects to these programmes, NHS Wales may not be the source of this innovation. Following this meeting, I met with the ERAS programme lead for NHS Wales to discuss my proposed research and this individual offered to arrange meetings for me with other programme leads and key programme personnel in my proposed case study sites.

As a result of this, I then met with the director of the national improvement service to introduce my research plan and seek some insight into the supporting theory and rationale for patient involvement in patient safety through an ERAS programme from his perspective. This meeting took place at the same time a large scale research project was about to be undertaken in NHS Wales, focusing on the NHS Wales improvement service and using a realist evaluation approach. The director informed me he had met recently with the principal investigator for that study and it was clear to me that the director was particularly

interested in discussing the research methodology I intended to adopt, whereas I was more interested in discussing the potential for patient involvement in safety through an ERAS programme and the director's views on this. This was challenging for me as, even though I had prepared questions and topics in advance, the meeting felt unfocused and I had difficulty explaining abstract concepts and was concerned at presenting myself as ill-informed as I had not come prepared for a discussion about research methodology and I was still a novice in this respect, I did not feel confident to discuss this in any great detail.

During the meeting I did have some opportunity to discuss ERAS and the associated HTGs and the director informed me that although the HTGs were aligned to programme areas within the national improvement programme, they were not policy, nor were they to be regarded as clinical guidelines. I explained that I would be focusing on discrete elements of ERAS, rather than the programme in its totality, and that ERAS was helping to provide a focus and boundedness for my research in relation to patient involvement in patient safety. The director informed me that ERAS was about 'quality of care', rather than 'patient safety', although there is content in the HTG that clearly makes reference to patient safety. He informed me that there were no elements of the ERAS HTG that were designed specifically to instruct or advise UHBs or clinical staff on patient involvement strategies or techniques. He commented that there may well be innovation taking place within the health boards in regard to this, but this was not under the influence or guidance of the improvement service.

Overall, I was unable to elicit any programme theories from the series of meetings I was involved in and was left reflecting that I was none the wiser in terms of what these particular programme authors and programme leads believed in relation to patient involvement in patient safety. Due to my inability to develop any insight into the programme theories following this series of meetings and informal conversations with some of the stakeholders in the ERAS programme in NHS Wales, and subsequent discussions with my academic supervisor, I opted not to carry out the formal interviews with the programme designers and developers, as I had initially intended. This decision was also influenced by the fact that I was already over a year into my three-year studentship and had not yet gained any ethical approval or access to potential research sites.

Pawson and Tilley (1997) acknowledge that it may not be possible for the researcher to talk with the programme originators, or indeed that programme originators may not always be able to articulate the programme theory. This was indeed the case for my research, which demonstrates that there are different ways to approach assembling the programme theory in a realist evaluation, acknowledging the practical constraints of 'real-life' research. Therefore, it was at this stage that I decided (in consultation with my supervisory team) to diverge from what purists would recognise as realist evaluation, to a research approach that was guided by the principles of realist evaluation. I was satisfied that the most appropriate course of action would be to exclusively base my conjectured CMOs on the literature, and policy and guideline documentation including the HTGs, as based on my experiences thus far I did not believe that data generated from these proposed interviews with programme designers and developer would have utility in enabling me to further develop my conjectured CMOs. This required that I take a more inductive approach to my research and so I developed a looser amalgam of conjectured CMOs to take into the case studies for testing, with a view to refining these conjectured CMOs as the fieldwork progressed during the respective case studies. This would require drawing on the empirical data produced from this second stage of the data generation process, to establish the conditions (contexts) in which these conjectured CMOs were likely to result in patient involvement in patient safety through an ERAS programme.

4.11 Data Generation Stage 2: The Case Studies

Realist evaluation is centrally concerned with testing and refining programme theories in the form of conjectured CMOs by exploring the complex and dynamic interaction between these contexts, mechanisms and outcomes (Greenhalgh et al 2009). In view of this, the second stage of fieldwork involved generating data from the three case studies through observations and interviews and further documentary analysis, which would allow interrogation of the initial conjectured CMOs I had developed. Although I had produced an array of conjectured CMOs it was only until I entered the field and began my observations and subsequent interviews that I was able to begin to make real sense of the complexities of these layers of context and begin building and analysing patterns of contexts and mechanisms in action in clinical practice. This involved data generation through field notes

of observed clinical encounters, patient education sessions and interviews with nursing staff and patients, allowing interrogation and development of these initial theories; specifically focussing on how did patient involvement in patient safety in an ERAS programme work in practice, compared to the conjectured CMOs I had developed.

4.12 Access to study sites

Ethical approval was granted from the NHS South East Wales Research Ethics Committee, with some minor clarifications and amendments. My study proposal was also referred to the UHB's research and development department (R&D) for consideration, as I required access to three clinical units within the UHB. Following my successful application to the NHS Research Ethics Committee, I was very keen to start my field work. However, the process of R&D access to the study sites was to take several more months to resolve and this was a very morale-sapping process and I was eventually granted access to carry out my study in the UHB approximately eighteen months after the start of my candidature, and almost three months after the favourable opinion from the NHS Research Ethics Committee. Feldman et al (2003) suggest the problems associated with obtaining access to data often comes as a rude surprise to researchers who have not anticipated the difficulties that could be involved and certainly I had not anticipated such a protracted process in relation to gaining access to the research sites.

As the research progressed, further access was negotiated in the respective cases with the surgical ward managers' group, senior nurse practitioners, surgical consultants and finally the respective ward managers. I also found myself subject to ongoing negotiation and renegotiation following the initial encounters, for example in relation to those staff who were involved in pre-admission processes and staff on the hospital wards.

4.13 Gatekeepers

The delays in my attempts to gain access to the UHB had severely dented my confidence and I was greatly relieved at the support I received on Albany from clinical staff, particularly the Specialist Nurse (SN) who from the very beginning of my fieldwork on Albany acted as

my key informant. I suggested to the SN that I could give a formal presentation of my research aims and objectives as I was aware that it is important what people are told about the research and what it may involve for them (Hammersley and Atkinson 2007). With this in mind, I had provided informal presentations to senior staff during the access negotiation process, which Neyland (2008) recommends as a means of building trust and demonstrating the utility of the research to potential participants. However, on Albany the SN did not feel that would be necessary as she believed that staff would not be particularly receptive to any formal presentation and suggested it would be sufficient to introduce myself to staff, say who I was, what I was doing and how long I would be around. I agreed to this and said I would provide staff with more information should they require it. This approach was very similar with the nursing managers of the two subsequent case studies, who declined my offer to present to the nursing staff.

4.14 How did I carry out my observations?

The realist evaluation approach I had adopted required that I seek out data that related to the theories I was developing – the conjectured CMOs (Pawson and Tilley 1997). One of the ways I chose to support this was through observations as one of the main strengths of this method is their capacity to show the different ways in which everyday life within different contexts is brought into being (May 1997). De Walt et al (1998) describe a spectrum of observer participation ranging from non-participatory through to complete participation and I adopted the role of passive participant observer, similar to that described by Delamont (2007) in which ‘participant’ does not mean doing what those being observed do, but interacting with them while they do it. Specifically, I was interested in observing those elements of an ERAS programme that I had identified in my conjectured CMOs which may provide patients with the opportunity for involvement in patient safety related behaviour or activities. I wanted to observe what people did in relation to this and why they did it and this was best done by spending time on the ward watching staff, patients and others go about their everyday business and work.

Hammersley and Atkinson (2007) advise that people will more often be concerned with what kind of person the researcher is than with the research itself. As a registered nurse, my

nursing knowledge was of some value in my fieldwork as a basis for establishing some level of reciprocity with participants, although I was careful not to exploit this, or overstep the boundaries of my research role. I had mentioned the possibility of wearing 'scrubs' when I addressing the group of ward managers prior to my fieldwork, but they felt this would not be necessary. In view of this, I chose what would best be described as a 'smart-casual' form of dress, which Hammersley and Atkinson (2007) suggest would distance me from constraining identities. For both the building and maintenance of trust I attempted to utilise particular strategies recommended by Neyland (2008), which included asking questions in a naive rather than challenging way and beginning conversations with 'safe' topics before moving on to more challenging issues (Neyland 2008).

My initial period of observations on each of the units involved shadowing individual nursing staff carrying out their working routines, which was useful in helping me orientate myself to new environments and familiarising myself with the day-to-day routines and processes and the people based on, and visiting, the clinical areas. The initial part of my observations in each case study was also about getting to know people on the hospital wards and trying to become familiar to as many people as possible during these early stages. I anticipated this investment early on would make my journey smoother through the case studies; answering questions about myself and my research early on, letting people get used to me being around and attempting to build trust and, hopefully, allay any suspicions, fears, doubts or concerns people may have about my presence on the ward. Overall my strategy seemed to pay off and I felt that by being conspicuous in the early stages allowed me to become less so as the study progressed, hopefully leading to people acting more naturally in my presence.

It was not practical for me to conduct fieldwork round the clock so I attempted some degree of time sampling where I attempted to build up an adequate representation in each of the cases (Hammersley and Atkinson 2007). This involved identifying particularly relevant periods during the day and week which related to my developing theories and then focusing on these periods during my later observations (Hammersley and Atkinson 2007). Developing this intermittent time mode approach (Jeffrey and Troman 2004) to the research sites meant gaining the compliance to enter the various clinical areas of the respective cases at different times, the gradual opening up of areas for access, gaining the trust of participants

and the opportunity to decide during the process of research where to focus (Woods 1996). This was gradually established over time and was assisted by my developing key relationships during the observational period and as the fieldwork developed in each case study I took a flexible approach to the frequency of site visits. This was a pattern that I followed for all three case studies. However, I was also very mindful of issues of privacy and dignity and did not want to intrude on sensitive situations without due regard and was I constantly careful to show discretion where and how I spent my time during observations on the respective hospital wards.

My time in the field was ultimately determined by practical limitations, predominately in terms of time resource. However, towards the end of each case study I was confident I had a good understanding of the daily rhythms and episodes of care, however this does not suggest that I was indifferent to the fact that things can change.

4.15 Fieldnotes: turning observations into data

Hammersley and Atkinson (2007) caution that memory is an inadequate basis for subsequent analysis so I made every effort to record as much detail as possible through the use of fieldnotes. However, realistically, fieldnotes are always going to be selective and it was not possible for me to capture everything and following the guidance of Hammersley and Atkinson (2007) there was a trade-off between my breadth of focus and my detail, and what I recorded was based on my general sense of what was relevant to the research aims in relation to the theories I was developing.

Hammersley and Atkinson (2007) warn against allowing one's fieldnotes and other types of data to pile up without regular reflection and review so following each observation period, I would write up the shorthand notes into my field journal, using this opportunity to work up, expand and develop these notes. As also recommended by Hammersley and Atkinson (2007) when writing-up my fieldnotes, I included detailed descriptions of what happened, discussion of my own feelings and impressions and my own analytical ideas. This would normally take place the same day of the observations, when my recollection of events was fresh in my memory. This process gave me the opportunity to develop my notes and

observations from my field work and allowed me to analyse and review the observational data, sort the data into preliminary themes and segregate the reflexive journal related writing from empirical data.

4.16 Who did I interview and why?

Programmes such as ERAS can only work through the reasoning and interpretation of those involved in the delivery of the programme, and knowledge of this is integral to helping the researcher develop a more in-depth understanding of the programme. Broadly speaking, one should expect to find various elements of the explanation in the reasoning and actions of different groups of stakeholders (Pawson and Tilley 1997; Pawson 2006, 2013) and based on this premise I decided to interview nursing staff and patients, as these were the groups who I anticipated were most involved in the elements under scrutiny.

Patients and nursing staff each have a set of different, but complementary, views which can be generated for analysis and cross fertilisation (Pawson and Tilley 1997). Patients normally experience just one journey through a programme, but they will know a great deal about that journey (Pawson 2006). Similarly, nurses' experience many of these patient journeys which means they can know a great deal based on a breadth of experience, which complements the depth of patients' experiences. The ERAS programme provides the reasons and resources which encourage patient involvement in patient safety and, as the persons on the receiving end of the programme interventions, patients are in a good position to know whether they have been encouraged (Pawson and Tilley 1997). Nursing staff translate the ERAS programme interventions into practice and will likely have ideas about how elements of the programme work amongst varying patients, or within particular contexts and are also likely to have experienced successes and failures, as a result nurses will have some awareness of the contexts in which the programme works. They may also have scope for discretion in shaping how the programme is delivered and thus develop personal views about the programme and its potential in enabling patient involvement in patient safety (Pawson 2006).

4.17 Sampling and recruitment

The question of how many interviews has particular implications for qualitative research and the academic literature offers various opinions and answers to this question (Baker and Edwards 2012). In general, the number of interviews needed will depend on the aims of the research and the kind or type of knowledge that the interviewer seeks (Johnson 2001). I had estimated a total of eight patients and eight nurses to interview in each case study, which I anticipated would provide access to enough data, and with the right focus enable me to address the research aims whilst remaining practical in terms of my ability to manage this data during the analysis process (Mason 2002). My primary aim was the opportunity to learn about patient involvement in patient safety in relation to an ERAS programme and in view of this nursing staff and patients, were purposively sampled based on their relevance to my research aims (Stake 2005), specifically that all participants were, or had been, involved with an ERAS programme in their respective cases.

4.18 What was my data generation schedule?

Case Study	Total Observations	No of patient interviews	No of nursing staff interviewed
Albany	80 hours made up of 30 site visits over 98 days	Six, totalling 432 minutes	Seven, totalling 423 minutes
Bishop	85 hours made up of 27 site visits over 71 days	Eight, totalling 447 minutes	Seven, totalling 485 minutes
Columbus	82 hours made up of 25 site visits over 66 days	Seven, totalling 360 minutes	Seven, totalling 413 minutes

4.19 Staff Interviews

In total, 21 nursing staff were interviewed, with seven taking part from each case study. I had initially ruled out the recruitment of HCSW's for this case, however there was a healthcare support worker on Bishop who obviously held a key role in relation to ERAS and fortunately this individual volunteered to take part in an interview. In each of the cases a senior nurse acted on my behalf in relation to potential interview participants and staff

were notified by this nurse that I was recruiting interviewees as part of my study and they should advise their manager if they wanted to take part, who in turn would let me know. I left participant information sheets on each of the wards for staff to review and they were also advised I was available to answer any questions about the study.

I discussed my intention to carry out staff interviews during my meetings with the respective ward managers, who agreed that it would be difficult to recruit staff to take part in an interview at the end of a 12-hour shift, but were receptive to staff interviews being fitted in during the working day as long as it did not interfere with patient care. I was mindful of a member of the nursing staff being away from the ward for a long period of time to take part in an interview, and how this may be perceived by other staff and so it was established that that interviews would last no more than 45 to 50 minutes.

Participants were asked to sign a consent form and a suitable time was arranged for the interview and all staff who agreed to participate were advised that they were free to opt out at any point. Interviews on each of the cases were coordinated by the deputy ward manager or ward manager who identified days and times during the shift where the interview would have least impact on the staffing and workload requirements of the ward and the nursing staff were very supportive in this respect. I was keen to establish that I was completely flexible about when I could carry out interviews and was able to come to the ward at short notice if that was necessary, including evenings and weekends. Those who agreed to take part in interviews were also given a cooling off period prior to the interviews taking place, should they wish to change their mind and withdraw. Interviews were usually carried out in the respective ward managers' private office by prior arrangement, or in some instances when this was not convenient an alternative private space was utilised, for example one of the treatment rooms on the respective wards. All interviewees were informed that the interviews were to be audio-recorded and then transcribed by me and that no one else would have access to the recordings. Assurances were provided to all participants that I would protect their anonymity and that all information generated in the interview was confidential, subject to any disclosure that could result in harm, or endanger themselves or others.

There were staff that I observed and spoke with during my fieldwork who would have been excellent candidates for formal interviews, to help me develop my analysis. However, as detailed in my ethical approval, those being interviewed had to be self-selecting and so I was not able to approach staff and ask them to participate and neither should any participant feel they have been coerced into an interview. However, overall I was very grateful to have so many willing volunteers, particularly as I was uncertain what sort of response I would get to my request for interviews with staff. There are, however, certain limitations to consider in regard to the self-selecting sampling I have described (Parahoo 1997), and these limitations can be exaggerated when participants are 'filtered' through line management. Firstly, the participants in my study were part of a 'captive' population and it could be questioned how 'voluntary' the participants' actions actually were. Parahoo (1997) describes a number of reasons why a captive population may 'volunteer' to take part in a study including a moral obligation, in which participants feel that the research may be of benefit to other patients. Patients may also agree to take part as gratitude in return for the care they receive, whilst some may take part due to fear of reprisals, or a fear of being labelled uncooperative (Parahoo 1997). Another area of consideration in relation to self-selected sampling is that volunteering itself is an act of cooperation and reflects the personality of those more likely to volunteer. Parahoo (1997) suggests these type of self-selecting participants may show more interest and motivation than those who do not, and this renders volunteer samples limited because we know little of those who do not take part in the study. For these reasons, there are some questions which could be raised regarding the absolute validity of my data.

4.20 Patient interviews

In total 21 patients took part in semi-structured interviews across the three case studies. I had originally planned to interview a maximum of eight patients from each case study, who had been involved in the ERAS programme. However eventually my recruitment process in one case, Albany, realised six patients, with seven and eight patients respectively in Columbus and Bishop. All the patients interviewed in Albany were male, as recruitment of female participants that matched the selection criteria had proved difficult. This was mainly due to the low number of ERAS patients on the unit at any one time and also the gender mix

of the patient population under study at the time of my research (males are also almost two times as likely to develop the condition associated with the ERAS programme on this particular case study (Cancer UK 2012). The gender mix for patient recruitment was more balanced in the subsequent case.

Due to the low number of patients enrolled on the ERAS programme at any one time on Albany, the recruitment process was more involved than the other two cases. The SN acted as a gatekeeper for the recruitment process and I explained that I would like to recruit eight patients to take part in interviews, but due to the challenges of recruiting these patients and the time constraints I was facing in relation to the fieldwork six patients were recruited. Three of these patients I had already met on the hospital ward during my observations and the SN acted as an intermediary for me with these patients, all of whom agreed to take part in an interview. The SN also contacted five other patients on my behalf who had been treated and discharged prior to my study commencing. This meant that I was not able to verify patient accounts of their experiences through any observational data.

Members of the nursing team also acted as intermediaries in the patient interview recruitment process during the Bishop and Columbus case studies, informing patients that I was carrying out research and that I was looking to recruit patients with experience of ERAS. As there were many more patients enrolled on ERAS on Bishop and Columbus, I did not face the same recruitment issues as those I had experienced on Albany in relation to numbers of participants, or verification of patients' accounts through my observations. All patients who took part were self-selecting and I went through an informed consent process with these patients prior to participation and assured them that I would protect their anonymity and that the interviews would be confidential. I also provided a cooling off period, to allow patients' the opportunity to change their mind and withdraw consent should they wish to do so (although none did). Each interview took place in the respective patient's home, firstly to ensure they were physically well enough to take part, in the sense they had been discharged from hospital care. Secondly, and as noted by Hammersley and Atkinson (2007), interviewing people on their own 'territory' and allowing them to organise the context the way they wish is deemed the best strategy, allowing them to relax much more than they would in less familiar surroundings. Talking in the patients' homes felt strange to me and

made me a little anxious at first. However, patients clearly appeared more relaxed in their own homes I think interviewing patients in this environment was a positive factor in relation to my data generation. Patients were also seemingly unconcerned about how long the interview would take, although I tried to limit the interviews to not much more than an hour, simply on the basis that I did not want to appear to be imposing on peoples in their own home. Although I was not always successful with the timing issues, patients were refreshingly open and frank and most seemed to welcome the opportunity to talk with me about their experiences.

4.21 How did I manage the interviews?

I prepared semi-structured interview schedules for patients and staff which had been developed on the basis of my conjectured CMOs and refined as an ongoing process in light of my evolving observational data from the respective cases. In line with the realist evaluation approach I was aware of the need to focus on the reasoning behind people's actions and behaviour and I discussed activities and interactions with staff and patients in relation to the CMOs I had developed and the observations I had carried out. Through these interviews my intention was to illicit views on what contextual factors may be important in relation to patient involvement in patient safety – the generative causation referred to in realism. The intention was that informants would then describe and either corroborate, complement or contradict my theories, in what could be described as an iterative or emergent approach to interviewing.

I engaged with the literature to support my interviewing practice and techniques, and from this became aware that it was important for me to recognise that although the interviews were conversational, they were never just 'a conversation' and as the interviewer I needed to retain some control over proceedings which allowed me to decide which bit of talk to follow up, where to open and close various topics, and the interaction as a whole (Rapley 2004; Hammersley and Atkinson 2007). It was also important that I did not monopolise the conversation, nor completely fade into the background and as Rapley (2004) recommends, I needed to be flexible, listen, ask questions and occasionally offer my ideas and opinions if I felt it was relevant.

4.22 Transcribing the interviews

Transcription is a time-consuming business (Hammersley and Atkinson 2007) and I had allowed for this in planning my research, having chosen to carry out full transcription of all interview dialogue myself. I found this exercise particularly useful in 'getting to know' the data, with the opportunity to listen to the interviews and as the transcription was an ongoing process it also provided me with the opportunity to reflect on my interview technique and develop strategies to enhance this as the research progressed. In this sense, listening back to the interviews was a revelation for me as it gave me a much richer perspective of the interactions and allowed me to spend time considering the talk in more detail. This also provided me with the opportunity to reflect on my interviewing style and technique, which proved useful.

4.23 How did I analyse the data?

As I have described, realist evaluation focuses on testing and refining programme theories in the form of conjectured CMOs that allow the researcher to explore the interactions between the contexts, mechanisms and outcomes defined in these CMOs. Using this approach, the primary expectation of this study is that there will be a nuanced pattern of outcomes within and across each of the three case studies and the emerging theory will allow me to explain contextual variations across these case studies which impact on the success or otherwise of specific elements of an ERAS programme relating to patient involvement in patient safety. The conjectured CMOs were developed during what I have referred to as data generation stage one, with the intention of 'testing' and refining these CMOs using data generated across the three case studies.

During the course of my data generation in the case studies I used a combination of methods which included interviews, observations and documentary analysis. Using MS Word and NVivo, the data generated during the case studies was coded and catalogued for each of the three case studies. When integrating data in this way, a key task is to weave the argument and analysis derived from the different data-sets together (Mason 2002). To

support this activity during my analysis I utilised data source triangulation, which involved the comparison of data relating to the same phenomenon but derived from different phases of fieldwork and the accounts of different participants. This approach was used in combination with method triangulation, which involved comparing data produced by the different data generation techniques I have described (Hammersley and Atkinson 2007). The use of triangulation reflects my attempts to secure an in-depth understanding of patient involvement in patient safety through an ERAS programme and this approach has generally been considered a process of using multiple perceptions to clarify meaning, allowing the researcher to verify the repeatability of an observation or interpretation (Flick 2002). Furthermore, by acknowledging that no observations or interpretations are perfectly repeatable, triangulation serves also to clarify meaning by identifying the different ways in which the case is being seen (Silverman 1993; Flick 2002). However, I am aware that what is involved in triangulation is not a matter of checking whether data are valid but, at best, of discovering which inferences from those data seem more likely to be valid. This aggregation of diverse kinds of data will not unproblematically add up to produce a more accurate or complete picture. It will, however, allow me some confidence in my conclusions (Hammersley and Atkinson 2007).

Analysis of the data was not a distinct stage of the research as, formally, it started to take shape in analytic notes from my observations and interviews, whilst informally it was embodied in my ideas and hunches throughout the course of the research process. To assist me in this process, when writing up fieldnotes and transcribing interviews I developed and recorded preliminary analytical ideas, which proved useful later when further analysing the data (Hammersley and Atkinson 2007). In support of my analysis, and being mindful that underpinning the process of analysis is the necessity to know one's data, I also undertook detailed and repeated readings of all my sets of data (Hammersley and Atkinson 2007), and this iterative process provided me with a progressive understanding of the data (Atkinson and Coffey 1996).

I was interested in elements of an ERAS programme which lend themselves to patient involvement in patient safety, which I have previously identified as 'prehabilitation', 'diet', 'discharge' and 'early and continuing postoperative mobility' and during the first stage of my

data generation (the conjectured CMOs) and I had developed ideas about how these different elements play out in a clinical setting. My intention was to then 'test' these conjectured CMOs across the three case studies through analysis of the empirical data generated from the cases, identifying the contextual factors which were amenable for the success of these CMOs, the objective being to develop a better understanding of what works for who and in what circumstances (Pawson and Tilley 1997; Pawson 2013). This approach can also shed light on the linkage of ideas and concepts from the initial programme design, to the implementation of ERAS in hospital units.

Drawing these types of realist conclusions about the generative causality of particular context-mechanism-outcome alignments with a programme such as ERAS is intended to be an interpretive task (Greenhalgh et al 2009). During analysis I undertook an iterative, explanation building approach and my overall analysis approach was typical of ethnographic type research such as this, with a characteristic 'funnel' structure being progressively focused over its course, with a gradual shift from describing events and processes towards developing and testing explanations. This iterative method of analysis provided me with a progressive understanding of the data sets, which I synthesised with my emerging thoughts and via this process I used my ideas to make sense of data, allowing me to change and develop my ideas (Hammersley and Atkinson 2007).

From here-on, the data analysis process focused on my attempts to identify and isolate those issues relating specifically to the mobilisation aspects of the ERAS programme across the three case studies and articulate this in CMO terms, developing and refining this programme theory and identifying contextual issues that influenced this aspects of the programme theory. This took place in several stages and became another iterative process which involved organising and collating primary data, producing thematic summaries of these data. During the process of data analysis, I also undertook repeated writing and re-writing of elements of the respective case studies and attempted to use cross case comparisons to determine how the same programme theory played out in different contexts and produced different outcomes, with a view to identifying the generative causality of patient involvement in patient safety through early and continuing postoperative mobilisation in an ERAS programme. During the course of my (rather lengthy)

data analysis process, I also engaged with my academic supervisors on several occasions to present, defend and also negotiate my interpretations of the data with them.

A caveat of this research is that there is a limit on what it can deliver using the described technique of realist evaluation. There will always be contextual variation within and between programmes and consequently a variation in the effectiveness of programme interventions and variations in the patterns of outcome (Pawson and Tilley 1997). A realist evaluation of this type will never be able to grasp the totality of these constraints or effectiveness of interventions and so, in line with realist traditions, I have attempted to provide an account of the workings of a complex intervention and, hopefully, a better understanding of how theory for patient involvement in patient safety can be improved (Pawson 2006).

Chapter 5: Implementation of ERAS

In this chapter I consider the different approaches taken by each of the cases under study in relation to the implementation of ERAS, as this was clearly an influential context on the subsequent involvement of patients in patient safety. Whilst recognising that implementation is a continual, ongoing process, for the purposes of this thesis I present my evaluation and analysis of implementation in two sections. Firstly, I consider the processes undertaken and resources engaged by each of the case studies to initially develop and then launch the ERAS programme on the respective units. Secondly, I consider the processes undertaken and resources engaged to sustain the operation of the programme as part of the ongoing implementation process in the respective clinical areas. For purposes of clarity, I have labelled these sections 'Implementation of ERAS: Developing the Programme' and 'Implementation of ERAS: Sustaining the Programme', respectively.

To support my evaluation and analysis of the data relating to this aspect of the case studies I made use of concepts relating to the theory of implementation research which Eccles et al (2009) describe as the scientific study of methods to promote the systematic uptake of evidence based practices in routine practice, thus improving the quality of healthcare. I also draw on less contemporary theory, in particular the work carried out by Greenhalgh et al in 2004, in which the authors carried out a systematic review of the literature relating to diffusion, dissemination and sustainability of innovations in healthcare organisations.

5.1 Implementation of ERAS: Developing the Programme

There is a growing body of evidence which supports the notion that a quality improvement initiative such as ERAS that has been successful in one location does not necessarily deliver the same results elsewhere (Pawson 2006; Bamber 2014). Therefore, the influence of context is important (Eccles et al 2009) and hence the multiple levels at which healthcare is delivered and the interplay between these factors should be considered when evaluating a programme such as ERAS (Ferlie et al 2001). Bamber (2014) describes three elements that make for the success of these programmes, namely what you do, the environment in which you do it, and how you do it. Bamber (2014) further contends that the interactions between

these three elements are what makes for successes (or failures) or quality improvement interventions.

It was apparent from my data generation and subsequent analysis that the implementation process was an important contextual influence in relation to the realist evaluation I was undertaking and, as mentioned previously, each of the three cases took a different approach to the implementation of ERAS. In this section of the chapter I will consider the implementation process for each of the cases, drawing on the literature relating to improvement research and Greenhalgh et al's (2004) work to present specific influential contextual factors relating to the processes undertaken and resources engaged by each of the case studies to initially develop and subsequently launch the ERAS programme. These factors are: organisational context; opinion leaders; project champion; and development of an integrated care pathway. I then conclude by offering a cross-case comparison in relation to these factors. The findings from this section will be taken into account when I present my evaluation of the conjectured CMOs that relate to patient involvement in patient safety in the subsequent findings chapters of this thesis.

5.2 Bishop: Implementation of ERAS -Developing the Programme

5.2.1 Organisational Context

Bishop was the first of the three cases to implement an ERAS programme and at the time of this study ERAS had been running on the unit for approximately two and a half years. Bishop was a surgical unit specialising in the care of patients undergoing lower gastrointestinal (colorectal) cancer surgery and patients with other conditions of the lower gastrointestinal tract. Most of these procedures were associated with the ERAS programme, the most common of which were large bowel resections (colectomy), which is surgery to remove all or part of the large bowel, which was a procedure carried out under general anaesthetic using minimally invasive laparoscopic techniques. The ward had capacity for twenty patients and during my observations the ward was usually running at full capacity with the majority of patients being planned admissions. The controlled and standardised admission criteria associated with Bishop was helpful when implementing the ERAS programme as the

organisational context of the ward lends itself to the fairly standardised approach to care associated with an ERAS programme.

5.2.2 Opinion Leaders

There was one main opinion leader who held a senior and apparently influential position and this individual had encouraged other members of the team to engage with the ERAS programme, creating a critical mass of interest and support in the implementation of ERAS Bishop. There were five consultant surgeons based on Bishop, of which four were engaged with the ERAS programme, as described in the following data extract. Although one consultant had elected not to engage with the programme, this did not appear to have a detrimental effect on the overall implementation of ERAS on the unit.

“The message from the top is a big influence. We’ve got five consultants here, four of whom are very positive and encouraging and push enhanced recovery”. [Case B: RN7]

One of these consultants was the main protagonist for the introduction of ERAS onto the unit and this individual was also involved in developing the ERAS programme for Bishop. The nurse who was tasked with leading the implementation project highlighted this consultant’s role in the development of the ward’s ERAS programme as an influential factor during the implementation process. This implementation lead nurse also explained how some of the nursing team took part in site visits to surgical units that had already implemented an ERAS programme, which she believed helped to develop a ‘critical mass’ of enthusiasm and support for ERAS among the staff on Bishop.

“The push was coming from [...] the consultant [...] when [consultant] came in, started talking about enhanced recovery [...] wanted us to be enthusiastic about the programme, so wanted us to go and learn about it. And we did. There was quite a few of us went so we all knew the background.” [Case B: RN7]

In addition to the support and encouragement of the surgical consultant, some of the nursing staff also took part in study days relating to ERAS and these formal processes served

to raise awareness throughout the nursing team. This strategy also helped to promote diffusion of information relating to ERAS via ‘word of mouth’.

“Some of us had been away on study days [...] we knew the aims of what we were trying to achieve with enhanced recovery and we could see all the things that we were doing were making a difference with the patient. So we were all quite enthusiastic and passionate about it and it was just bringing it all together.” [Case B: RN7]

5.2.3 Project Champion

Bishop appointed a member of the staff to lead and coordinate the implementation process of ERAS on the unit and this individual took responsibility for encouraging and supporting involvement in the implementation process from other members of the team. Additional funding had been provided to Bishop to support the post of ERAS programme implementation lead and this role was assigned to a member of the nursing team. This nurse’s role was commonly referred to by other members of the team as the ‘ERAS Nurse’ and this individual acted as the champion for ERAS on the unit, actively encouraging nursing staff to become involved in the implementation process. The ERAS Nurse spoke about how she had striven to make staff part of the change associated with an ERAS programme and had also encouraged staff to take ‘ownership’ of the programme, describing specific strategies to support this approach.

“When we set things up I very much wanted it to be that it was part of the ward and that they had ownership of it [...] I had a board in the staff room which on every day we’d write comments on [...] I encouraged them (nurses) to write things as well [...] any ideas they had. Just try to include them in it [...] I had a daily nag as well. Anything that wasn’t being done, put it on there.” [Case B: RN7]

The ERAS Nurse indicated that she believed her dedicated role was a positive factor in encouraging other members of the nursing staff to become involved in the implementation process.

“So really my job was easy ‘cos they (nurses) were all receptive, wanted to do it and my job was just to put it all together. [...] And having me [...] totally focused on, and being able to monitor on a daily basis as well what was being done, what wasn’t being done, what wasn’t working from the patients’ point of view and we could look back and change things straight away. Maybe they (nurses) felt more involved because of that.” [Case B: RN7]

During the period leading up to the launch of ERAS on the unit, nursing staff were also provided with protected time away from their core duties to take part in teaching sessions about the ERAS programme, and these sessions were coordinated by the ERAS Nurse.

“We took the staff off and just did teaching sessions. Teaching them the principles of enhanced recovery [...] and took them through the pathway document before we launched it”. [Case B: RN7]

5.2.4. Development of an integrated care pathway (ICP)

Integrated care pathways (ICP) are multidisciplinary care management tools which map out chronologically key activities in a healthcare process, simultaneously acting as a workflow system and a record of care (Allen 2009). ICPs have becoming popular tools for service improvement and implementing standards within the health board under study and this was no exception on Bishop where a multidisciplinary project team was convened for the purpose of developing an ICP to use with the ERAS programme on the unit. Again, this team was led by the ERAS Nurse, who regarded the development of an ICP as an opportunity for providing consistency for nursing staff when were expected to engage with patients enrolled on the ERAS programme.

“[...] to try to get some consistency and get them all to agree we thought if we came up with a pathway that they all agreed at the outset [...] the nursing staff would know where they stood” [Case B: RN7]

The creation of an ICP helped formalise the ERAS programme on Bishop, integrating the programme interventions into the existing workflow. This process also provided staff with a further opportunity for involvement in developmental and implementation aspects of ERAS on the unit, with the support and guidance of the ERAS Nurse.

5.3 Albany: Implementation of ERAS - Developing the Programme

5.3.1 Organisational Context

At the time of this study an ERAS programme had been running on Albany for approximately eighteen months. Albany was a surgical unit specialising in the care of patients undergoing upper gastrointestinal, hepatobiliary and pancreatic surgery and the procedures associated with the ERAS programme were oesophagectomy, which is the removal of all or part of the oesophagus, and gastrectomy, where all or part of the stomach is removed. These procedures were carried out under general anaesthetic using an open surgery technique, in which a large incision is made in the patient's abdomen or chest. All ERAS patients treated and cared for on Albany were planned admissions and out of the many consultants aligned to the ward from the various specialties, there was only one consultant surgeon enrolling patients onto ERAS. Although the unit had capacity for 38 patients and was usually running at close to full capacity, this surgeon carried out approximately 80 operations per year on ERAS which resulted in a relatively low prevalence of ERAS patients on Albany at any one time. However, as Albany also provided treatment and care for urology patients, trauma and orthopaedic patients and 'general medical' patients, commonly referred to as 'outliers' this resulted in an unpredictability of patient admissions and many unplanned admissions. This unpredictable mix of patients on Albany could cause uncertainty in the planning and management of nursing care on the ward and these factors in turn, did not lend themselves to the fairly standardised approach of care associated with an ERAS programme.

5.3.2 Opinion Leaders

Only one of the consultant surgeons on Albany was engaged with ERAS and this individual had been the main protagonist for the adoption and implementation of an ERAS programme

on the unit. However, unlike Bishop, there had been little effort to engage members of the wider team in the development or implementation of ERAS on Albany, with much of this work being carried out by a small group staff which did not include any of the staff nurses employed on the unit. In summary, as with Bishop there was one main opinion leader who held a senior and apparently influential position, but this individual did not invoke strategies to encourage other members of the team to engage with the ERAS programme, other than the creation of a MDT project team which I will now describe.

5.3.3 Project champion

Albany appointed a member of the nursing staff to lead and coordinate the implementation process of an ERAS programme on the unit. Unlike their counterpart in Bishop, this individual did not engage with staff outside of the MDT group designated as the project team. A multidisciplinary project team was set up by the aforementioned consultant surgeon and this team was tasked with the development and implementation of an ERAS programme on Albany. The team was led by a specialist nurse who was seconded from their substantive post for two months, specifically to carry out the role of ERAS implementation lead on Albany. Although there was this project team in place, there was little attempt made by this team to involve the nursing staff based on Albany in the development or implementation process and nursing staff referred to a lack of teaching and preparation in relation to ERAS. Nursing staff I spoke with appeared disappointed with this and disillusioned with the ERAS project as a result of this perceived lack of opportunity for involvement in the programme development and implementation.

“When enhanced recovery was put in, it was just sort of like, um, plonked on us really. We didn’t have any sort of teaching [...] It was just developed and just, ‘this is what we’re gonna use now’ [...] in hindsight I think maybe it would have been nice for us to have a bit of teaching on it, you know? So we felt more involved.” [Case A: RN1]

5.3.4 Development of an ICP

The implementation project team were also tasked with developing an ICP for use with the ERAS programme on Albany, although again there was no engagement with any staff from Albany outside of the project team. The Specialist Nurse explained that due to the complexities of the conditions of the ERAS patients being treated on Albany, the ICPs that were developed by the team were more involved than other areas. This Specialist Nurse specifically referred to Bishop in this context and described how she was aware that colleagues on Bishop had previously developed an ICP for ERAS during their implementation phase. It is rare that pathways are developed anew (Allen 2014) and it is common practice to build on pathways developed elsewhere, or to modify locally developed pathways (Allen 2014) and the Specialist Nurse described how the Albany team had ‘borrowed’ a copy of the ICP from Bishop and adapted it to suit what she described as the ‘completely different needs’ of the patients being cared for on Albany.

“They [Bishop] had started their programme. So we borrowed a copy of theirs [ICP] and sort of started adapting it, really. But then, ours is completely different because there are a completely different set of patients with a completely different set of needs”. [Case A: SNP]

This criticism of the fitness for purpose of the ICP ‘borrowed’ from Bishop was highlighted by the fact that the project team on Albany had developed a unique ICP for each of the three surgical procedures aligned to ERAS, which in turn is likely to have increased the complexity of the implementation process. This was also a rare example of shared learning between Albany and Bishop during the implementation process, as there was no other collaboration between the units or sharing of best practices related to ERAS. The Specialist Nurse appeared somewhat dejected when reflecting on the implementation process on Albany, citing a ‘missed opportunity’.

“It felt a bit of a cobbler, to be honest, in the beginning [...] I thought it was a real missed opportunity for the upper GI team.” [Case A: SNP]

The creation of ICPs helped formalise the ERAS programme on Albany, integrating the programme interventions into the existing workflow. Unlike Bishop, this process did not provide staff outside of the project group with any opportunity for involvement in developmental and implementation aspects of ERAS on the unit. That three distinct ICPs were developed may have added to the complexity of the implementation process, and it was clear the specialist nurse involved was not satisfied with the process that took place on Albany in relation to the implementation of ERAS.

5.4 Columbus: Implementation of ERAS - Developing the Programme

5.4.1 Organisational Context

At the time of this study an ERAS programme had been running on Columbus for approximately two years. Columbus was a surgical unit used exclusively for the treatment and care of elective orthopaedic patients and although patients were admitted for a range of orthopaedic procedures, the only one associated with the ERAS programme was a total knee replacement (TKR), in which the knee is replaced by an artificial joint. All admissions to Columbus were planned in advance and there was only one consultant surgeon at the time of this study who was enrolling patients onto ERAS, carrying out approximately 100 operations of this type in a year. This resulted in a relatively low prevalence of ERAS patients on the unit at any one time. The ward had capacity for 27 patients and during my observations there was a wide variation in the bed occupancy levels, ranging from fully occupied some days, to less than half occupancy on other days. As with Bishop, the controlled and standardised admission criteria associated with Columbus was helpful when implementing the ERAS programme, as the organisational context of the ward lends itself to the fairly standardised approach to care associated with an ERAS programme. However, as I will now discuss, the implementation process was much different to that of Bishop.

5.4.2 Opinion Leader

The implementation of ERAS on Columbus appears to have been quite low key and although there were over thirty consultants aligned to the unit, only one of these had adopted the use of an ERAS programme. The implementation process on Columbus did have similarities

with that of Albany, with only one consultant using ERAS with a specific group of patients, which had seemingly resulted in a lack of, or certainly a reduced level of staff involvement during the development and implementation of ERAS on Columbus. In summary, as with the other two cases, there was one main opinion leader who held a senior position, but this individual did not invoke obvious strategies to encourage other members of the team to engage with the ERAS programme implementation or development.

5.4.3 Project Champion

The nurse manager of Columbus had been designated as the 'lead' for the ERAS programme on the unit, although this appeared to be a 'notional' role, with no direct involvement in ERAS. There were also three other members of the nursing team who were involved with certain aspects of ERAS, although this was limited to collecting audit data for the consultant surgeon. Other than this, there was no formal project team involved in the development of ERAS related documentation. It was apparent from my discussions with the nurse manager during my observations that she believed insufficient resources had been made available to Columbus for staff to effectively engage with and sustain an ERAS programme on the unit. The nurse manager also specifically referred to the additional resources required for the data collection element of the audit process, which certain nursing staff were engaged in on behalf of the consultant surgeon. The nurse manager also described how she was aware of the additional funding that had been provided to Bishop to support their programme implementation and it was evident this was a matter of contention. When discussing the implementation of ERAS on Columbus, one nurse described to me how they felt disengaged from the process and explained that they hadn't been made aware of the programme prior to its introduction on the unit. This is reminiscent of the comment made by a nurse from Albany who referred to ERAS being 'just plonked' on the nursing staff.

"When it all came in it was sort of like, 'this is ERAS', and I feel we should have all been brought together and said, 'Right, this is ERAS. This is what's going to happen'."

[Case C: RN4]

5.4.4 Development of an ICP

As described, in contrast to Bishop and Albany, there was not ICP developed for use with the ERAS programme on Columbus. Some of the challenges associated with developing a single pathway for ERAS patients were highlighted to me by staff on Columbus during my observations, for example it was common for nurses to relate to me that there were over 30 consultants aligned to Columbus with each of these surgeons having a slightly different approach to surgical treatment and care and during my observations this was often cited as the main barrier to the introduction of ICPs on the unit.

5.5 ERAS Implementation: Developing the Programme - Cross Case Comparisons

I will now provide a brief summary of those factors associated with the implementation of ERAS, specifically in relation to the initial development and subsequent launch of the programme across the three case studies. As discussed, these factors have an influence on the subsequent efforts of the respective cases to sustain ERAS on their units and this will be taken into consideration during the course of my findings chapters.

5.5.1 Organisational Context

There were diverse groups of patients being treated and cared for across the three units under study, although Albany had considerably more diversity than the other two. Of the three cases, Bishop was the one which best lends itself to a standardised approach to care as exemplified in an ERAS programmes, and this was predominantly related to the fact that the vast majority of patients admitted to Bishop would be enrolled onto an ERAS programme. This was not the case in Albany and Columbus, where only a small minority were treated as ERAS patients. This was likely to impact on the acceptance of the ERAS programme by staff on the respective units, as those on Bishop would have far more opportunities to familiarise themselves with the ERAS programme than staff on Albany and Columbus, due to the number of ERAS patients they would encounter. It should also be noted that, although all patients taking part in an ERAS programme are designated as undergoing 'major surgery', there are varying degrees to this and it was clearly the case that

those patients being treated on Albany were exposed to the most severe type of surgery of all the cases, with the likelihood of the most complex and lengthy recovery.

5.5.2 Opinion Leaders

In all three cases it was clear that ERAS was an initiative that was identified and driven by consultant surgeons, but one that nurses were depended on to support implementation. The implementation process on Bishop was reinforced by the fact that four of the five consultant surgeons were engaged with, and supportive of, the ERAS programme, acting as what Greenhalgh et al (2004) defined as 'expert opinion leaders', with evidence from the literature demonstrating that such opinion leaders can influence through their authority and status. The approach taken by Bishop had clearly led to engagement of wider members of the team in the process and enabled the unit to develop a 'critical mass' of support for the programme during the early stages of implementation. This was not the case with Albany and Columbus, where the consultants driving the implementation, although they held similar influential positions, had chosen to keep the numbers of staff involved in the process to a minimum. This had rationed the opportunities for diffusion of ERAS on these units and ultimately restricted the opportunity for nurses to become involved in the early stages of the implementation process.

5.5.3 Project Champion

Early and widespread involvement of staff at all levels can enhance the success of implementation of an innovation such as ERAS and implementation can also be supported by a formal dissemination programme (Greenhalgh et al 2004). Successful implementation can also depend on the motivation, capacity and confidence of individual practitioners and to enhance the chances of this appropriate training and support should be provided to inform staff how the innovation will fit in with their daily work and how it may affect them personally (Greenhalgh et al 2004). Bishop set the standard among the three cases in these respects, providing formal dissemination and training whilst striving to generate interest and enthusiasm for ERAS, mainly through the work of the designated project champion, the ERAS Nurse. This nurse acted as a key individual during implementation of ERAS on Bishop

with seemingly good personal relationships with colleagues and a willingness to back the innovation. These are traits which Greenhalgh et al (2004) associate with a 'change champion' and are more likely to result in a positive adoption of innovations.

Conversely, on Albany and Columbus there was seemingly little effort made to raise awareness of nursing staff through any training or formal dissemination of information relating to ERAS. There were 'lead' nurses associated with the implementation of ERAS on these units but, in the case of Albany, this individual did not engage with the wider teams outside of the core project team, whilst on Columbus the role was seemingly a notional one. There was obvious dissatisfaction among some of the nursing staff on Albany who believed there was little support for the perceived changes in their practice associated with an ERAS programme and they also spoke about their lack of involvement in the implementation process. On Columbus, the implementation process was very low key with few staff seemingly aware of this taking place and although an individual was assigned as 'ERAS lead, there was seemingly little involvement from this individual in relation to the development and implementation of ERAS and subsequently there was little engagement from the wider nursing team, some of whom seemed unaware of the ERAS programme implementation.

5.5.4 Development of ICPs

The ICP development process on Bishop encouraged staff to engage with development of the ICP and implementation of ERAS, whereas the process on Albany indicated that the project team were isolated from the wider cohort of staff. There was no ICP or associated documentation devised for Columbus in relation to the ERAS programme and there was seemingly little obvious change required as no formal implementation process had appeared to have taken place for the ERAS programme. This is interesting in the context of the work of DiMaggio and Powell (1991), who suggest that, in some situations, the value of pathways may lie primarily in their role as legitimising devices, as there was no opportunity for this 'legitimation' to take place on Columbus, in contrast to the other cases. Further to this Bryan et al (2002) suggest that the implementation of pathways is a distinctive stage of the programmes implementation process which should involve raising staff awareness of the documentation and its use, and cultivating commitment and enthusiasm among staff

who are expected to use the pathway. Again, this opportunity was afforded to staff from Bishop to a far greater extent than staff on Albany, whereas once again, the lack of an ICP meant this was not something that Columbus staff would have experienced.

Overall, the implementation process undertaken by Bishop had seen attempts to engage with and involve the wider cohort of nursing staff in relation to the initial development and launch of ERAS. This approach helped to generate a positive attitude and provide staff with some insight into the rationale and benefits associated with patient care in relation to the programme. In contrast, the approach taken by Albany in the early stages of implementation had not allowed for engagement with the wider nursing team who were expected to work with the ERAS programme on the hospital ward. It was apparent from my fieldwork that nurses based on Albany were not particularly satisfied with this lack of involvement and made reference to a subsequent lack of insight into the ERAS programme on the ward.

The overall comparison of data between Albany and Bishop suggests that the early stages of implementation process were a less favourable experience for Albany and this appears to have had a negative influence on the receptiveness of Albany ward based nursing staff towards ERAS. Columbus was very different to both Bishop and Albany as there was no obvious implementation process undertaken and the activities relating to the initial development of ERAS appeared to have taken place 'behind the scenes'. It should be noted that, as my research developed, it became apparent that there was little to distinguish between the differences in care provided to ERAS patients compared to 'non ERAS' patients on Columbus, certainly in relation to the overall aims of this research and I will explore the implications of this in more detail as the thesis progresses.

This section has drawn attention to the relevance of involving staff in the early stages of healthcare quality and safety improvement initiatives and consequently the role of healthcare staff in patient involvement in patient safety. We have already seen in the literature review the importance of healthcare staff in any attempt to involve patients in their own safety and an understanding of the processes involved in ERAS and their relevance of these to patient care is an important factor when considering the outcomes

across the three case studies. This will be taken into consideration when I present the conjectured CMOs and my subsequent evaluation of these CMOs across the three case studies. However, prior to this, I will firstly give further consideration of the implementation process for ERAS during the pre-admission and ward aspects of the programme across the three case sites.

5.6 Implementation of ERAS: Sustaining the Programme

In this section of the chapter I consider the processes undertaken and resources engaged to sustain the ERAS programme as part of the ongoing process of implementation in the respective clinical areas. This is presented in such a way that reflects the two distinct phases of ERAS under study, the pre-admission stage and the ward based stage. I present this on a case by case basis, starting with the preadmission elements of ERAS which involves patients attending a pre-assessment appointment and, in the case of Columbus a patient education session, prior to their hospital admission. In accordance with the aims and objectives of this thesis I will be focusing on the provision of information to patients during these appointments which relates to their potential involvement in patient safety aspects of the ERAS programme through early and continuing postoperative mobility. Again, I will use the detail presented here to support my subsequent evaluation of the conjectured CMOs. Before providing detailed analysis of the pre-admission aspects of ERAS, I will firstly present a brief overview of the pre-admission arrangements for ERAS patients in each of the cases under study.

5.6.1 Pre-admission: An overview of the cases

All patients scheduled for surgery on Bishop and Albany who were enrolled on an ERAS programme were required to attend a compulsory pre-assessment appointment. On Bishop and Albany, the fitness for surgery and education elements required as part of the pre-admission process were combined in a single appointment, however on Columbus they were delivered in two separate appointments. This resulted in patients scheduled for surgery on Columbus having to attend a compulsory one-to-one pre-assessment appointment to establish physiological fitness for surgery, whilst also being invited to

participate in a separate group 'patient education session'. These group education sessions were not specifically for ERAS patients, rather they were designed for patients scheduled for either a total knee replacement (TKR) or a total hip replacement (THR) and although all these patients should receive an invitation to a session it was not compulsory for patients to attend. As all ERAS patients on Columbus were scheduled for a TKR, they would also be eligible to attend a patient education session.

I will now present detailed analysis of the pre-admission aspects of the respective cases, focusing on the provision of information relating to patient involvement in patient safety through an ERAS programme. This section is presented on a case by case basis, with each case divided into key themes which were derived from my data in relation to patient involvement in early and continuing postoperative mobilisation. Each of these cases are supported by data extracts from my observations and my interviews with nursing staff. I start each case by providing details about the structure of the appointment, and consideration of what staff were involved and where and when the appointment took place. I then consider the information provided to patients during the appointments in relation to the ERAS programme. This information is generally related to attempts by staff to manage patients' expectations in terms of their upcoming hospital care and includes staff efforts to explain the mobility expectations to patients, including goals for this mobility. There are also attempts by staff to encourage patients to adopt an 'active' approach to their postoperative care and to consider themselves 'part of the team'. Staff also use the pre-admission appointment to present a rationale to patients for their involvement in the mobility elements of an ERAS programme, specifically in relation to patient safety.

5.7 Bishop: Pre-assessment appointments

On Bishop the sequence and content of the pre-assessment appointments were structured in accordance with the ICP which had been developed as part of the implementation process for ERAS. The appointments were delivered by a multidisciplinary team and during the course of the appointment each patient met on a one to one basis with a registered nurse, a dietician, a junior grade doctor and a physiotherapist. Each appointment took on average around two hours to complete and a considerable amount of information was

collected by healthcare professionals and imparted to patients during this process. Only a relatively small proportion of this information related directly to ERAS, which included establishing with patients the need for early and continuing postoperative mobility.

On Bishop the nurses involved in the pre-assessment appointments were part of the ward based nursing team, who were also responsible for the day-to-day nursing care of patients on the ward. The ward based nurses' involvement in the pre-assessment appointments was organised by the ward manager on a rotational basis to ensure as many of the nurses as possible were given the opportunity to take part, which can be identified as a useful strategy in terms of engaging nursing staff with the ERAS programme. During pre-assessment appointments the assigned nurse was required to facilitate and coordinate the appointment, for example the nurse was required to introduce the patients to the other members of the MDT involved in the appointment and complete relevant elements of the ERAS ICP. The nurse was also responsible for delivering information and education relating to ERAS, including the need for early and continuing postoperative mobility. This involvement in the pre-assessment appointment provided the ward based nurses with an opportunity to begin to establish a degree of rapport with patients prior to their hospital admission. In some instances, this could promote continuity of care between patients and nurses.

“A lot of the time we see patients come into pre-assessment clinic, you kind of feel like you have ownership of those patients early on [...] we would have met most of them before” [Case B: RN4]

The involvement of nurses in pre-assessment could also provide nurses with the opportunity to learn about patients and allow patients an opportunity to tell their stories. One nurse described how this information could be useful in facilitating communication between nurses and patients and assisting nurses to develop relationships with patients during their hospital stay.

“You still learn a lot from sitting down and talking to a patient. Which sometimes you don't get a lot of time to do when you're working on the ward. [...] talk to them about

their illness and plans and that sort of thing. You can reinforce it once they're here [...] But I think it's nice as well that you can sort of chat. [...] they see you as a person, rather than a nurse." [Case B: RN3]

The appointments on Bishop took place in a room on the hospital ward a routine part of the pre-assessment appointment involved patients being shown around the hospital ward as part of an orientation exercise. There were perceived benefits associated with this, as described by some of the nurses.

"In pre assessment I do try to walk them around. Walk them round the circuit [...] so I think they know the layout of the ward as well." [Case B: RN3]

"We're meeting patients' pre-op [...] they get to know staff. [...] We show them round the ward so they're familiar with where they're going to come." [Case B: RN6]

As part of this orientation, patients would usually meet other members of the nursing team although due to the variation in shift patterns it was not guaranteed that during their hospitalisation patients would be under the care of these same nurses. Other potential benefits to this spatial orientation and reference to a 'circuit' in which patients' would be expected to carry out their postoperative mobilisation are in relation to preparing patients in advance for their admission and the expectations associated with this. This approach can be considered as an early introduction to patients of the concept of an 'active' type of recovery.

5.7.1 Bishop: Explaining the ERAS programme to patients

On Bishop, patients were informed during the pre-assessment appointment that they will be taking part in an ERAS programme which would require them to sit out of bed and walk as soon as possible following surgery. Patients were made aware that the timing of this postoperative mobility would be dependent on the type of operation they have and the outcome of this operation and that, following their return to the ward after surgery, they will be advised by physiotherapy staff and nursing staff when they should start this

mobilisation. In the following extract from observational field notes of a pre-assessment appointment, a nurse is introducing a patient to the ERAS programme for the first time.

The nurse introduced the ERAS programme to the patient. The overall purpose of the programme was described to the patient as 'Getting you back to normality as soon as you can' [...] The nurse re-emphasised the expectations of postoperative mobility during the course of the appointment: 'Key to it all is that we get you moving as soon as possible and keep you moving'. [Case B: Field Notes Pre-assessment]

This observational data is supported by data generated in interviews with nursing staff and the ERAS Nurse made reference to 'key messages' relating to ERAS which patients should be aware of during the pre-assessment appointment, whilst another nurse made reference to addressing patients' preconceptions.

"The key messages from the patients' point of view is that they're mobile, that they don't stay in bed." [Case B: RN7]

"It's kind of getting rid of those preconceptions [...] pre-assessment kind of busts those myths [...] They're not surprised when we get them moving quicker. They're not surprised when they're going home a lot quicker". [Case B: RN4]

During the pre-assessment appointment on Bishop, patients were also presented with specific mobility goals relating to ERAS. For example, it is explained to patients that once they start walking postoperatively they will be encouraged to walk a longer distance each day with the aim being to walk at least 60 metres, four to six times per day. This information was presented with the caution that it will be dependent on what each individual patient can 'manage'. This is demonstrated in the following data extract from observational field notes in which a nurse is discussing postoperative mobilisation with a patient.

'We like to get you out of bed the same day [...] we don't always manage it. If you are up to it, sitting in the chair, no more than that. Next day will be laps, four a day if you can manage it.' [Case B: Field notes Pre-assessment]

The pre-assessment appointment was also used as an opportunity for staff to encourage patients' to consider taking a different role to their postoperative recovery than might be traditionally expected and to support this, patients were advised to prepare themselves to take an active role in their postoperative care, and were encouraged to think of themselves as part of the clinical team.

The nurse emphasised the expectations of postoperative mobility and provided reassurance to the patient that they would be supported in this, stating 'We're here to help you. You won't be on your own.' [...] The nurse reinforced this later on in the appointment, telling the patient 'You are part of the team.' [Case B: Field notes Pre-assessment]

5.7.2 Bishop: Presenting a rationale for involvement

During the pre-assessment appointment on Bishop, patients were provided with a rationale for taking part in an ERAS programme, specifically in relation to postoperative mobility, which was presented in the context of the reduced risks associated with an ERAS type approach to postoperative care.

The patient was told they would be expected to be 'sitting up and sitting out of bed' which would reduce the risks of chest infection. [...] The nurse then explained the rationale behind the enhanced recovery process – 'It's about getting you up and about as soon as possible, it reduces the risk of blood clots, fatigue and chest infection'. [Case B: Field Notes Pre-assessment]

There was also information provided to patients in relation to the benefits associated with a shorter hospital stay, but this was not elaborated on in relation to specific risks associated with hospital care.

“It’s about patient expectation changing as well. You know, you do learn all about the enhanced recovery programme and what we do and all the benefits of it. And the benefit of it is to get you home earlier. That’s our ultimate goal.” [Case B: RN6]

In respect to presenting the rationale for ERAS, there was also evidence that there was a strategy on Bishop to present safety-related information to patients in such a way that they were provided with what could be described as a ‘sanitised’ version of the risks associated with their forthcoming healthcare.

“We paint a rosy picture in pre-assessment [...] we don’t tell them all the things that could go wrong, all the risks”. [Case B: RN7]

5.8 Albany: Pre-assessment appointments

As with Bishop, the sequence and content of the pre-assessment appointments on Albany were pre-defined in accordance with the ICPs which had been developed for ERAS. The appointments were delivered by a multidisciplinary team and each patient met on a one to one basis with a registered nurse, a dietician, a junior grade doctor and a physiotherapist. A notable difference in the approach taken by Albany in comparison to Bishop was that the pre-assessment appointment was led by one of the specialist nurse team aligned to the consultant surgeon using ERAS, but who were not part of the nursing team responsible for the day to day nursing care of patients on the hospital ward. In relation to the pre-assessment process, the specialist nurse was responsible for facilitating and coordinating the appointment, requiring them to introduce patients to the other members of the MDT involved in the appointment and complete relevant elements of the ERAS ICP. The specialist nurse was also responsible for delivering information and education relating to ERAS, including the need for early and continuing postoperative mobility. The pre-assessment appointments for Albany took place either in a side room on the hospital ward or in the main outpatients’ department of the hospital, depending on the availability of these rooms. The outpatients’ department was in a separate part of the hospital so it was not feasible for patients to visit the ward in this case. In contrast to Bishop, those patients who had a pre-assessment appointment on the hospital ward were not afforded the opportunity to view

the ward, which according to one nurse appeared to relate to concerns about patients being unsettled during these visits.

“Sometimes when they’re seen on the, come onto the ward, they might come at a very difficult time for the ward staff. [...] say there’s an arrest, something that’s a medical emergency and they witness that [...] that can be quite scary can’t it?” [Case A: RN6]

5.8.1. Albany: Explaining the ERAS programme to patients

On Albany, as with Bishop, patients were told during the pre-assessment appointment that they were taking part in an ERAS programme which would require them to sit out of bed and walk as soon as possible following surgery. In the following extract from observational field notes of a pre-assessment appointment, the specialist nurse is introducing a patient to the ERAS programme for the first time.

The specialist nurse introduced the ERAS programme as being ‘all basic, common sense stuff, brought into one programme’ [...] The specialist nurse went on to tell the patient ‘Getting up and moving are the principles of enhanced recovery’ [Case A: Field notes pre-assessment]

Patients were also presented with specific postoperative mobility goals relating to ERAS which were the same as those presented on Bishop with the overall aim being to walk at least 60 metres four to six times per day.

“Getting the patient involved in [...] what goals are expected for them [...] All that comes out in the pre-assessment process and they’re hopefully told that this is what we’re gonna be expecting of them” [Case A: SNP]

This information was presented with the caveat that this involvement will be dependent on what each individual patient can ‘manage’, dependent on their physical condition postoperatively, as ERAS patients on Albany were scheduled to undergo full or partial

oesophagectomy or gastrectomy. In support of this, patients were prepared for the potentially severe physical effects of the operation.

During the appointment, the specialist nurse attempts to prepare the patient for the effects of the surgery they will be undergoing, emphasising the severity of the operation and the immediate and early postoperative implications of this surgery. The nurse also makes specific reference to the physical attachments the patient may have in place when they regain consciousness following the operation. These attachments could comprise of a catheter, an intravenous drip, an oxygen mask, a naso-gastric tube, various drains, an epidural and a jejunostomy. This was discussed in the context of how it may have a detrimental effect on patients' attempts at postoperative rehabilitation, particularly mobilisation. [Case A field notes]

During another pre-assessment appointment, the specialist nurse told a patient they would be 'as weak as a kitten' following the operation, whilst in another pre-assessment the specialist nurse commented to the patient that the operation would 'knock them for six'. In spite of this, patients were still encouraged to prepare themselves for an active role in their ERAS postoperative care, with the following data emphasising the expectation for this particular patient to do things for themselves, in contrast to more 'traditional' convalescence.

An active approach was supported by staff during the pre-assessment appointment. The nurse remarked to the patient that ERAS was about 'Getting you to do things for yourself. This is the thing about enhanced recovery'. [Case A: Field notes pre-assessment xx]

5.8.2. Albany: Presenting a rationale for involvement

During pre-assessment patients on Albany are presented with information about the rationale for early and continuing postoperative mobility as part of an ERAS programme, with clear links made to the advantages of patient involvement in patient safety.

The importance of early and continuing mobility was emphasised and it was explained to the patient that there were clear links between postoperative mobilisation and a reduced risk of blood clots (DVTs) and chest infections [Case A pre-assessment field notes xx]

However, there appeared to be some concern among nursing staff that patients would be overwhelmed by too much information relating to the potential risks associated with their treatment and subsequent hospital care. So, as with Bishop, risks are presented to patients as a rationale for enrolment in an ERAS programme and in a sanitised form, rather than a full account of the myriad of risks patients may be exposed to.

“Obviously they’ve been told a lot of these things when they’re consented for theatre. [...] They’ve already had this barrage of information. [...] And then there’s obviously the risk, you know, the things that we are trying to do. Preventing pressure sore [...] preventing deep vein thrombosis, you know the chest infections, things like that. They’re already told a lot of things and then we come along and we’ve got a whole new load of risk.” [Case A: RN1]

There were many similarities between Albany and Bishop in regards to the pre-assessment appointment. As with Bishop, the appointment was compulsory so all ERAS patients on Albany were expected to attend a pre-assessment appointment prior to surgery. During the appointment information was provided to patients about the ERAS programme and the active role patients would be expected to undertake, although on Albany it was emphasised to patients that the effects of their operation would have a strong influence on their postoperative mobility, particularly in the early stages of postoperative recovery. Associated risk and safety related information was provided to patients which provided a rationale for their involvement in this aspect of the programme and this information was focused on the benefits of early and continuing postoperative mobility. In contrast to Bishop, the appointment on Albany was coordinated by one of the specialist nurses aligned to the surgical consultant engaged with ERAS, rather than a member of the ward based nursing team. Unlike Bishop, patients on Albany were not provided with the opportunity during pre-assessment to familiarise themselves with the ward.

5.9 Columbus: Patient Education Session

On Columbus the delivery of information and education took place by way of a group 'patient education session' consisting of between 20 and 30 participants for each session rather than on a 'one-to-one' basis as part of a pre-assessment appointment, as was the case in Albany and Bishop. These patient education sessions were run twice weekly, once for patients who were scheduled to undergo a total hip replacement (THR), and once for those scheduled for a total knee replacement (TKR). The sessions were delivered by a multidisciplinary team consisting of specialist nurses alongside a physiotherapist, and an occupational therapy technician. Each session was led by one of the specialist nurses who was responsible for facilitating and coordinating the session and who was also responsible for delivering many elements of the education session. This specialist nurse was not involved in the day to day nursing care of the patients on the hospital ward and there was no representation in the education session from the ward based nurses. The patient education sessions took place in a seminar room adjoining the orthopaedic outpatients' department in the main hospital and patients were not afforded the opportunity to visit the ward during the session.

The patient education sessions on Columbus were not specifically aligned to the ERAS programme and pre-dated the introduction of ERAS onto the unit by approximately five years. (Patients who were to be enrolled on ERAS were made aware of this by their consultant surgeon during a pre-assessment appointment which took place separately to the education session.) This being the case, the information and education presented during each session was designed to be applicable and relevant to all those patients who attended, not just those enrolled on ERAS. One of the specialist nurses responsible for coordinating the sessions described the approach taken to delivering the information during patient education sessions as 'general' and 'vague' and remarked that 'we don't segregate people in this session'. This was supported by another of the specialist nurses involved in the sessions who explained that the team delivering the education session were careful not to label patients and attempted to be inclusive in the sessions, thus avoiding alerting patients to any possible variations in their treatment plan, compared to other patients.

“This ERAS programme, when it was rolled out first, we felt in patient education we didn’t want to say ‘Oh you’re an ERAS patient. And you’re not.’ ‘Well, am I being treated differently?’ So it’s how you word it. Cos you’re alienating, or they felt they’re having special treatment.” [Case C: RN7]

5.9.1 Columbus: Explaining the ERAS programme to patients

The main purpose of the education session was to inform patients of what they could expect before, during and after surgery and to explain to patients what they could do to help prepare for this. So although the sessions were not specifically designed for ERAS patients, the aspirations of the session were analogous to the requirements of an ERAS programme in relation to the provision of information and education. Although there was no specific reference made to ERAS during the sessions I observed, patients were made aware of the requirements for early and continuing postoperative mobilisation.

The physiotherapist explains to the group, ‘for most of you, you will be up the same day of your operation’. There was no specific reference made to ERAS. [Case C: Field notes patient education session]

Patients were also presented with information about postoperative mobility and the related exercises they would be expected to carry out postoperatively, being told they would be expected to meet what were referred to as ‘physio goals’. There was a less flexible approach presented in relation to these postoperative expectations than in the other two cases where patients had been made aware that postoperative goals would be dependent on the outcome of their surgery. In contrast to this, patients on Columbus patients were told they would be expected to mobilise on the day of surgery, or at the latest on the following day. As all patients participating in the education sessions on Columbus were scheduled for the same type of surgical procedure, it was made clear by staff in the education sessions that the expectation was the vast majority of patients would follow a similar recovery and rehabilitation trajectory.

The physiotherapist announced to the group that in relation to the exercise 'For most of you, you will be up the same day of your operation'. The physiotherapist went on to explain to patients 'The quicker you can do this, the quicker you can go home [...] this is why we nag and nag and nag you'. There was no reference made to specific mobility goals during this education session. [...] The physiotherapist also told the group 'It's hard work and it's gonna be sore for you [...] if you're expecting it, you can better prepare for it'. [Case C: Field notes patient education session]

It is clear from this that patients were under no allusions that they would be expected to undertake an 'active' type of role in their postoperative recovery. There was also some data which demonstrate that staff encouraged patients to consider themselves as part of the team during their hospital stay.

The nurse said to the group "We are a team and you are the centre of it". [Case C: Field notes patient education session]

5.9.2 Columbus: Presenting a rationale for involvement

Patients on Columbus were advised that the main aim of the healthcare staff was to help to get them back to full health as quickly as possible, without jeopardising their safety.

"Our aim is to get you in and out as quickly as possible. But safely." [Case C: RN7]

Information was also presented to patients during the patient education sessions relating to the rationale for early and ongoing postoperative mobilisation, with specific reference made to 'best evidence'.

The group are told 'Best evidence is early mobilisation, not bed rest' [...] and the quicker they are up postoperatively, the less chance there is of developing a chest infection or a blood clot. [Case C: Field notes patient education session]

Patients were also told that every effort would be made to expedite discharge as they will 'recover better at home' [Case C: Field notes]. This is an extension on the information provided in the pre-assessment appointment carried out by the other case studies, where there was a focus on the risks associated with postoperative immobility. In the following extract a nurse explains how they would advise patients to be wary of 'bugs' in the hospital, emphasising their risk to exposure following major surgery.

"Our message is, the less time you're in hospital the better it is for you. And a lot of patients (ask) 'Why is that?' Well if you think of hospitals, there's lots of patients. Bugs. Patients' relatives come in and could be bringing anything in." [Case C: RN7]

5.9.3 Columbus Patient Education Sessions: Who attends and when?

A consequence of Columbus holding optional patient education sessions separately from the compulsory elements of the pre-assessment appointment was the relatively low proportion of eligible patients who attended. Statistical data provided by the specialist nurse involved in coordinating the sessions demonstrated that there were a total of 677 attendees to the patient education sessions in 2011/12, comprised of 346 patients scheduled for a THR and 331 for a TKR. Data provided by the National Joint Registry (2014) demonstrates there were 911 TKRs carried out in the Health Board during the corresponding year, which equates to an attendance rate to the education sessions of approximately 36% of eligible patients. Staff responsible for the education sessions were not satisfied with this low level of attendance and explained how efforts had been made to address this issue, including attempts to ensure that all eligible patients were receiving invitations to a session and that these invitations were sent at an appropriate time. However, it was clearly a source of frustration for staff and an issue that was proving difficult to resolve due to the perceived complexities of the referral process.

"The referral to get patients into education clinic is so hard [...] if we had more people it would be brilliant. It's just how we would get those patients in. We need to explore more again, to work on that [...] we've tried to sort out a way of doing it [...] cos it's a complex, complex, referral process." [Case C: RN7]

Although attendance to the education sessions was low, staff explained that there were certain advantages to this format, as opposed to a one-to-one type appointment. The education sessions took place in a seemingly more relaxed non-clinical environment providing an open forum, encouraging patients to ask questions.

“It’s also about giving them (patients) another opportunity to ask questions. Cos they’re usually quite intimidated when they go in to see the consultants. So it’s giving them [...] a bit of an open forum. In a very informal, non-clinical setting.” [Case C: RN6]

We can see that Columbus took a different approach to the other cases in respect of how they delivered the pre-admission education and information. However, the fact that the patient education session was not compulsory meant that there was a low rate of uptake from patients, which meant that many patients were not being exposed to any information and education prior to their hospital admission. Those patients who did attend an education session were provided with information about the benefits of taking an active role during their postoperative recovery, and were informed of the risks associated with their hospital stay which, during my observations, was presented in more detail than in the other two cases I had observed. There was an expectation from staff that Columbus patients undergoing TKRs would have relatively similar recovery trajectories and hence would be able to engage with the postoperative mobility as a matter of course. As with Albany, there were no members of the ward based nursing staff involved in the education sessions and similarly, patients’ were not afforded the opportunity to familiarise themselves with the hospital ward.

5.10 Summary of pre-admission implementation: cross case analysis

Although there were variations in each of the cases with respect to the ways in which education and information were presented to patients during a pre-admission appointment, the general content and overall aims and objective of delivering this information and education was very similar across all three cases. In particular, the information and

education aspects of the appointments were focused in each of the three cases on managing patients' expectations in relation to their upcoming hospital care and was related to the evidence base and rationale underlying early and continuing mobility. In all three cases patients were encouraged to think of themselves as taking an active role in their postoperative care and to consider themselves as a member of the clinical team, rather than as passive recipients of care. This can be related back to the ERAS programme and 'contracts of care' and suggestions of 'co-production' that are referred to in the related policy, and was in contrast to the more 'traditional' passive role that patients may be anticipating during their hospital care.

Across all three cases patients were also made aware they could expect a goal-orientated focus in their postoperative recovery and quite specific information was provided to patients to support this approach in relation to mobility. Of the three cases, it was only during pre-assessment appointments on Albany that consideration was made to the potentially severe effects of surgery on patients and how this might restrict their ability to take part in the expected postoperative mobility. During my observations this was not highlighted by staff on Bishop and observations of education sessions on Columbus revealed that staff were expectant that all patients would be in a position for involvement with postoperative mobility at an early stage of their recovery.

Only Bishop involved nursing staff from the ward based cohort in the pre-assessment appointments, with Albany and Columbus relying on specialist nurses to adopt the equivalent role during their respective pre-admission activities. This was similar to the level of involvement of nursing staff in the respective cases during the early stages of the implementation process previously discussed and has a potential impact on the ability of staff to understand the requirements and rationale of ERAS, and the subsequent support and involvement they would be expected to undertake during patients' care on the ward. As many of the nurses on Bishop who would be providing postoperative care to patients were given the opportunity to take part in pre-assessment appointments, there is a perceived advantage that this can help develop a sense of 'ownership' among staff in relation to ERAS and ERAS patients and this can be viewed as a further extension of the engagement of nursing staff on Bishop with the ERAS programme. This was not the case with Albany and

Bishop, where there were seemingly few (or no) opportunities for ward based nursing staff to engage with the pre-assessment activities relating to ERAS.

A feature shared by Albany and Bishop was that the pre-assessment appointment was compulsory for all ERAS patients, which ensured they were all exposed to the pre-determined educational and informational requirements of the ERAS programme. On Columbus, although there were no compulsory appointments in which to deliver the required information and education and thus a much reduced rate of attendance, the patient education sessions did focus specifically on patient information and education. This was in contrast to Albany and Bishop where wider issues relating to fitness for surgery and admission procedures were also considered alongside ERAS related information and education.

In general, how ERAS was implemented for the pre-admission appointments across the three case studies reflects the work of Carmen et al (2013) and Grande et al (2014) which has been previously described. Specifically, patients receive information about what actions they can take to reduce their risks in hospital and then make decisions about this information to support the management of their postoperative recovery. At face value the reality appears to be that this information is presented to patients as instructions, rather than as an option for them to consider and discuss with healthcare professionals. Furthermore, and again in relation to the work of Grande et al (2014), it is evident that the implementation of the educational and informational elements of ERAS during pre-admission appointments has been factored into existing workflows to some extent for each of the cases. (Although there are some major differences in the approach taken by the respective case studies, as I have outlined.) The implications of the similarities and differences between the three cases under study in relation to their implementation of the pre-admission appointments will be considered during the presentation and subsequent evaluation of the conjectured CMOs later in the thesis.

To conclude, the pre-admission element of the ERAS programme can be seen as the 'information' element of the 'information + activation' model described by Grande et al (2014) and the first step in the potential for 'co-production' of patient safety between

patients and healthcare workers. The approach taken in the pre-admission appointments across all three cases can be viewed as attempts to manage patient expectations of their upcoming hospital treatment and care through the provision of patient information. In the next section I will consider the implementation of the ward based elements of ERAS under study in this thesis, which is analogous to the 'activation' aspect of Grande et al's (2014) model.

5.11 Implementation: The Hospital Wards

Patients' were admitted to the respective hospital wards of Albany, Bishop and Columbus for their surgical treatment and care and in this section I present detailed analysis of the of the approach taken by each of the respective cases' in relation to the implementation of ERAS at this ward level.

As discussed, patients are the only individuals physically present during every treatment and consultation and so carry with them important contextualized information as they move through a complex and distributed process of care. The information and education provided to patients during their pre-admission appointment in relation to patient involvement in patient safety is an example of this type of contextualised information. In accordance with the ERAS programme, there is an expectation that this information and education will be reinforced by the members of the healthcare team who engage with ERAS patients' during their hospital stay. There is also an expectation that these same staff will encourage and support patients' in their endeavours to carry out the postoperative mobility requirements. I now present a detailed analysis of how each of the respective cases implemented these elements of ERAS at the ward level, making consideration of the processes undertaken and resources engaged to sustain the programme in the respective clinical areas.

This section is presented on a case by case basis, with each case divided into key themes which were derived from my data in relation to patient involvement in patient safety through early and continuing postoperative mobilisation at the ward level. Each case is supported by data extracts from my observations and my interviews with nursing staff. The detail presented in this section will be taken into consideration during my presentation and

evaluation of the conjectured CMOs in the upcoming findings chapters. I start each case by providing details about specialist nursing roles associated with the ERAS programme and then make consideration of the role of the physiotherapist in relation to the ERAS programme and ERAS patients. I then consider how staff in each of the cases reinforce the information and education provided during pre-admission and subsequent efforts by staff to support patients' during postoperative mobilisation.

5.12 Bishop: The Hospital Ward

5.12.1 Bishop: Specialist Nursing Roles

The ERAS Nurse who has been discussed previously in relation to developing the programme on Bishop was also directly involved in the ward based activities relating to ERAS for a period of approximately three months following the launch of ERAS on the unit. These activities related specifically to the coordination and management of postoperative ERAS patients on Bishop. During this initial transitional period following implementation the ERAS Nurse would visit patients enrolled on the programme on a daily basis to ensure they were involved in the required elements of the programme, including early and continuing postoperative mobility. The ERAS Nurse would also ensure the 'message' of ERAS was being reinforced in respect of what patients were expected to do as part of the programme.

"In the early days [...] what I wanted to do as part of my enhanced recovery nurse role was [...] to see the patient and be that continuity with the patient. So I would see them every day [...] we were reinforcing the message of what the patients needed to do." [Case B: RN7]

However, this arrangement was deemed unsustainable by the ward manager and ERAS Nurse due to the temporary nature of the post and the other demands associated with the role. As a result, a new role was created by the ward manager to ensure continuing levels of postoperative support for ERAS patients. The ward manager believed this role did not necessarily need to be carried out by a registered nurse, therefore a healthcare support worker (HCSW) who was a long-standing member of the nursing team was appointed to the

position on a part-time basis of 15 hours per week. The ERAS Nurse and the HCSW both describe this role:

“She’s the main person putting that message across now [...] the aim of her (HCSW) hours was to see the patients from an enhanced recovery point of view, but also to pick up the things that might be forgotten if the nurses are having a busy shift. To make sure the patients have done their walks and if they haven’t, help them to do that. [...] And that the message is still being reinforced every day.” [Case B: RN7]

“They felt like they did need involvement from a support worker, basically. Just to facilitate and keep it moving [...] It’s just me kind of motivating the patients and stuff.” [Case B: RN2]

Nursing staff on Bishop appeared to welcome the role of the HCSW and some I spoke with viewed this role as being linked specifically to ERAS patients and postoperative mobility, describing how the HCSW would support patients’ during postoperative mobility, which relieved the workload of the other nursing staff.

“A role like the role [HCSW] has got, I think that helps massively with things. It’s just reinforcing it really, you know. Even if she gets somebody up to walk once. Once she’s done that once they remember that they’re meant to be doing it four times and they’ll do it again.” [Case B: RN4]

“It takes a lot of the load off the staff that’s looking after that, say six or seven patients. If you know that somebody’s there that can walk and assess your ERAS patients.” [Case B: RN3]

This was acknowledged by the HCSW, who described how staff tended to rely on the support she was providing for ERAS patients.

“The permanent staff are very grateful. You know? And they kind of tend to rely on the fact that [HCSW] is doing ERAS today.” [Case B: RN2]

However, it was also apparent there was a risk that nurses saw the postoperative support of ERAS patients as being the primary responsibility of the HCSW, as one described to me.

“Very much I think that people think that’s [HCSWs] job.” [Case B: RN4]

I put this question of responsibility and accountability for ERAS patients directly to the HCSW:

“Do you think there’s an expectation that, ‘Well, this is [HCSWs] area?’ [DR]

“Some people. But then other people, no. [...] It’s not just my role, is it? It’s everybody’s. It’s everybody’s job to make it work.” [Case B: RN2]

It was also apparent that the ward manager was alert to the possibility of nursing staff not taking responsibility for ERAS patients, when posed with a similar question.

“I think possibly, if you’ve asked other people, yeah. Yeah. [...] How do I tackle that? Well I just say it’s everybody’s job.” [Case B: RN6]

5.12.2 Bishop: The role of the physiotherapist

There was a physiotherapist assigned to Bishop on a full time basis, with responsibility for helping to ensure ERAS patients achieved their postoperative mobility goals and a handover would take place each morning between the physiotherapist and nursing staff to establish the status of ERAS patients in relation to these mobility goals.

“We always have a catch up in the morning (nurses and physiotherapist). Normally they come here first thing so then we’ll have a quick go through with the patients. What each person had done, were they are with that, with their mobilisation.” [Case B: RN6]

The physiotherapist was seemingly autonomous in relation to the planning and enacting of ERAS patient mobility requirements, although they would also request support from the nursing staff when required.

“If they (physiotherapist) need help they take help, if not they just go mobilising patients on their own.” [Case B: RN6]

As previously described in relation to the role of the HCSW, the nurse manager pointed out that the mobility requirements of ERAS patients were not just the responsibility of the physiotherapist, but rather it was a shared responsibility.

“Whoever gets to the patient first, really. It’s everybody’s role to get everybody mobilising, walking around.” [Case B: RN6]

This approach of a shared responsibility between nursing staff and the physiotherapist for the support of ERAS patients was acknowledged by other nursing staff.

“The thing with ERAS is that it doesn’t have to be all the nurses doing the work cos [...] there’s the physio doing this. As long as you’ve got the communication [...] whoever you’re working with. Say you’ve done something then you tell the physio.”
[Case B: RN1]

In summary, there was a full time physiotherapist aligned to Bishop with responsibility for supporting the postoperative recovery of ERAS patients and exhibited a large degree of autonomy in this role. Nursing staff acknowledged that patients’ postoperative mobility was a shared responsibility with the physiotherapist and the ward manager reinforced to me the responsibilities of the nursing team in relation to this aspect of patient care.

5.12.3 Bishop: Reinforcing information and supporting postoperative mobility

On Bishop, the fundamental principles of an ERAS programme in relation to the benefits of a quicker recovery from surgery, which had been communicated to patients during a pre-

assessment appointment, were subsequently reinforced to patients on the hospital ward. Nursing staff also described how they encouraged patients to consider themselves as part of the team, in-line with the ERAS programme policy aspirations of 'co-production'.

"We tell them that enhanced recovery is about helping them to get better quicker and that they are part of the team that's going to do that." [Case B: RN7]

The mobility elements of the ERAS programme were also reinforced to patients on the hospital ward and during my observations I frequently witnessed the ERAS HCSW, physiotherapist and members of the nursing team encouraging and supporting patients with their postoperative mobilisation. The following extract from observational field notes is a typical example of this taking place.

The HCSW was 'doing laps' around the ward with some ERAS patients who were at the start of their postoperative care. Each 'circuit' of the ward is approximately sixty metres and there is a whiteboard on the wall on which patients will mark off their 'laps', to show how many laps they have done that day. [Case B Field notes xx]

During my observations the majority of ERAS related mobility carried out by patients in the early stages of postoperative recovery was with the support of the ERAS HCSW and / or the physiotherapist, whilst patients who were further into their postoperative recovery journey would often mobilise independently of staff. Members of the nursing team on Bishop were also engaged with supporting and encouraging patients with the postoperative mobility requirements of ERAS, as two nurses describe in the following data extracts.

"There's none this lying in bed for days on end regardless [...] when you've had surgery, you're encouraged to get up and moving". [Case B: RN4]

"We encourage them to do their laps and [...] staying out of bed". [RN3]

However, it was certainly the case that the majority of support and encouragement for ERAS patients' in respect of mobilisation was provided by the HCSW and physiotherapist and

among the nursing staff, the HCSW acted as the main protagonist for these activities. In this sense, although the original intention of the role had been to support the nursing staff, the role appears to have developed into one of direct responsibility for ERAS patients' postoperative care in relation to mobilisation, despite the ward manager's protestations that it was 'everybody's responsibility'. Of course, as this was a part time role the HCSW was not always on duty and in the absence of this staff member, the requirements of the ERAS programme were addressed by other nursing staff. During my observations on Bishop it also became apparent that the practice of early and continuing postoperative mobility was not confined to those patients who were enrolled on ERAS, but was also being encouraged for other 'non ERAS' patients.

"I try to think of everybody on the ward. But that's what I'm saying, the difference in our culture. We've had people who've had emergency surgery [...] we're telling them what the ethos of the ward is. You know, you won't be sitting around in bed. [...] We treat everybody the same." [Case B: RN6]

"We mobilise all out post-op patients. [...] even if they're not ERAS because it is proven that you're not going to get a chest infection if you mobilise [...] I'll try and treat them all exactly the same. Cos if it works for ERAS, it's gonna work for everybody [...] every member of staff here will try and treat those patients exactly as we do these (ERAS) patients cos we know it's going to get them better." [Case B: RN2]

Although nursing staff acknowledged that certain aspects of the ERAS programme were missing from the surgical care of these 'non-ERAS' patients, this did not detract nurses from encouraging and supporting this activity with patients, citing the perceived benefits associated with this type of mobilisation.

"Although with emergency patients we haven't got the luxury of the different things of anaesthetic and individualised fluid therapy and things like that – because that's not done for emergency patients in theatre – we can employ the principles

postoperatively. So we can't do anything up to the time they go to surgery, but afterwards we can encourage them to mobilise.” [Case B: RN7]

This demonstrates a diffusion of ERAS principles into the ward ‘culture’ and ‘ethos’ of postoperative care on Bishop and, although there was one consultant on the unit who was not engaging with the programme, it was apparent that nursing and physiotherapy staff were applying the ERAS mobility principles to all surgical patients admitted to ward. However, this approach was interesting as there were specific elements of ERAS which were designed to help support patients through the quite demanding postoperative expectations of an ERAS programme, which were not being applied to these ‘non-ERAS’ patients. These include, for example, the ‘individualised fluid therapy’ referred to in the previous quote along with other elements of an ERAS programme which are designed to support patients through the postoperative expectations such as carbohydrate loading. As discussed, although the ‘non ERAS’ patients were not exposed to these interventions, they were still expected to carry out ERAS mobility requirements, the implications of which were unfortunately outside the scope of this study but do lend themselves to further investigation in future research.

5.13 Albany: The Hospital Ward

5.13.1 Specialist Nursing Roles

All ERAS patients on Albany were assigned a specialist nurse at an early stage of their care who took responsibility for a wide range of care and would accompany the patient at stages through their journey from diagnosis to discharge, and for up to five years as an outpatient. As discussed, this nurse would also take part in the pre-assessment appointment, which included delivering the information and education relating to the ERAS programme. The specialist nurse role on Albany was something quite different to that discussed on Bishop, with these nurses on Albany forming a relationship with ERAS patients over a long period of time during what was clearly a very intense experience for these patients. In the following data extract, a specialist nurse describes her perception of the relationship between ERAS patients and their respective specialist nurse.

“By the time you’ve got to pre-assessment you’ve met them (patients) at least two or three times before. [...] we see these patients at least once a day and we’ve got a different relationship with them [...] these patients almost see us as something quite separate to the team in its entirety. They don’t see us as part of the nursing team. They don’t see us as part of the medical team. They see us as this separate person.”
[Case A: SNP]

The specialist nurses did not have responsibility for the day to day nursing care of ERAS patients and, as described in the previous extract, they appeared to exist somewhere in the boundaries between medical and nursing personnel. However, in relation to the postoperative nursing care of patients, it did seem to cause some confusion and lack of clarity of areas of responsibility for nursing staff based on the ward (and sometimes patients). Although the specialist nurses would monitor ERAS patients’ postoperative care, and discuss this with them during consultations on the ward, it was not their responsibility to support patients during their postoperative mobilisation. The SN was seemingly alert to the risks of the specialist nurses’ interactions with patients encroaching on the attempts of ward based nursing staff to engage with ERAS patients and explained how she made a concerted effort to try and avoid any conflict.

“I try and back off a little bit. Especially on the first day, because I’ll say hello to them [...] but that’s the time when the nurses on the ward need to make a relationship with them. So I’m very aware of that. [...] They’re the ones looking after them [...] I am careful. I do try not to step on their toes.” [Case A: SNP]

Rather, it was expected that the monitoring, support and encouragement provided to ERAS patients was carried out by the nursing staff and also the physiotherapists aligned to Albany, which I will now discuss in more detail.

5.13.2 Albany: Role of the physiotherapist

There was a physiotherapist aligned to Albany and part of their remit was to support ERAS patients during their postoperative recovery. As there were usually few ERAS patients on Albany at any one time the physiotherapist would not spend a long period of time on the ward, instead they would visit at points during the day to discharge their responsibilities. From my observations it was apparent that the nursing staff based on Albany viewed this aspect of ERAS patient care to be the primary responsibility of the physiotherapist, although nursing staff would also engage in this activity under the instruction and guidance of the physiotherapist.

“They’ll (patients) have the physio as well [...] sometimes we work with them, sometimes they (physiotherapists) ask us to” [Case A: RN4]

Unlike Bishop, there was no specific nursing role engaged on Albany to support and monitor ERAS patients postoperatively and this was expected to be carried out by members of the nursing team during the course of their working day. However, as was seen with Bishop, nurses had a tendency to defer responsibility to the physiotherapist, although this was more pronounced on Albany with nurses tending to await instruction and guidance from the physiotherapist.

5.13.3 Albany: Reinforcing information and supporting postoperative mobility

As with Bishop, there was an expectation that ward based nursing staff on Albany would reinforce the information provided to patients during their pre-assessment appointment. Of course, a major difference between these two cases was the level of engagement the ward based nursing staff had with the pre-assessment process and this is something that I will return to during my evaluation of the conjectured CMOs. However, during my fieldwork some nurses on Albany described how they would reinforce the information provided to patients in pre-assessment once they had been admitted to the hospital ward.

“Everything’s been explained to them. Thoroughly in pre-op assessment [...] and they know what to expect. [...] and then we’ll go through it again with them.” [Case A: RN4]

One nurse explained to me that it was necessary to reinforce the information and education provided as patients would sometimes revert back to the more ‘traditional’ notions of postoperative recovery through passive convalescence, rather than the ‘active’ approach required as part of the ERAS programme.

“But even though they’ve had that information, sometimes you find that they revert to the ideas that a lot of patients still have. That when they’ve had major surgery, they need to lie in bed for two weeks and do nothing to get better. [...] So they’re quite reluctant sometimes to do what has been discussed previously. So it needs a bit of reinforcing again and reminding.” [Case A: RN3]

As with Bishop, and also in the spirit of the policy aspirations of ‘co-production’, ERAS patients on Albany were reminded of the importance and relevance of their role within the clinical team, with one nurse describing this as a ‘partnership’ approach to care.

“It’s working in partnership with patients. It’s patients to get involved in their care [...] you need that interaction with patients, you need them to, er, to assist you in giving the best care really, because it can’t just be all nurses [...] It’s not about ‘I know everything, you do as I say’. It’s about let’s work together to do the best we can for you.” [Case A: RN1]

There were no nurses or nursing roles on Albany specifically associated with the postoperative mobility of ERAS patients, rather there was an expectation from ward management that all nursing staff should engage in this process, albeit usually under the guidance of the physiotherapist and some patients would mobilise independently when able. Unlike Bishop, there was no spread of ERAS principles to other ‘non-ERAS’ patients, which may be a reflection of the variety of patient groups being cared for on Albany as opposed to Bishop where the patient group was much more homogenous in terms of their

treatment and postoperative care. This notwithstanding, it was clear that ERAS patients were having information and education reinforced and were also being supported in their attempts to engage in mobility when appropriate, albeit on a rather more ad-hoc basis than seen on Bishop.

5.14 Columbus: The Hospital Ward

5.14.1 Columbus: Specialist Nursing Roles

As we have seen in the section relating to pre-admission activities, there was a specialist nurse involved in the patient education sessions run by Columbus but this nurse had not responsibility for the day to day nursing care of patients. In this respect, there were no 'specialist' nursing roles associated with the nursing cohort responsible for patient care on Columbus and the role of ERAS 'lead' as mentioned previously appeared to be a notional one. As the ERAS programme appeared to have a very low profile and take place almost 'behind the scenes' there was a sense on Columbus that all patients, irrespective of their ERAS status, were afforded similar postoperative care and this is something I will return to during my evaluation of conjectured CMOs. It was clear that the physiotherapy staff took overall responsibility for all postoperative mobility activities, which I will now discuss in more detail.

5.14.2 Columbus: The role of the physiotherapist

There was a large team of physiotherapy staff aligned to Columbus ward and members of this team took overall responsibility for organising and coordinating the postoperative mobility (and other associated physiotherapy related activities) of all patients on the ward. As part of the standard ward routine on Columbus a physiotherapist would carry out an initial assessment of each patient prior to any postoperative mobility and it was standard practice that only following this assessment would the nursing staff then take part in assisting patients with mobility. It was clear that many nurses subscribed to this approach to the postoperative care of patients.

“The physios are supposed to get them up as soon as they can [...] we wouldn’t mobilise patients at all unless the physios have seen. Especially in ERAS, we leave that up to the physios [...] if the physios are happy to then I will follow the physios, I take guidance from them about mobilisation.” [Case C: RN3]

“It’s usually physios who get people up first and then they’ll come and tell us and we’re quite happy then to transfer back into bed” [Case C: RN4]

However, not all nurses conformed to the arrangement in place between nursing staff and physiotherapy staff and one described how they would initiate the initial postoperative transfer from bed to chair to support the physiotherapy staff, particularly if there were a lot of patients to attend to at any one time.

“I think the physios don’t mind us doing it either [...] if there’s a lot of post-ops it can take them a while to get to everyone [...] So what I tend to do is either sit them up, or transfer them to the chair if they’re able to [...] I know some people would rather the physios do it. But I think [...] as long as everything’s OK, there’s no harm in them getting up.” [Case C: RN2]

As with the other cases, the postoperative mobility was led by physiotherapists, however on Columbus this was formalised and seemingly an agreed protocol between nurses and physiotherapists. However, as noted in the previous extract, nursing staff did not conform unanimously with this arrangement. This notwithstanding, it was clear that physiotherapy staff took overall responsibility for postoperative mobility for all patients, including ERAS.

5.14.3 Columbus: Reinforcing information and supporting postoperative mobility

As we have previously discussed, the ward based nursing staff on Columbus were not involved in any of the pre-admission aspects of patient care and did not attend patient education sessions, so were seemingly unaware of what information and education patients were provided during these sessions. This has implications for the implementation of ERAS on Columbus, which will be explored in due course, and this was compounded by the fact

that there was clearly confusion among nursing staff regarding which patients were enrolled on ERAS and which of the thirty or so consultants were using ERAS. Nurses I spoke with told me they were certainly aware that the one consultant was taken part for patients undergoing a TKR, but also intimated that other consultants were 'taking parts' of ERAS.

"There's only certain consultants that do it, but then there's a few others kind of like trying to get in on it. And then it's a bit of confusion over who is ERAS, who isn't."

[Case C: RN 4]

"Some of the consultants, they take parts, but we know [ERAS Consultant] is doing it, you know, fully [...] we know with [ERAS Consultant] what he wants [...] we know he wants them to get up day of surgery." [Case C: RN1]

As we can see in the previous extract, there was recognition that there were in fact relatively minor differences in the postoperative care of ERAS patients, with one nurse referring to patients getting up on the day of surgery. However, during my observations there was an expectation that this would be the case for some patients', irrespective of whether they were taking part in the ERAS programme. When patients began their postoperative mobility would also depend on the type of surgery, when during the day the surgery took place and hence when the patient returned to the hospital ward from theatre / recovery. Although there was an expectation that all ERAS patients would mobilise sooner than non-ERAS patients, this was difficult to discern as it was common practice for all patients who had undergone a TKR to mobilise with a day of surgery.

"I think the care is very similar to that of an ERAS patient to that of somebody who isn't [...] It's not about the care patients are having postoperatively. No, I think we give the same care to an ERAS patient" [Case C: RN7]

Nurses also explained that there were differences to patient treatment for ERAS patients on Columbus which related mainly to the type of anaesthetic used intra-operatively and the analgesia provided postoperatively and that these factors in combination would help support ERAS patients in postoperative mobility more than 'standard' care.

“There are things we would be doing for consultants with patients on the ERAS protocol, rather than patients who aren’t [...] not every patient goes to theatre having the Pregabalin, but with ERAS patients, they all have the Pregabalin”. [Case C: RN5]

“Basically it’s exactly the same expect for the type of anaesthetic they’ve had and it means they can get out of bed earlier, if they’re stable enough” [Case C: RN4]

Although the ward based nursing staff were not involved in the patient education sessions, they were still aware of the requirement to reinforce certain aspects of information and education in relation to the need for early and continuing postoperative mobility. This information was given to patients, regardless of whether they were enrolled on ERAS or not.

“I think it comes with explaining [...] saying to them, this is what we expect of you and, you know, this is what would happen afterwards. [...] what we want them to achieve [...] getting them up and moving, really.” [Case C: RN2]

Nurses on Columbus also alerted patients to the safety aspects of postoperative activities, specifically in relation to the benefits associated with a reduced length of hospital stay and the risks associated with prolonged bed rest.

“Our key message is basically [...] the less time you spend in hospital, the better it is for you” [Case C: RN7]

“I think it’s really important for them to know the risks [...] you tell them the risks [...] Cos if you don’t know what’s going on, you’re not likely to understand or take notice, or do anything.” [Case C: RN3]

“I tell them the risks, really, of staying in bed [...] I always explain the risks of chest infections, blood clots, all of that” [Case C: RN4]

As with the other two cases, nursing staff on Columbus would reinforce the information and education relating to modifying the 'traditional' patient role and emphasise the importance of patients working with the clinical team to help to achieve the best possible outcomes.

"I think it's putting emphasis on the patient to take control, rather than us doing everything. [...] It's just an old-school way of patients' thinking 'I'm going to hospital; I don't need to do anything'. Our message is for you to take control. And for this to work you need to do as much work as we're putting into you." [Case C: RN7]

On any given day on the ward there could be up to ten patients involved in mobility and associated activities, which required a high level of input from nursing and physiotherapy staff throughout the course of the day.

"At eight o'clock in the morning, en-masse, there were just all these physio people on the ward. [...] It all became very, very busy. With them doing work with us [...] all the physio people would appear and they would go off to their relative patients and do their relative work." [Case C: Patient 3]

On Columbus ward, although many patients did not attend a patient education session, all patients were provided with information relating to early and continuing mobilisation and the rationale for this as a matter of course during their hospital admission. The team of physiotherapy staff aligned to the ward took primary responsibility for postoperative mobilisation of all patient. There were no specialist nursing roles associated with ERAS and there was an expectation from ward management, as with the other two cases, that nursing staff provided support for these activities, although this was usually under the guidance of physiotherapy staff. Although there were relatively few ERAS patients on the ward at any one time all patients who had undergone a TKR, ERAS or otherwise, were expected to mobilise on the day of surgery, or the following day at the latest.

5.15 Summary of ward based implementation: cross case analysis

Although there were variations in each of the cases with respect to the ways in which education and information were reinforced, how patients were encouraged and supported in their postoperative mobility and which staff were primarily responsible for enacting this, the overall aims and objectives were very similar across all three cases. Hospital patients were again provided with a rationale for their involvement in activities relating to the potential patient safety risks associated with their hospital stay. For all three cases the information and education was clearly linked to patient safety and patient involvement therein, with patients also being encouraged to think of themselves as taking an active role in their postoperative care and to consider themselves as a members of the clinical team. The approach of early and continuing postoperative recovery was not restricted to ERAS patients for Bishop and Columbus, where all patients were expected to be involved in these activities, whilst on Albany it was only expected of those patients enrolled on ERAS.

As with pre-admission, at face value the reality appears to be that patients are expected to follow these instructions, rather than being provided with an option to consider and discuss with healthcare professionals. Furthermore, in relation to Grande et al's (2014) work, and as described previously, it is evident that the implementation of ERAS on the respective hospital wards has been factored into existing workflows to some extent for each of the cases, although there are some differences in the approach taken by each case study, as I have outlined. The implications of the similarities and differences between the three cases under study highlighted here in respect of their respective approaches to the implementation of an ERAS programme will be considered in more detailed during my presentation and subsequent evaluation of the conjectured CMOs later in this thesis. To conclude, this ward based implementation of elements of the ERAS programme can be seen as the 'activation' element of the 'information + activation' model described by Grande et al (2014) and an essential step in the potential for 'co-production' of patient safety between patients and healthcare workers. The approach taken on the hospital wards across all three cases can be viewed as attempts to initialising and sustaining patient involvement in patient safety through an ERAS programme, specifically in relation to early and continuing postoperative mobility.

Conclusion to Part II of the thesis

In conclusion to this second part of the thesis, 'The Study', I have presented an overview of my methods and some reflections of the research process. I have also provided an analysis of empirical data generated during the three case studies in relation to the implementation of ERAS. This includes analysis of the initial development and launch of the programme and the ongoing implementation process across the three case sites during pre-admission and ward based elements of the ERAS programme. I will consider the contextual influence of this data in relation to the programme theory – the conjectured CMOs – during the next part of this thesis in which I evaluate patient involvement in patient safety through an ERAS programme in each of the three cases under study.

Part III: Patient involvement in ERAS: The interaction of context, mechanisms and outcomes

In this part of this thesis I will firstly introduce the programme theory in the form of three distinct conjectured Context-Mechanism-Outcome configurations (the CMOs). I then present three chapters, each of which represents an evaluation of one of the three conjectured CMOs, drawing on my empirical data to identify the contextual factors in each of the three case studies that influence the outcomes of each of the CMOs. Based on these findings, I present a 'remodelled' CMO at the end of each chapter which takes into account my empirical findings in relation to these contextual influences.

Introducing the Conjectured CMOs

In this introductory section, I will present the conjectured programme theories relating to patient involvement in patient safety through an ERAS programme and these theories will be articulated in the form of Conjectured-Context-Mechanism-Outcome configurations (conjectured CMOs). The first of these conjectured CMOs, 'involving healthcare staff', considers the theory relating to how staff might be enrolled onto an ERAS programme to support patient involvement in patient safety. Following this, the second conjectured CMO relates to 'preparation for ERAS' and considers the activities that take place in the context of the pre-admission phase of the patients' journeys, specifically considering the provision of information to manage patients' expectations and prepare them for their upcoming hospital care. The final conjectured CMO, 'sustaining involvement', considers those actions and behaviours which take place on the hospital ward in relation to attempts to encourage and sustain patient involvement in patient safety related aspects of an ERAS programme. Within each of these sections I will explicitly articulate the elements of the conjectured CMOs.

The broad aim of this study is to explore the extent to which patients are involved in attempts to improve their own healthcare safety through enrolment in an enhanced recovery after surgery (ERAS) programme. Recognising that patient safety is just one aspect of the ERAS programme theory, this research evaluates those elements of the programme that see patients taking a role in their own healthcare safety. This is achieved by considering in realist terms the mechanisms of effect by which patients might contribute to their healthcare safety and investigating the conditions and circumstances (contexts) that are required to enable this involvement. The overall aim of this research is to seek out regularities in the patterns of these contexts and mechanisms which result in patient involvement in patient safety. The emerging theory will explain implementation variations, and the experiences of the programme participants in the different cases will provide an opportunity to make comparisons with initial programme theories, the objective being to better understand when and why patient involvement in patient safety works in an ERAS programme.

Following the logic of realist evaluation this exploration begins by eliciting and formulating the programme theories to be 'tested', otherwise referred to in realist evaluation parlance

as the Conjectured-Context-Mechanism-Outcome configurations (conjectured CMOs). These conjectured CMOs are propositions stating what it is about a programme that works for whom and in what circumstances and are described by Pawson and Tilley (1997) as the launching pad for realist evaluation. Simply stated, this stage of the inquiry involves generating ideas about how patient involvement in patient safety is perceived to work by those who have developed the ERAS programme in the cases under study and what contextual factors are necessary for its success. This involved me generating theories about which elements of an ERAS programme are designed to facilitate and encourage patient involvement in patient safety. As described in the methods chapter, I chose to use mobilisation as a 'tracer' for the three case studies, so the focus of the conjectured CMOs is on early and continuing postoperative mobilisation and the required effects of this element of an ERAS programme in relation to patient involvement in patient safety. These programme theories (conjectured CMOs) can be elicited from a number of sources including documents, previous studies and the academic literature.

In this study the conjectured CMOs are derived from national policy guidelines, specifically the ERAS How to Guides (HTGs) (NHS Wales 2010; NHS Wales 2011). I have also used data from the Department of Health (England) ERAS Guidelines (Department of Health 2010) as this document is referenced on several occasions within the NHS Wales HTGs and appears to be the sources for much of their content, although this is not always acknowledged in the NHS Wales documents. These conjectured CMOs are further informed by other literature, including the ERAS Society Guidelines (Gustafsson et al 2013) and other professional bodies guidelines, along with prior research on patient involvement in patient safety which has been identified in my literature review chapter. Combining these sources of data allows me to critically discuss these conjectured theories. In subsequent findings chapters these conjectured CMOs are then explored in relation to each case study using empirical data generated from documentary analysis of ERAS ICPs and patient information documentation developed and utilised by the respective cases. This will be synthesised with the analysis of observational data and interview data generated with nursing staff and patients from each of the cases. These multiple sources of rich data will be used to further interrogate the conjectured CMOs in order to identify how patient involvement in patient safety works

through early and continuing postoperative mobility in an ERAS programme, and what specific contextual factors are necessary for the successful outcome of these endeavours.

Conjectured CMO1: Involving healthcare staff with ERAS

Conjectured Theory 1: Members of the healthcare team who interact with patients enrolled on ERAS [C] understand the requirements for early and continuing postoperative mobility as part of an ERAS programme and the rationale associated with this [M] thus facilitating (and sustaining) staff involvement with this aspect of an ERAS programme [O].

We have seen from the review of the empirical literature that interrelationships and communication between patients and healthcare professionals have been shown to be an important factor in patients' perceptions of patient involvement in patient safety, and this is clearly related to healthcare professionals' knowledge and beliefs about such involvement (for example, Davis et al 2007; Watt et al 2009; Vaismoradi et al 2014). To promote successful patient involvement in safety, healthcare staff will need to be aware of the expectations and requirements of patients and the rationale for the actions patients are expected to take to help improve their safety. Furthermore, to support and sustain effective patient involvement in the mobility requirements of an ERAS programme there is an expectation that there will be information provided to patients at a pre-admission stage which will be reinforced by healthcare workers who engage with patients when they are subsequently on the hospital ward. In this respect healthcare workers are clearly a vital stakeholder group in an ERAS programme and the knowledge and beliefs of these workers is important when delivering and reinforcing this information to patients.

There is also support from a policy perspective for the involvement of staff in quality and safety initiatives such as ERAS and NHS Wales recognise through their quality delivery plan for the NHS in Wales (NHS Wales 2012) that engagement of the workforce in quality and safety improvement strategies and interventions is integral to their success. Similarly, the Department of Health guidelines (2010) demonstrate a specific expectation that healthcare staff involved in ERAS will be aware of the evidence base for the programme.

As established in the review of the literature (for example Watt et al 2009) many patients would be willing to play a role in their safety if the context and nature of the relationship with healthcare providers was conducive to supporting this. This is supported by the NHS HTG, which specifically refers to ‘partnership’ of care to achieve this co-production of improvement in patient safety.

“Improving patient safety requires everyone on the care team to work in partnership with one another and with patients”

(NHS Wales 2010, p3).

Therefore, this conjectured theory embodies a first step in establishing patient involvement through engaging staff with the programme and there is an expectation that all members of the care team work with the patient to achieve the desired outcomes of patient involvement in patient safety through early and continuing postoperative mobility as part of an ERAS programme.

Conjectured CMO2: Preparation for patient involvement in ERAS

Conjectured Theory 2: Providing information to patients during a pre-admission appointment about the postoperative mobility requirements of an ERAS programme and the rationale associated with this [C] will help to manage patients’ expectations, address preconceptions and promote patients understanding of their expected role [M] thus facilitating patient involvement with the mobility aspects of an ERAS programme [O].

The HTGs (NHS Wales 2010; 2011) state that information about the ERAS programme should be delivered to patients as part of a pre-admission appointment. In accordance with conjectured CMO2, I will demonstrate how this pre-admission appointment provides an opportunity for achieving the changes required in patients’ understanding and expectations to support their involvement in the postoperative mobility aspects an ERAS programme.

We have seen from the review of the literature that a commonly held belief among policy makers and healthcare providers is that the most effective way to involve patients in attempts to improve patient safety is to provide them with relevant information and

guidance (Entwistle et al 2005; Koutantji et al 2005; Waterman 2006). We have also seen that patient involvement in direct care, such as that anticipated in an ERAS programme, can be seen on a continuum which ranges from one end of the continuum as a patient simply receiving information to active involvement and partnership between patients and healthcare providers (Carman et al 2013). As discussed, there is an expectation that the information provided to patients during this pre-assessment appointment will be acted on, as described by Grande et al (2014) in their model 'information + activation'.

ERAS guidelines position patient preoperative information as an important and strongly recommended stage of the patient's ERAS surgical journey (Gustafsson et al 2013). This is supported by the ERAS HTGs (NHS Wales 2010; 2011) which state that ERAS information should be delivered to patients as part of a pre-admission appointment and a required intervention, as specified in the HTG (NHS Wales 2010, 2011), is that enhanced recovery is explained to patients during this pre-admission phase. The HTG goes on to describe an intended outcome of the preoperative assessment appointment as being:

"A fully informed and prepared patient who has been given all knowledge required before surgery commences" (NHS Wales 2011, p20).

The pre-admission appointment and the information provided to patients therein is also described in policy documents as playing an essential role in how the patient understands and ultimately participates in the enhanced recovery programme.

"All patients undergoing elective surgery should undergo pre-operative assessment. [...] The patient's pre-operative assessment appointment plays an essential role in how the patient understands, considers and ultimately participates in the ERAS pathway."

(NHS Wales 2010, p17).

"Relevant preoperative education ensures fully informed patients who are able to participate in their own recovery"

(DH 2010, p12).

The conjecture here is that providing patients with information about ERAS at an early stage in their healthcare journey will promote and encourage patients' active involvement in recovery from surgery, which in turn is expected to have a positive effect on patient safety outcomes in relation to a reduced risk of adverse events, as previously outlined. Another intended outcome of providing information to patients during a pre-admission appointment is to ensure they do not arrive for their operation with inaccurate preconceptions of their hospitalisation and postoperative recovery. The conjecture here is that by managing expectations via information giving, patients will be more prepared to be involved in a different approach to 'traditional' surgical recovery. Support for this can be demonstrated in national policy documents which identify managing patients' expectations for their involvement in an ERAS programme as a major factor in determining success, although it is also recognised by policy makers that managing patients' expectations is particularly challenging (DH 2010).

"Managing patients' expectations of what will happen to them [...] is particularly challenging, but crucial in achieving success and is a major factor in determining patient satisfaction"

(DH 2010, p12).

As patient preconceptions may be inaccurate or misguided, national guidelines also recommend that patients' ideas about their upcoming treatment, care and recovery should also be explored during a pre-admission appointment. This presents staff with an opportunity to ensure that patients' expectations match the realities of the ERAS programme.

"Explore the patient's preconceived ideas about care, and then present them with a consistent but flexible plan of care"

(DH 2010, p12).

National policy presents expectation management as crucial in achieving success in an ERAS programme and suggests that providing patients with an understanding of their role will

make it more likely for them to feel as though they are entering a ‘contract of care’, which again resonates with the notion of ‘co-production’

“When a patient has a full understanding of what to expect and what is expected of them, they are more likely to feel as if they are entering into a ‘contract of care”

(DH 2010, p12).

As highlighted in the policy literature, a further desired outcome from the provision of information during pre-admission is to modify the traditional role of the patient as a passive recipient of care, toward a more active and involved role. Developing a partnership between clinicians and patients is presented as a means of changing this traditional patient role, which in turn can encourage patient involvement in specific aspects of an ERAS programme.

“A partnership between clinician and patient involving open, honest communication and the timely provision of good quality information is essential to enhanced recovery”

(DH 2010, p12).

National policy also encourages a partnership approach to patient care that is based on openness and mutual trust and the HTG states that ERAS can *“instil a greater confidence of patients in their healthcare organisation”* (NHS Wales 2011, p7) and also make reference to patient / healthcare professional relationships (and hence partnerships) being built on mutual trust and respect. In addition, national policy documentation refers to empowering patients and suggests that a reported benefit of the ERAS programme is *“empowering patients as partners in their own care”* (DH 2010). There is a wealth of literature relating to the benefits of ‘empowering’ patients in their care (for example, Aujoulat et al 2007), although this mostly relates to those patients with long-term conditions and there is limited evidence relating to empowering patient involvement in aspects of their direct care or patient safety. (These notions of trust and patient empowerment will be explored in more detail during the discussion chapter.)

The national guidelines further recommend that patients be provided with a rationale for the ERAS programme in general, and for their personal involvement in the programme. As we have seen, there is evidence from the literature to support this approach (for example, Davis et al 2012) which demonstrates the importance of patients' understanding why behaviour advocated by healthcare providers is beneficial and, conversely, why non-involvement in this behaviour could be detrimental to them. In support of this another important element of the pre-admission process conjectured programme theory is the provision of information which relates particularly to the evidence base and rationale underpinning elements of an ERAS programme. The provision of this information is intended to secure patients' understanding of ERAS and legitimise the programme by presenting patients with a rationale for their involvement, in this case specifically in relation to the mobility requirements. In support of this, national policy describes the importance of patients understanding the principles of the ERAS programme, as well as the evidence supporting it, so they can take an active role in their recovery (Department of Health 2010; NHS Wales 2011; 2012).

"Knowledge about the evidence base for enhanced recovery needs to be conveyed to the patients with enthusiasm and belief by the health care professional and should be communicated on a basis of a two-way healthcare professional / patient relationship based on mutual trust and respect"

(DH 2010, p12).

This information provision is also associated with raising patients' awareness of the risks associated with hospital care and what they can do to help reduce these risks. As discussed, one of the main aims of the enhanced recovery programme is to provide a reduction in the average length of stay, without compromising patients' safety or recovery (NHS Wales 2010; 2011) and related to this is the specific benefit of reducing length of stay through ERAS is described in national policy as reduced exposure to hospital infections (Department of Health 2010). This approach is framed within a discourse of hospitals being inherently risky places and that it is in everyone's best interests to spend as short a time as possible as an in-patient. This approach is a combination of persuading patients of the necessity of, for example, early mobilisation by reference to the risks of hospital acquired infection or

thrombosis associated with not doing this, whilst also incentivising patients with a reduced length of hospital stay and associated lowering of the risks of contracting an infection.

In summary conjectured theory CMO2 is based on the preparation of patients for involvement in ERAS through the provision of information during a pre-admission appointment. The provision of this information is intended specifically to manage and / or change the preconceived expectations of patients prior to their hospitalisation. This is related to the anticipated role of ERAS patients during the healthcare journey and is expected to promote a sense of active partnership and co-production of safety, reflected in the phrase 'contract of care, thus preparing patients for the more 'active' role which is expected of them during their postoperative rehabilitation. During the appointment patients are not simply told what to expect, but are also provided with a rationale for these expectations based on independent evidence, not merely economic expediency or professional preferences. Provision of this information is designed to provide patients with a rationale for their involvement through alerting them to the risks associated with hospitalisation and postoperative recovery. Patients are informed of the steps required to reduce these risk, which is intended to create 'buy in' to specific elements of the ERAS programme and encourage involvement from patients in postoperative mobility. Ultimately, this provision of information can be described as an attempt to influence patients' willingness and ability to follow prescribed recommendations and instructions.

Conjectured CMO3: Sustaining patient involvement with ERAS

Conjectured Theory 3: Members of the healthcare team who interact with ERAS patients during their hospital admission [C] will reinforce / provide patient information in relation to the rationale for postoperative mobility and also create a goal-orientated focus [M] thus encouraging and sustaining patient involvement with the ERAS programme postoperative mobility requirements [O].

This third and final conjectured CMO is associated with policy guidelines that outline strategies to involve patients in patient safety elements of an ERAS programme during their time as a hospital in-patient. In accordance with conjectured CMO3, I will demonstrate how

information provided to patients during a pre-admission appointment is reinforced and supported by clinical staff during ERAS patients' hospital care, with the expectation that this will result in patient involvement in mobility elements of an ERAS programme. It is evident that the key to success in this programme theory is to 'activate' the information provided in a pre-admission appointment. As discussed, patient involvement in their own care, such as that anticipated in an ERAS programme, can be seen on a continuum and in this aspect of the patients' journey there is an expectation that the information received by patients during pre-admission is now converted into an active involvement in an attempt at co-production of patient safety. This can be seen as being analogous to the 'activation' element of Grande et al's (2014) 'information + activation' model.

As detailed in the NHS Wales HTGs, clinical staff who engage with patients during their hospital stay are expected to encourage, support and sustain effective patient involvement in an ERAS programme through reinforcing information that has been provided to patients at the pre-admission stage.

"The effectiveness of ERAS to improve outcomes is dependent on the engagement, commitment and involvement of all members of the multi-disciplinary team at all stages of the patient's journey"

(NHS Wales 2011, p5).

In support of this, other ERAS guidelines refer specifically to the need to continuously remind patients of the importance of their involvement in the success of ERAS, for example the Association of Surgeons of Great Britain and Ireland (ASGBI 2009). The goals relating to postoperative mobility expectations and predicted length of hospital stay have been introduced to patients during a pre-admission appointment with the policy expectation that these goals will be discussed with patients and subsequently reinforced and monitored by ward based staff. This will also entail clinical staff supporting and encouraging patients' in their ERAS related postoperative goals, specifically in this instance those relating to mobility and discharge. In relation to this, the NHS Wales HTG refers to patients being "*empowered*

to follow the care plan” (NHS Wales 2010, p7; 2011, p8) and other ERAS national guidelines state that patient goals are key to assisting patient independence:

“Encouragement and reminding the patient of pre-determined goals are key to assisting the patient’s independence”

(DH 2010, p23).

It is acknowledged in the HTG that the approach to mobilisation is earlier than that which occurs in ‘traditional’ surgical care (NHS Wales 2010) and the HTG states that all expectations in relation to mobility should be discussed with the patient preoperatively. The HTG also provides an example of a plan for postoperative mobilisation, with the caveat that the undertaking of any such plan will be dependent upon the nature of the surgery and the condition of the patient (NHS Wales 2010; 2011). The following is an example of a postoperative plan, as presented in an NHS Wales HTG:

“Patient sat out in chair 6 hours post-operative on day 0 of surgery

Patient sat out in chair daily for 6-8 hours from day 1 after surgery

Patient achieved 4 x 60 metre walks daily after surgery”

(NHS Wales 2010, p. 29)

In addition to managing patients’ expectations, discussing discharge goals with patients is also expected to act as a means of incentivising and motivating patients to engage with postoperative rehabilitation requirements of ERAS. For example, every ERAS patient should also be provided with a predicted date of discharge (PDD) at their pre-admission appointment, based on the average length of stay for their particular type of operation.

“The pre-operative assessment appointment should [...] Discuss and plan discharge dates”

(NHS Wales 2011, p15).

“The expected length of stay should have been discussed at the pre-operative assessment appointment [...] Therefore patients and their families and carers should be aware of the day for discharge if surgery was uncomplicated”

(NHS Wales 2010, p33).

Interestingly, although the ERAS programme in the cases under study is a standardised pathway with specific expectations in relation to the goal-orientated approach required, it is acknowledged by NHS Wales that each patient has individual needs which should be taken into account during their postoperative recovery.

“ERAS is a series of guidelines leading to standardised care, but each patient must still be treated as an individual and their individual needs taken into account”

(NHS Wales 2010, p7).

Although this is the case, there is an overwhelming education and goal setting focus with the policy which is premised on and promotes patient involvement with a clear focus on patient enrolment, along with staff and patient awareness of the benefits associated with an ERAS programme (and the risks associated with non-compliance). Clearly, there are tensions here in relation to the policy makers’ aspirations for standardisation of care and the aspirations for individualised patient care, which I will consider this in more detail during the discussion chapter.

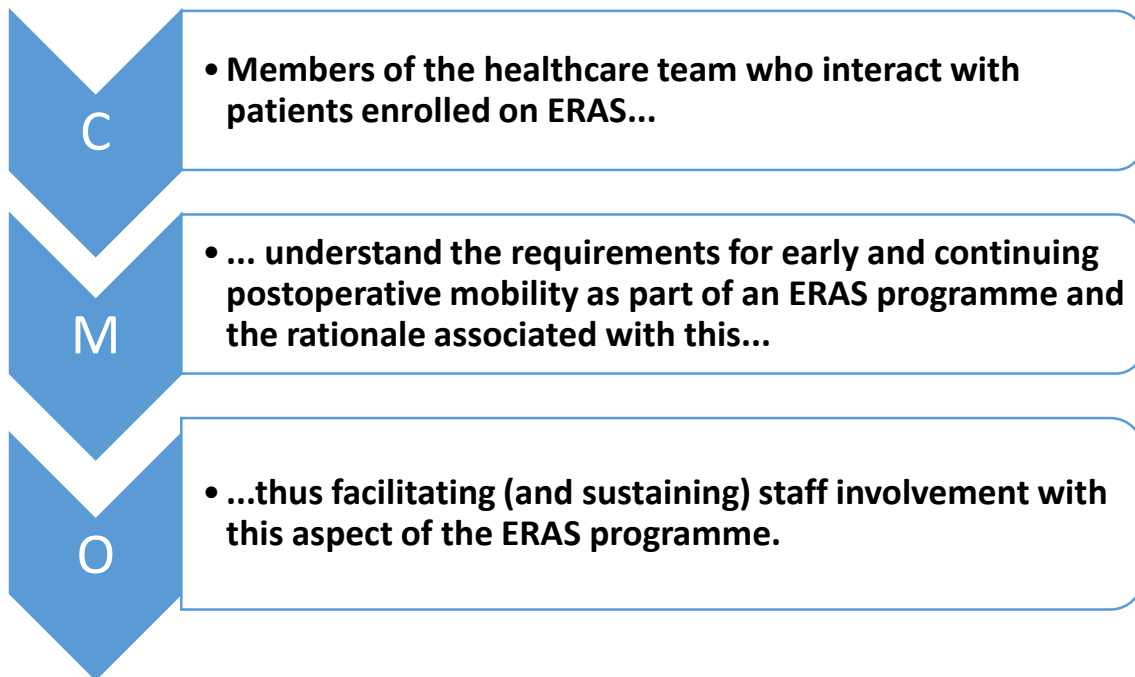
In summary, this third CMO is based on the activation of the information provided to patients during a pre-admission appointment, with the expectation that this will result in patients being involved in certain aspects of their care, with a focus on early and continuing postoperative mobility. There is an expectation that a goal-orientated focus will be encouraged and the rationale for this mobility is also presented to patients to encourage and motivate this type of patient involvement in patient safety. As with pre-admission, this is specifically related to the reduced risk of experiencing an adverse event and a reduced length of hospital stay (and the benefits associated with this in relation to patient safety).

To summarise this section, in keeping with a realist evaluation approach I have deconstructed key ERAS national policy and local programme documents into three areas of programme theory related to patient involvement in patient safety and synthesised these with the wider literature to produce conjectured Context-Mechanism-Outcome configurations (CMOs). Overall, the three conjectured CMOs I have presented are clearly linked together and the outcome of patient involvement in patient safety is influenced at some stage by all three of these CMOs. Firstly, we saw how healthcare staff caring for patients enrolled on an ERAS programme should themselves understand the rationale and evidence relating to the mobility aspects of patient involvement. This will enable staff to support patients in their involvement in patient safety. Secondly, we saw how the provision of information at a pre-admission appointment is designed to manage patients' expectations and prepare them for involvement into the particular postoperative rehabilitation expectations of an ERAS programme.

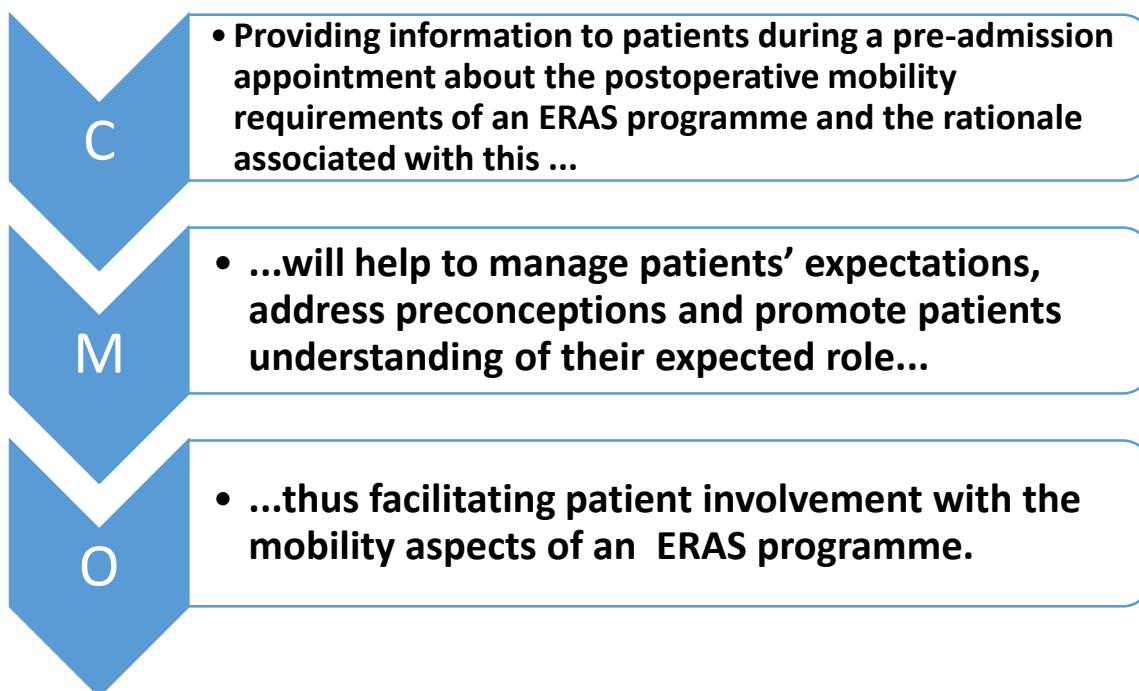
Finally, continuity between pre-admission information giving and hospitalisation is considered in the policy and programme requirements, with the expectation that healthcare staff reinforce pre-admission information during ERAS patients' hospital care. This is designed to result in ongoing patient involvement in postoperative mobility, with the support and encouragement of the ward based staff. This is related to the anticipated role of ERAS patients during the healthcare journey and is expected to promote a sense of active partnership and co-production of safety, reflected in the phrase 'contract of care, thus preparing patients for the more 'active' role which is expected of them during their postoperative rehabilitation.

Over the course of the next three chapters I will present an evaluation of each of these conjectured CMOs, drawing on my empirical data to identify the contextual factors across the three case studies which influence the outcomes of each of these CMOs and present my 'remodelled' CMOs based on these findings. During the evaluation, I will present the three CMOs in the following pictorial form.

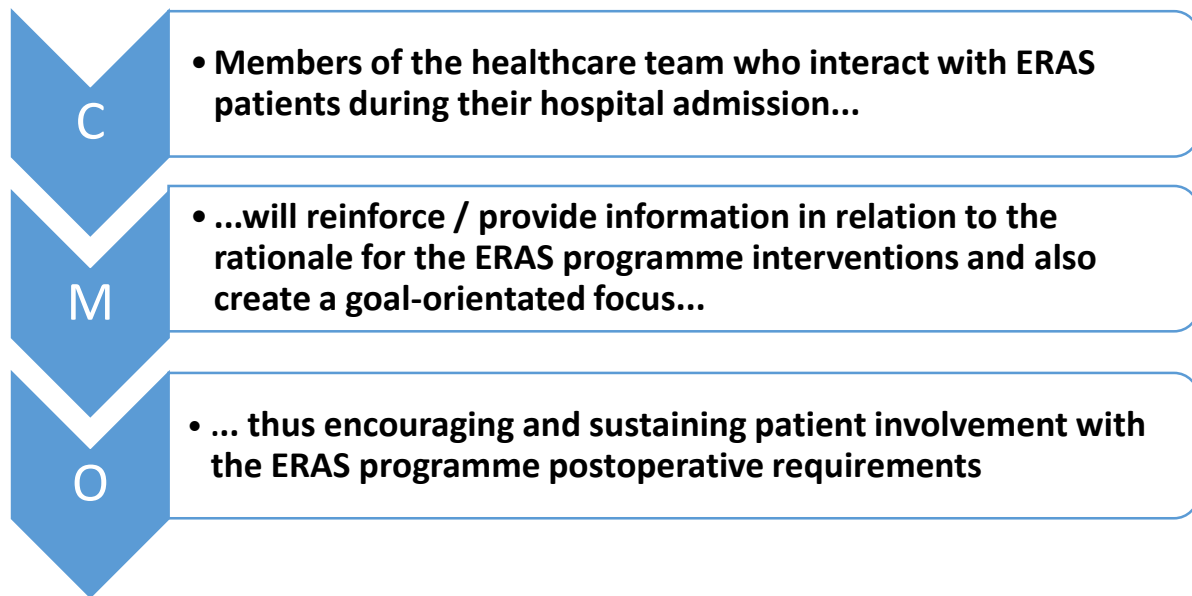
Conjectured Context-Mechanism-Outcome (CMO) configuration 1



Conjectured Context-Mechanism-Outcome (CMO) configuration 2



Conjectured Context-Mechanism-Outcome (CMO) configuration 3



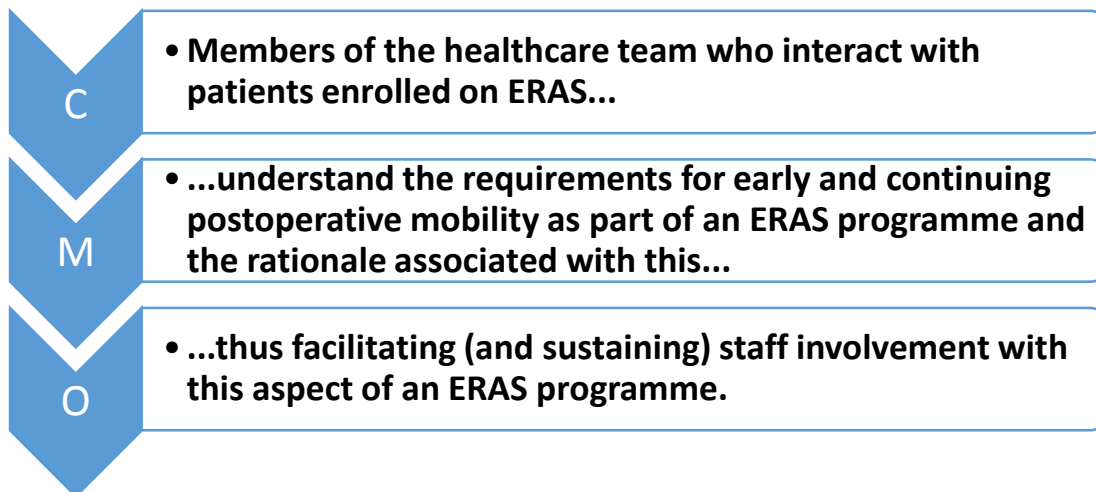
Evaluating the CMOs

Following the logic of realist evaluation, the next stage of my thesis involves asking questions relating to the contextual factors that influence the conjectured CMOs I have developed and how attempts at patient involvement are shaped enabled or constrained by interaction between these contexts and the identified mechanisms of change within the programme. This strategy is based on the realist principle of generative causation – that is, what conditions are necessary to achieve the desired effects of the programme theory I have postulated. This involved me generating data to allow the ‘testing’ of these conjectured CMOs in terms of the identified outcomes and the contextual influences involved. Therefore, during these next three chapters I will present each of the conjectured CMOs in sequence, and my analysis and evaluation of these CMOs in relation to the data I have generated from each of the case studies through my documentary analysis, ethnographic observations and semi-structured interviews with patients and nursing staff.

I have already presented a detailed analysis of what I consider to be key ‘overarching’ contextual features of the respective case studies in relation to the implementation of ERAS in the respective case studies and the findings from this data will be taken into consideration and synthesised into my evaluation of the three conjectured CMOs. Following my analysis and evaluation of each of the CMOs, I will present a ‘re-modelled’ CMO, which will take into consideration the contextual influences at play in the respective cases, thus demonstrating what conditions were necessary to support attempts to involve patients in their safety through postoperative mobility. In this next chapter I begin with analysis and evaluation of conjectured CMO1, which relates to staff involvement in ERAS. I will begin with Bishop, I then consider Albany and finally Columbus and retain this sequence in subsequent chapters.

Chapter 6: Evaluating CMO1: Staff Involvement

6.1 Bishop CMO1



To remind ourselves, Bishop was a surgical unit specialising in the care of patients undergoing lower gastrointestinal (colorectal) cancer surgery and patients with other conditions of the lower gastrointestinal tract and most of these procedures were associated with the ERAS programme.

We have already seen during the course of the literature review the importance of healthcare staff in any attempts at patient involvement in patient safety and my review of the implementation of ERAS across the three case studies also drew attention to the relevance of involving staff in the early stages of quality and safety improvement initiatives in healthcare. During implementation on Bishop formal dissemination and training was provided to nursing staff, which was intended to generate interest and enthusiasm for ERAS. My analysis of the implementation process undertaken by Bishop also revealed that attempts were made by influential members of staff to engage with and involve the wider cohort of nursing staff employed on the unit who were expected to work with the ERAS programme following the implementation. I concluded from this that the implementation strategy undertaken by Bishop helped to generate a positive attitude and some insight into the rationale and benefits associated with patient care among nursing staff on Bishop in relation to an ERAS programme. The approach taken by Bishop had clearly led to

engagement of wider members of the team in the process and enabled the unit to develop a 'critical mass' of support for the programme. This is not to say that all nursing staff were initially enthusiastic or welcoming of the changes to practice associated with the implementation of an ERAS programme.

"We were very wary, yeah. But then it's new. People are a bit wary of anything that's new. And it's different, I suppose." [Case B: RN3]

"Huge big change [...] we wanted to embrace the change of doing it [...] personally I found it quite difficult to begin with." [Case B: RN6]

However, following the initial implementation period, staff adjusted to the changes in practice associated with ERAS and described how this programme had become embedded into ward practice and become part of the ward 'culture'.

"It became more sort of embedded in the day to day thing [...] it was embedded in the ward culture." [Case B: RN6]

"Once the change has been embedded, it just becomes standardised practice" [Case B: RN7]

Nursing staff on Bishop seemed to display a positive attitude towards ERAS and nurses I spoke with demonstrated an understanding that interventions associated with the programme could translate into benefits for patient care.

"I think using it and working with it, I think it's the benefit of how well the patients are, as opposed to what they used to be." [Case B: RN4]

"To my knowledge, the things that we're doing area for the benefit of the patient and there isn't an argument otherwise [...] if it's something that's for the benefit of the patient then I think we're gonna automatically change practice across the board."
[Case B: RN7]

One nurse I spoke with also made specific reference to the research evidence base that ERAS was based on.

“It’s evidence based, everything in the pathway [...] you’re not doing anything you shouldn’t be doing. It it’s in there, then it’s been researched and it’s been found to be the best way to do things.” [Case B: RN4]

Nurses also demonstrated an understanding of this evidence base, making reference to specific elements of ERAS that were associated with improved patient care and safer outcomes through, for example, reducing risks of hospital acquired infections and DVTs, and reducing exposure to adverse events by a reduced length of stay.

“Sometimes I don’t think they realise that laying down all day can cause [...] chest infections, DVT. I think when you explain the mobilisation [...] then you can see them sort of thinking, ‘Oh yeah’. There’s a rationale behind what we’re asking them to do. Cos I think if patients know why they’re doing something, they’ll do it won’t they? [...] If they realise it’s aiding their recovery, they’re more keen to do it. [...] we do try to involve them [...] cos it means less hospital infections. It’s worth enforcing”. [Case B: RN3]

“When you come into hospital obviously you put yourself straight away into the risk of harm and managing to avoid as much of that as you can is really what we would kind of hope [...] So things like encouraging people to mobilise, making people aware of [...] the reasons why they’re doing these things. I think it can encourage them and people are more likely to do something if they know why they’re doing it really.” [Case B: RN4]

“I do think a lot of it is about the mentality of it. [...] We’re telling patients, yeah they’ve had an operation but it’s positive. Now it’s positive and you’re gonna get well [...] and let’s get you up [...] instead of lying in bed feeling, well, like a patient. [...] And you see them being positive and genuinely feeling better.” [Case B: RN7]

The preceding data extract also demonstrates nurses’ understanding of the relationship between improved patient safety and postoperative mobility. We also see that in addition to supporting the evidence based rationale of an ERAS programme, nurses on Bishop also supported the rationale that providing information to patients about such risks would encourage patient involvement in the required mobility associated with ERAS. Further to this, however, it is noteworthy that the nurse manager of Bishop appeared somewhat

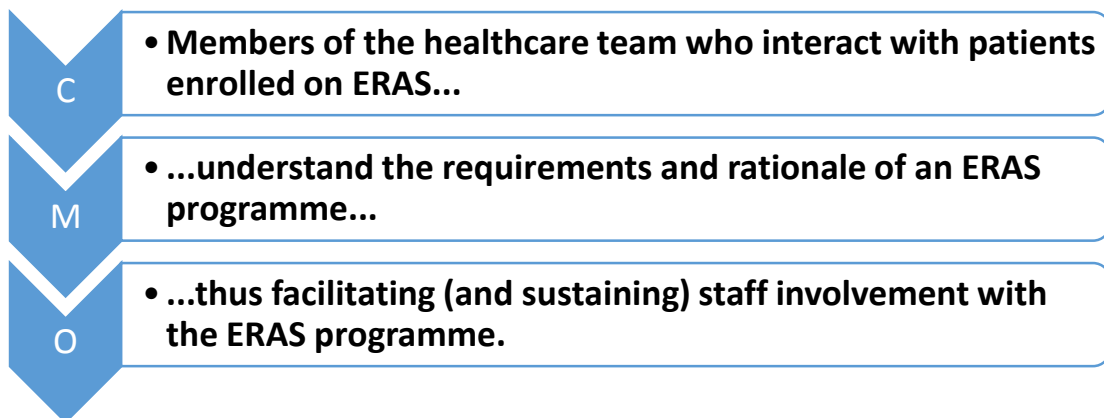
cynical about certain elements of the ERAS programme being presented as ‘innovation’ and commented that the evidence base for early and continuing postoperative mobility was not new and this was something that they would carry out as a matter of course, even prior to the introduction of ERAS. However, this does raise some questions in relation to how innovative the ERAS approach to postoperative care actually is.

“Early mobilisation was something I personally used to do anyway [...] cos I understood the benefits of getting people up, out of bed, mobilising early [...] from a chest point of view, that sort of thing [...] It (ERAS) was just connecting it all together I guess and giving it a title.” [Case B: RN6]

To summarise my evaluation of conjectured CMO1 on Bishop, nursing staff demonstrated an understanding of the evidence base supporting ERAS and the rationale associated with the postoperative mobility requirements in relation to patient involvement in patient safety. It was also apparent that the approach taken to ERAS implementation had a positive effect on the attempts to involve nursing staff with the programme. The widespread prevalence of ERAS patients on the unit also helped to support the perceived change of ‘culture’ of the ward towards ERAS and helped developed the embeddedness of the programme that was referred to by nursing staff in interviews and also noted during my observations. This was likely to impact on the acceptance of ERAS by staff on Bishop as they would have many opportunities to familiarise themselves with the programme due to the relatively high number of ERAS patients they would encounter during the course of their nursing duties.

The notion of postoperative mobility reducing the risk of adverse events and improving patient outcomes was something that was already familiar to the ward manager and other nursing staff. The formalisation of these requirements through an ERAS programme and associated ICP was, to some extent, simply a reinforcement of a strategy that was already adopted by some. These factors also have an important contextual influence on the two subsequent CMOs as the ward based nursing staff on Bishop are expected to provide the information to patients during a pre-assessment appointment and are also expected to encourage and sustain patient involvement in postoperative mobility aspects of ERAS during patients’ hospital stay.

6.2 Albany CMO1



Albany was a surgical unit specialising in the care of patients undergoing upper gastrointestinal, hepatobiliary and pancreatic surgery with three procedures associated with the ERAS programme; full and partial gastrectomy and oesophagectomy. Albany had a diverse patient population with only a small percentage of patients being enrolled on the ERAS programme which resulted in a low prevalence of such patients on the hospital ward at any one time. This was likely to impact on the acceptance of ERAS by nursing staff on Albany as there were few opportunities for staff to familiarise themselves with the ERAS programme, due to the low number of ERAS patients they would encounter. In addition, there was seemingly little effort made to raise awareness of nursing staff on Albany through any training or formal dissemination of information relating to ERAS. This was a cause of dissatisfaction among some of the nursing staff who believed there was little support for the perceived changes in their practice associated with an ERAS programme and expressed disappointed about their lack of involvement in the implementation process. There was a 'lead' nurse associated with the implementation process, but this individual did not engage with the wider team outside of the core designated project team and this team appeared to be isolated from the wider cohort of staff. This had further rationed the opportunities for diffusion of ERAS on these units and ultimately restricted the opportunity for nurses to become involved in the implementation process.

The Specialist Nurse (SN) referred to fear and anxiety among the nursing staff on Albany during the early stages following the ERAS programme implementation. However, this nurse went on to suggest that these feelings had subsided over time and she believed that the

ward nursing staff had subsequently adjusted to the expectations associated with caring for patients enrolled on an ERAS programme.

“I think initially when it (ERAS) first started there was, as with anything new, there was a fear [...] and so now people are very cool with it [...] I think if you’d have come when it first started, there was a real anxiety about it.” [Case A: SNP]

There were data to suggest that nursing staff on Albany understood the requirements of an ERAS programme in relation to postoperative mobility and one nurse described to me elements of the pre-assessment process, indicating this nurse’s awareness that patients would have been prepared for this approach to their care during a pre-assessment appointment.

“When they’re pre-assessed they’re told a lot about enhanced recovery [...] I know they understand they are expected to do certain things on certain days. Like, for example, the day after surgery we will be getting you up.” [Case A: RN1]

There were also data which demonstrated some nursing staff were aware of the research based rationale for encouraging patient involvement in postoperative mobility.

“Things are done differently. When it was acceptable for patient to be lying in bed, it isn’t now. And research has proved that.” [Case A: RN2]

Some nurses also understood and supported the rationale that providing patients with the opportunity for a more active role in their postoperative care would increase their motivation for recovery. This is demonstrated in the following data extracts in which one nurse refers to motivating patients through a goal orientated approach (in relation to measuring recovery progress), whilst the other nurse refers to giving patients ‘control’ as a means of increasing their motivation.

“I think patients are, generally will be more motivated the more involved they are. And if they can see progress that will increase their motivation.” [Case A: RN3]

“You try and get the patients to be involved as much as possible because if they’ve got the control it appears to affect their care and their health and their improvement and their motivation” [Case A: RN6]

However, there was also contradictory data generated during interviews with nurse respondents from Albany which indicated that although some of the nursing staff were aware of the postoperative requirements for ERAS patients and the associated evidence based rationale, this approach to care was not 'embedded' to any extent on Albany ward. One of the main factors relating to this, as described by the nursing staff, was that patients who were being cared for on Albany were not always in a suitable physical state to adopt an 'active' approach to their care. In the following data extracts one nurse describes how patients on Albany are 'acutely ill'. This in turn would require a high level of postoperative nursing care, which could certainly hamper the programme aspirations that require nurses to encourage patients to adopt a more 'active' postoperative role during their hospital care. Another nurse describes the 'real world' of hospital care for these patients and this quote highlights that, according to this respondent, patients' are treated more passively and objectively in relation to the nursing tasks that need to be carried out. Both these quotes reflect the tension between the expectations of the ERAS programme theory relating to patient involvement in patient safety and the reported and observed actions of some of the nursing staff on Albany ward when they did not deem this 'active' approach appropriate.

"For us it's an acute ward. So people are in with an acute illness or having surgery. So things are changed for the time they are in with us in any case. It's not normal. It's not carrying on as normal." [Case A: RN3]

"Even if they've come in and they're well, they've got their pyjamas on within two minutes, haven't they? So you're taking away their identity straight away. You're putting a band on them. Taking bloods. You're, you know, doing all your jobs already. [...] They don't wear their clothes till they leave, do they? [...] It doesn't work in the real world, does it? Because if they've got drains and catheters and drips and oxygen, you're not gonna get someone in shirt and trousers, are you?" [Case A: RN6]

Another issue identified which appears to have an impact on staff involvement with the ERAS programme relates to lack of involvement of the ward based nursing staff during the pre-assessment appointments. When ERAS was initially introduced onto Albany it was the intention of the implementation team that ward based nursing staff would take part in the pre-assessment process, carrying out a similar role to that which the nurses on Bishop took. However, this strategy was not enacted and instead the specialist nurses were asked by the

ward manager to lead the pre-assessment appointments in lieu of the ward nurses. The specialist nurses agreed to this, although this was seemingly with some reluctance with the SN stating that this role should be the responsibility of the ward based nurses.

“The nurses on the ward should be doing the nursing assessment. But we (specialist nurses) were specifically asked if we would do it [...] by the ward manager. Because the nurses felt we should be doing it. Because I was quite surprised they didn’t want to do it.” [Case A: SNP]

Ward based nurses described how their lack of involvement in pre-assessment was a cause of discontent and there are contradictory opinions between these nursing staff and the SN in this regard, as in the next extract a nurse describes how the ward nurses were not given the opportunity to take part in pre-assessments.

“We didn’t have any opportunity to go to pre-assessment and see what it was like. We don’t see the whole process [...] our knowledge is very limited of what they’re told in pre-assessment. We just know what we have to do here (the ward) [...] what exactly are their expectations? We’ve got a very basic idea, but we’re not really sure of what exactly they’re told [...] If we don’t know, then sometimes we can’t reinforce things.” [Case A: RN1]

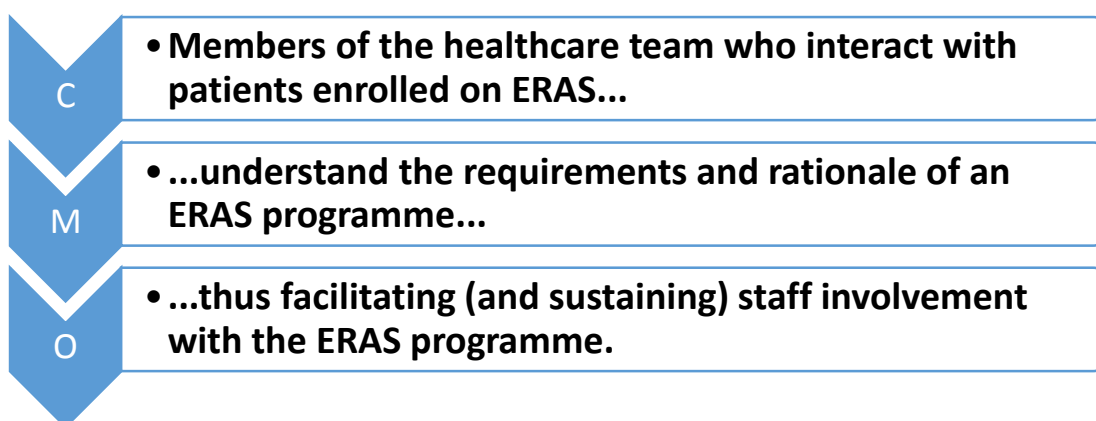
However, as mentioned there was some conflicting information provided by this particular nurse during interviews as they had previously described specific elements of ERAS and shown some understanding of the postoperative expectations for ERAS patients. So although the ward nursing staff did not attend the pre-assessment appointments, some were obviously aware of the ERAS programme requirements in relation to mobility and also demonstrated knowledge of the supporting rationale for an enhanced recovery approach. This was despite protestations from some nurses that lack of nursing staff involvement in the pre-admission phase had created a negative impact on the ward based nurses’ ability to support ERAS patients postoperatively.

In summary of the evaluation of conjectured CMO1 on Albany, some nursing staff demonstrated an understanding of elements of the evidence base supporting ERAS and the rationale associated with the postoperative mobility requirements. However, it is apparent that the lack of nursing staff involvement in ERAS implementation had a negative effect on

subsequent attempts to involve nursing staff with the programme. The low number of ERAS patients being cared for on the ward also had an effect on attempts to embed ERAS, as nursing staff Albany ward were not exposed to these types of patients with any frequency.

Another important contextual influence was the lack of involvement of the ward based nurses in the pre-assessment appointments, which appears to be grounded in the historical events of the implementation process and has contributed to an apparent reluctance from ward nursing staff to take responsibility in relation to certain aspects of the ERAS programme. Nurses claimed that this lack of opportunity for involvement in the pre-assessment process was a hindrance to any attempts to engage with ERAS patients on the hospital ward with one nurse describing how this situation compromised the ward based nurses' ability to reinforce the information that had previously been provided to patients. Again, the factors I have discussed are an important contextual influence on the two subsequent CMOs as the ward based nursing staff on Albany are expected to encourage and sustain patient involvement in postoperative elements of ERAS during patients' hospital stay.

6.3 Columbus CMO1



Columbus was a surgical unit for the care of elective orthopaedic patients, although the only procedure for which patients were enrolled onto ERAS was a total knee replacement (TKR) under the care of one specific consultant surgeon. This resulted in a relatively low prevalence of ERAS patients on the unit at any one time. In conjunction with this, no obvious implementation process took place for ERAS and the activities related to ERAS

development and implementation appeared to have been carried out in isolation by the aforementioned consultant. In accordance with this approach there was also seemingly little effort made to raise awareness of nursing staff through any training or formal dissemination of information relating to ERAS. There was also an absence of any ERAS related pathway documentation, and hence no opportunity for staff involvement in the development of such documentation, which may have had a detrimental effect on attempts to legitimise ERAS on Columbus.

Although the implementation of ERAS on Columbus had been low key and there were few patients on the ward enrolled in ERAS at any one time, some nurses on the ward were aware of the programme and the associations with a faster recovery from surgery for patients.

“I know it’s enhanced recovery after surgery. It’s like a quick recovery, like, to less the stay in hospital after your operation. [...] There’s not a lot of ERAS patients [...] I just don’t think it’s taken off here.” [Case C: RN3]

However, it was also the case that although some nurses were aware of the existence of an ERAS programme on Columbus they could not differentiate to any extent between the care provided to ERAS patients in comparison to ‘non-ERAS’ patients.

“I don’t particularly notice any difference; I have to say. But then I don’t think it’s been particularly pushed either. I think, you know, there’s a feeling that ‘yes, it exists’. But I can’t say I’ve noticed any great difference.” [Case C: RN6]

“It’s what we do anyway [...] this (ERAS) is just putting it on paper.” [Case C: RN7]

In spite of the lack of noticeable differences between the postoperative care of ERAS and ‘non-ERAS’ patients there was still support from nurses on Columbus for the theory associated with providing a rationale for patient involvement in ERAS and a recognition that patient ‘compliance’ with ERAS would promote a faster recovery.

“They’ll comply with you if they have a justification for why they are doing it. [...] If they have a reason for it and they know that reason will make their stay in hospital shorter, they’re gonna do it more likely than if you just tell them that’s what they need to do.” [Case C: RN1]

A potentially influential contextual factor for staff involvement with ERAS on Columbus was the complete lack of involvement by the ward based nursing staff in the patient education sessions. This resulted in some uncertainty amongst the nurses about the information provided during these sessions and a lack of insight into the content of patient education sessions.

“I’ve never been to an education class so I’m not sure what information they get altogether” [Case C: RN1]

Staff cited lack of time and a lack of opportunity as reasons for not taking part in the education sessions and nurses associated this with the perceived ‘fast pace’ of Columbus.

“Never been down there (education session) [...] I suppose it’s just the way it is here [...] I’ve been here four years. You just hit the ground running when you come on this ward and its’ – that’s the pace. It’s just a very fast pace. You just tend not to get involved in stuff like that.” [Case C: RN4]

Although nurses cited time and ‘busyness’ as barriers to their involvement in patient education sessions, some also recognised there was a deficit in their knowledge and understanding of the information delivered to patients during the education session and which hindered their ability to fully engage with ERAS patients.

“For us (ward nurses) there’s not the understanding of what the patient’s’ taught. I’ve never asked out pre-assessment guys what’s actually involved in the pre-education clinic [...] And I think the anxiety may be from our staff, may well be that they have [...] concerns about whether they’re telling them (patients) to do the right thing. So we as nurses might need a little bit more education.” [Case C: RN5]

The lack of nursing staff involvement in patient education had the potential to cause a barrier to nurses own involvement in, and support of, patients on the ERAS programme. Some staff acknowledged that if they were to attend the sessions, this could help them to develop an awareness of the information provided to patients, which had the potential to enhance their patient care, and in turn improve the patient experience.

“I think it would be a good idea for maybe other staff to go down there and see it (education session) [...] it’s just having the time to get down there”. [Case C: RN2]

“I haven’t had a chance to go downstairs (education session) and see what they do. I’m thinking of going and spending some time seeing what really happens [...] to get a more, a better, understanding. Cos then I can teach the patient [...] I think it would benefit my care to other patients [...] to sit on a few sessions and see what they actually do and talk about”. [Case C: RN3]

It was apparent there was little to distinguish between ERAS and ‘non-ERAS’ patients in regard to their postoperative care and to summarise the evaluation of CMO1 for Columbus, it was clear that on this ward the postoperative mobility expectations of ERAS was something that staff were already engaged in and thus this aspect of ERAS was a formalisation of a strategy that was already being enacted. The use of an ERAS programme for certain patients on Columbus was therefore seemingly not particularly significant to nursing staff and had little bearing on their approach to postoperative nursing care, as any changes to practice associated with ERAS were subtle. There was full compliance with early and continuing postoperative mobility on Columbus, but this was already embedded into ward practice prior to the implementation of an ERAS programme. However, interestingly nursing staff acknowledged there were potential deficits in their knowledge and agreed that more involvement in the ERAS programme would support their role and potentially enhance patient care.

Following my analysis and evaluation of conjectured CMO1 (Staff Involvement) across the three case studies, I now present a reconfiguration of this CMO to take into account the contextual factors necessary for successful outcomes in this aspect of the ERAS programme theory relating to patient involvement in patient safety.

6.4 Reconfigured CMO1

[C] Members of the healthcare team who interact with patients enrolled on ERAS

[C] Are involved and supported through the development and ongoing implementation of an ERAS programme

[C] Are provided with ongoing education and information to support their role in the programme

[C] Are provided with opportunities for involvement in the pre-admission element of the patient journey

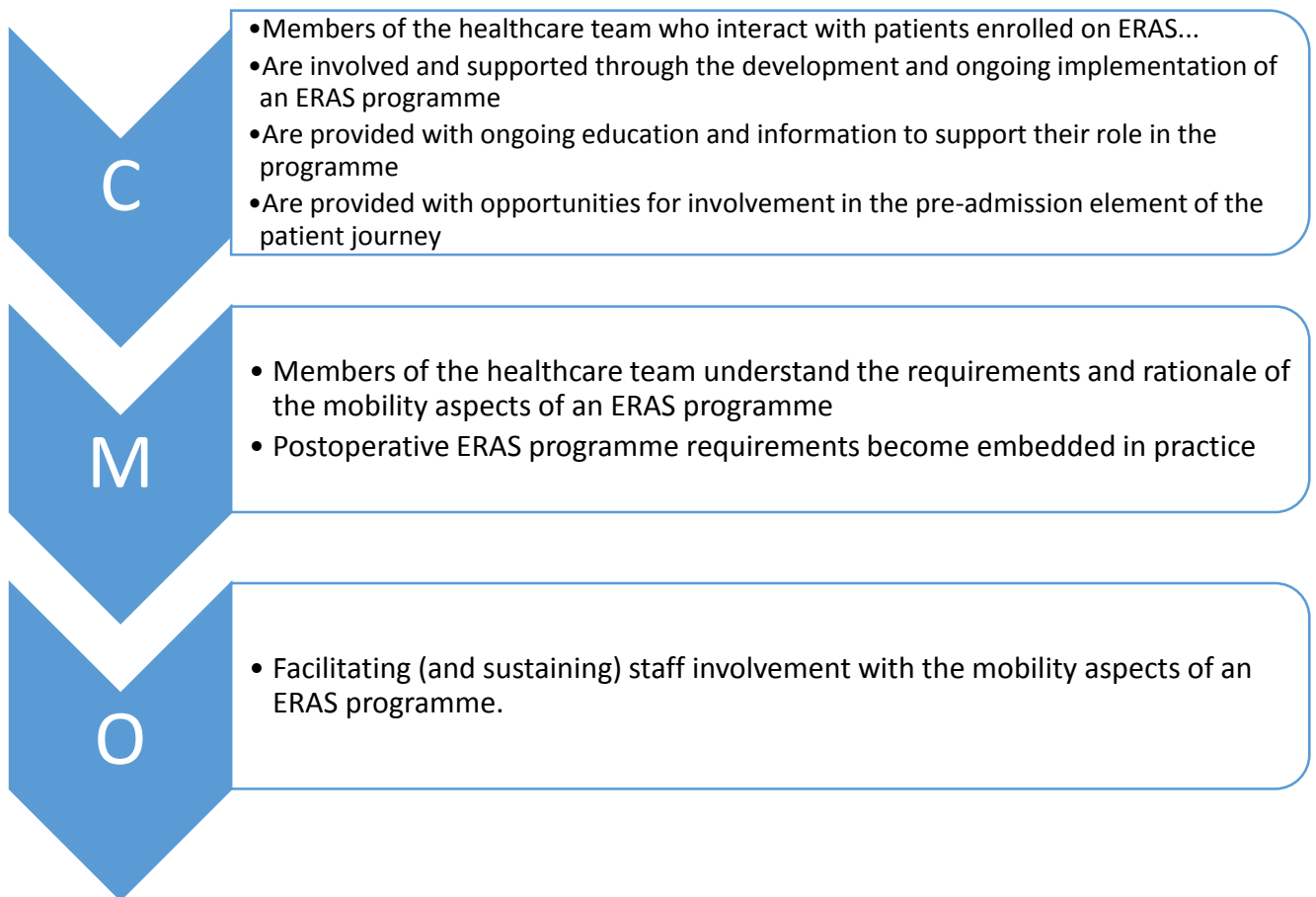
[M] Staff understand the requirements and rationale of the mobility aspects of an ERAS programme

[M] ERAS postoperative mobility requirements become embedded in routine practice

[O] Facilitating (and sustaining) staff involvement with the mobility aspects of an ERAS programme

We can see from these findings the importance of involving staff in any quality improvement initiative. This includes supporting and encouraging staff to take part in the implementation, and ongoing development and evaluation of quality and safety initiatives such as ERAS. It is also important that staff who are expected to engage with improvement initiatives understand the rationale for the associated changes to practice and to aid this, staff should also be provided with formal and information training and education. Further to this, I have considered the mechanisms of effect in light of my data analysis and conclude that not only is there a mechanism relating to staff understanding of the ERAS programme, but also a mechanism which relates to the programme requirements becoming embedded into routine practice. To successfully achieve the desired outcome of staff involvement with an ERAS programme, healthcare organisations should strive to create the conditions outlined here.

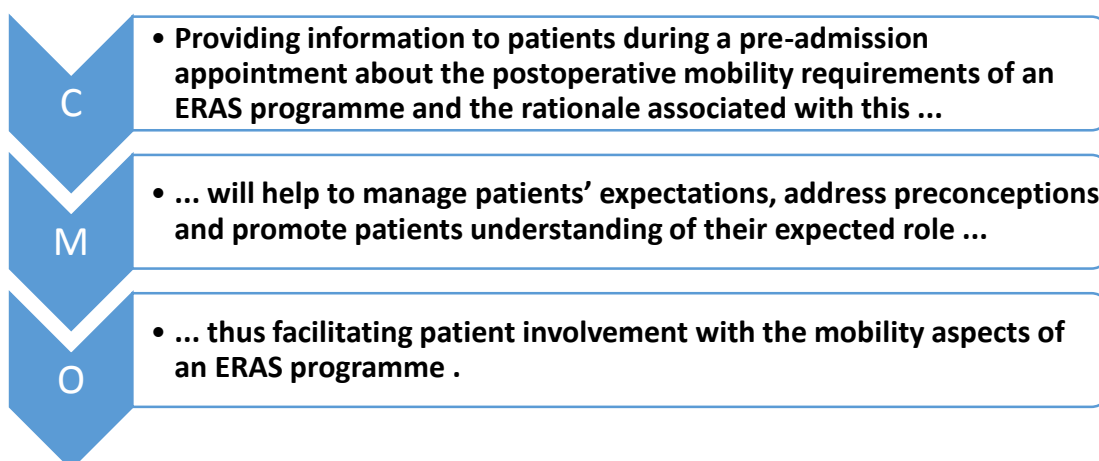
Reconfigured CMO1



Chapter 7: Evaluating CMO2 - Preparation for patient involvement in ERAS

In this chapter I present conjectured CMO2 for analysis and evaluation. This conjectured CMO relates to the provision of information to patients during a pre-admission appointment, which in turn is designed to manage patient expectations and prepare patients for their involvement during their hospital care. Again, I ask questions relating to the contextual factors that influence this conjectured CMO which involved me generating data to allow the 'testing' of this conjectured CMO in terms of the identified outcomes and the contextual influences involved. I have already presented a detailed analysis of what I consider to be key 'overarching' contextual features of the respective case studies in relation to the implementation of ERAS in the respective case studies and, as with the previous chapter, any relevant findings from this data will be taken into consideration and synthesised into my evaluation of this conjectured CMO. At the close of the chapter I will present a 're-modelled' CMO, which will take into consideration the contextual influences at play in the respective cases, thus demonstrating what conditions were necessary in this study to support attempts to educate and inform patients during a pre-admission appointment.

7.1 Bishop: Evaluating CMO2



7.1.1 Bishop: Providing information during a pre-assessment appointment

Patients admitted to Bishop attended a compulsory pre-assessment appointment prior to their operation in which the ERAS programme was explained to them. This included details about how patients would be prepared for surgery, how they would be cared for after surgery and how they could play a role in their postoperative recovery. Patients were also made aware during this appointment that taking part in an ERAS programme required a different approach to 'traditional' surgical care convalescence, particularly in relation to postoperative mobility. Patients from Bishop described how they were presented with information relating to ERAS and in the following data extract a patient describes their experience of a pre-assessment appointment in terms of the information provided.

"I thought they were extremely thorough that day and really prepared you for what was going to happen." [Case B: Patient 7]

The same patient commented on how, prior to the pre-assessment appointment, they were not aware of the ERAS programme and so being provided with information about this this helped manage their expectations in relation to their anticipated postoperative recovery. It was also clear this patient was receptive to the notion of an early and active approach to their surgical recovery.

"I suppose, you know, after any sort of major surgery the expectation is there that you would need to rest, etcetera. But I knew with the type of surgery I was having it would allow me to be mobile a lot quicker. [...] I wasn't aware they actually had that recovery enhancement programme and thought, yes this sounds great. And anything that would get me up on my feet as quickly as possible sounded good to me!" [Case B: Patient 7]

There was also evidence demonstrating that the information provided during pre-assessment was successful in managing patient expectations in respect of addressing inaccurate preconceptions patients' may have in regard to their potential length of hospital stay. (It should be noted that this reduced length of stay was not exclusively related to ERAS interventions, but also relates to the type of surgery patients were undergoing and whether

a laparoscopic technique was being used, which would also have an effect on the anticipated recovery period.)

“When we were first told that I’d need such a big operation we thought straight back to those patients who were in hospital for weeks [...] I thought it was gonna be like that.” [Case B: Patient 3]

“I mean years ago, when you’d be in for a week or a fortnight or three weeks.” [Case B: Patient 8]

Whilst some patients had expectations in relation to bed-rest and ‘traditional’ approaches to surgical care, it was also the case that others had no preconceptions of their recovery pathway. In such instances, whilst the information provided would not specifically manage existing expectations, it could still provide patients with an understanding of what they could expect during their hospitalisation.

“Well of course, I’d never been through anything like this so I didn’t have any different expectations [...] I had no idea what it should be like, or what it was like in the past, so I was just like, ‘Yeah, that’s fine’.” [Case B: Patient 6]

The attempts to manage patients’ expectations during a pre-assessment appointment also included the provision of information in relation to the specific goal-focused orientation expected during the postoperative elements of the ERAS programme.

“They get you up six hours afterwards to sit in a chair if your operations in the morning. And I’m like, fine. And if it’s the next day, you’ll be sitting up in a chair the next morning after the operation.” [Case B: Patient 6]

There were further attempts on Bishop to manage patient expectations by orientating patients to the ward during the pre-assessment appointment and there were patient interview data to demonstrate this was a helpful strategy for some patients.

“Knowing what was gonna happen and where it was gonna happen. That definitely helped, having been in the ward before. That was definitely a help, yeah. You know, to picture myself there.” [Case B: Patient 8]

There was also evidence that some patients on Bishop were aware of the potential benefits associated with taking part in an ERAS programme in relation to reduced risk of hospital acquired infections, as conjectured in the CMO. For the following patients, this was successful in facilitating their involvement in the ERAS programme during their hospital stay.

“It was complete determination to get out. Cos I knew that the longer I was in there, the more at risk I was with hospital acquired infections.” [Case B: Patient 3]

“Well I certainly understood the whole basis of the programme [...] why it was important and the success they had from it. Yes, that was all explained to me [...] which is why I think I was so keen to do it [...] (less chance) to pick up infections, etcetera.” [Case B: Patient 7]

7.1.2 Bishop: Patient receptiveness to information

In the preceding section we have seen examples of when the conjectured CMO relating to the provision of information to patients during a pre-admission appointment is successful in managing patients' expectations, addressing preconceptions and promoting patients' understanding of their expected role in their upcoming hospital care. I have also presented data which demonstrate that this, in turn, has been successful in facilitating patient involvement in the ERAS programme. However, the programme theory presupposes patient 'receptiveness' to this information and in relation to this, a clearly influential contextual feature relating to these theories which emerged during analysis of the data on Bishop was individual patient's receptiveness to the information provided during the pre-assessment appointment.

There was potential for some patients to become overwhelmed by the information being provided during the pre-assessment appointment and the risk of this was exaggerated for patients who had been diagnosed with cancer, which was often the case for ERAS patients on Bishop. There was certainly a proliferation of information provided to patients during the pre-assessment appointment, not just information relating to ERAS, and this could be difficult for some patients to follow and assimilate.

“I think you get so much information. As a patient. [...] If you’re coming in with a diagnosis of cancer, for instance, you’ve only just come to terms with that. Or have you come to terms with that diagnosis? And then you come in and you’re seen by a dietician, you’re seen by a physio, you’re seen by a nurse, you’re seen by a doctor. [...] I think sometimes it can be a little bit too much to take it all in. When you’ve come and you’re nervous anyway because people don’t always know what to expect of pre-assessment [...] the majority of people would be nervous going to a hospital appointment, so how much (do) they retain?” [Case B: RN4]

Due to the respective health board’s approach to the management of cancer waiting lists there was also usually a relatively short space of time between a patient’s diagnosis and the operation. Whilst this can only be acknowledged as a positive factor in relation to improved clinical outcomes, it also left patients with little time to ‘deal with’ a diagnosis of cancer.

“The speed you go through the system can never be a bad thing when you’ve got something like cancer. [...] It’s found and next you’re [...] through the system. And you haven’t had time to deal with your diagnosis before you’re having it (cancer) removed.” [Case B: RN4]

There was evidence to support this from a patient’s perspective. For example, one ERAS patient described how being given a diagnosis of cancer and then the prospect of imminent surgery and uncertainty with the prognosis had compromised their ability to engage with the pre-assessment appointment and they had found it challenging to comprehend and retain the information being provided.

“I was traumatised that I was going to have it done [...] I think that’s the hard part really. The sort of accepting that that’s what’s happening [...] I was so scared I think my brain had stopped working. It really was a bit of a blur. [...] And you don’t know how bad it is. Although they’d assured me as much as they could [...] but inwardly I was worried to say the least. [...] Well I tend to block things out [...] It’s a job to face the fact that you’ve got cancer [...] I do sometimes bury my head in the sand. I find too much knowledge is not a good thing. For me.” [Case B: Patient 8]

In support of this, it became apparent during my observations that some patients were distracted by the experience of their diagnosis and also had concerns about their prognosis.

For example, during one pre-assessment appointment a patient was concerned about the results of the chemotherapy and radiotherapy treatment they had undergone in the lead up to their planned operation. This patient was also keen to find out information about a scan that had taken place. It was clear the patient was distracted by this, however the nurse coordinating the pre-assessment appointment was unable to answer any of this patients' enquiries [Case B: Pre-assessment observations]. It was obvious from my observations and subsequent interview data that the pre-assessment appointment on Bishop was not the designated arena for staff to discuss specific details about patients' prospective surgery.

"We don't really go through the procedure that they're having [...] the medic normally goes through the procedure [...] That's done normally at the bedside the day before they come in. So they get more information when they're consented really. About their procedures." [Case B: RN3]

However, during pre-assessment appointments on Bishop some patients wanted to find out details about their upcoming operation, for example, in one appointment a patient was very keen to find out whether they were likely to have stoma as part of their treatment. The nurse was unable to provide details or assurances about this [Case B: Pre-assessment observations]. This was a relatively common phenomenon in other pre-assessment appointments I observed where patients asked questions about their surgery, for example whether it would be 'open' or 'laparoscopic'. Nurses in pre-assessment were unable to provide specific details and emphasised to patients the uncertainty about the surgical procedure, *'It's all ifs and buts till you get down there'* [Case B: Pre-assessment observations]. Nurses also tried to reassure patients that they were in safe hands *"You'll be fine. They do it all the time here"* [Case B: Pre-assessment observations], without providing any specific details to the patients.

In respect of patients' receptiveness to information, it was acknowledged by the ERAS Nurse that different patients may have different informational needs and that this was something that was taken into consideration during the pre-assessment appointment, suggesting a degree of flexibility and the individualisation of patient information.

"Not everybody wants to know everything about [...] what's going to happen. And we take that into account as well and I hope we wouldn't [...] push people into knowing

things they wouldn't want to know. [...] But there's still certain things that it's important they understand." [Case B: RN6]

However, although reference was made by nurses to *'not pushing'* patients during pre-assessment in terms of their receptiveness to this information, reference was also made to *'certain things'* that patients were expected to understand during the appointment. In addition, despite acknowledging that different patients may require different levels of information, it was apparent from my observations that the pre-assessment appointment was delivered in the form of a *'script'*, based on the ERAS ICP, which nursing staff were reluctant to diverge from even when it was evident that patients were not receptive to the information being delivered. This was demonstrated during my observations in an extract from field notes in which a patient remarked during a pre-assessment appointment that there was *'too much information'*. The patient told the nurse *'I just want to come in and have it (the operation) done'*. During this particular appointment, the patient commented two further times about how they felt there was too much information being provided, but this did not alter the nurse's delivery of the pre-assessment appointment [Case B: Pre-assessment observations].

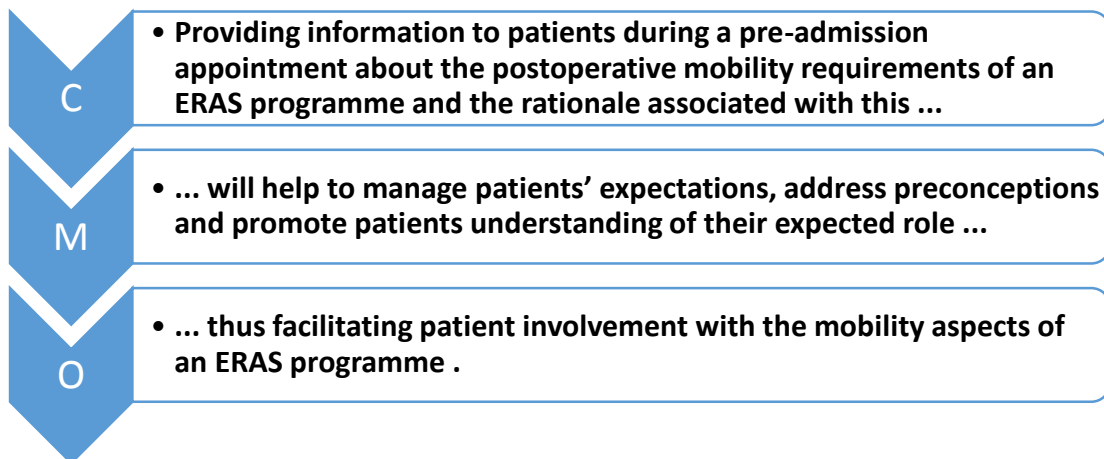
There were also other instances I observed during pre-assessment appointments on Bishop where patients' commented on the large volume of information being provided. For example, one patient remarked to the nurse delivering the appointment *'I don't want to go too deep or I'll start worrying'*. This did not appear to deter the nurse coordinating the appointment, who continued to deliver information to the patient. Interestingly, at the end of this appointment the nurse agreed with the patient, stating that *'sometimes you get too much information'* [Case B: Pre-assessment observations]. During another session, a nurse concluded the appointment by commenting to the patient *'I've bombarded you a bit!'* [Case B: Pre-assessment observations].

To summarise, during this analysis and evaluation of conjectured CMO2 in relation to Bishop we have seen that although there have been successes in relation to the programme theory aspirations, this is often reliant on patient's receptiveness to the information being delivered. This can be affected by patients' level of anxiety, which is associated with their diagnosis, prognosis and upcoming treatment. Patients are also interested in other information relating to results of particular tests they may have undergone in preparation

for their surgery, although it was clear this pre-assessment appointment was not the forum for discussing this type of information.

There was also a lot of information being imparted to patients' during the pre-assessment appointments, with only certain elements relating to the conjectured CMO. Similarly, there was a relatively large amount of information being collected from patients in relation their biography, past medical history and so on. In addition to this, patients were also subjected to interventions relating to their fitness for surgery, which as we have discussed, formed a significant part of the pre-assessment appointment. Although nurses were aware of the issues relating to the volume of information, there was also nursing work that needed to be carried out as part of the pre-assessment appointment and this process is also influenced by the nurses' requirement to complete the required documentation in the form of the ERAS ICP in an efficient and timely manner. All these factors made patient receptiveness during the pre-assessment appointment a more complex entity than that presented in the programme theory.

7.2 Albany: Evaluating CMO2



7.2.1 Albany: Providing information during a pre-assessment appointment

As with Bishop, all ERAS patients on Albany were required to attend a mandatory pre-assessment appointment during which they were provided with information about the ERAS programme. This included information relating to attempts to manage patients'

expectations for an earlier recovery from surgery than ‘traditional’ surgical care in relation to postoperative mobilisation

“When we’d seen [specialist nurse] she went over things [...] it prepared you, yes. It did, fair play [...] I assumed that it was to get you recovered and out of hospital as soon as possible”. [Case A: Patient 1]

For patients who had preconceptions in relation to their upcoming treatment and hospital care the provision of information gave them an understanding of what to expect during their hospitalisation and helped to manage their expectations. In this next extract a patient describes how the provision of this type of information helped build their ‘confidence’.

“All my preconceptions about being a patient were completely wrong [...] I knew exactly what was going to happen [...] that’s part of ERAS, ‘cos they tell you exactly what’s going to happen. I was just amazed at how thorough it was. I mean there was nothing left to chance. And, er, that builds up confidence.” [Case A: Patient 2]

The attempts to manage patients’ expectations during pre-assessment on Albany also included information in relation to the specific goal-focused orientation for the postoperative elements of the ERAS programme.

“I know they put me on the programme [...] they said you should be doing this, you should be doing this, at these certain times. To get me up walking, innit? Like the first day I should have been up”. [Case A: Patient 3]

There was some limited evidence that patients on Albany were aware of the potential benefits associated with taking part in an ERAS programme in relation to reduced length of hospital stay and reduced risks.

“Well it’s to stop you having the clots and things like that. That’s what they told me.” [Case A: Patient 1]

Another patient described how the information provided had helped manage expectations in relation to postoperative expectations and the risks associated with hospital care.

“I was expecting to be in hospital for up to three weeks, ‘cos that’s what it used to be [...] but know it’s eleven days [...] If I’m eleven days instead of twenty-one, then I’ve

got less chance of getting infection. And they've got a bed spare. I mean, the advantages are colossal, aren't they?" [Case A: Patient 2]

7.2.2 Albany: Patient receptiveness to information

Thus far, we have seen examples of when conjectured CMO2 relating to the provision of information to patients during a pre-admission appointment is successful in managing patients' expectations, addressing preconceptions and promoting patients understanding of their expected role in their upcoming hospital care. However, in comparison to Bishop, this evidence is rather limited. However, as we will now see, to some extent this is a reflection of the approach taken by staff to the provision of information and education during pre-assessment on Albany.

We know that the conjectured CMO2 presupposes patient 'receptiveness' to the information being delivered to patients during a pre-assessment appointment and on Albany, as was the case with Bishop, an influential contextual feature which emerged during analysis of the data on Albany was individual patient's receptiveness to this information. Analysis of the data demonstrates there was clearly less emphasis placed on providing information to patients in relation to managing their expectations on Albany, than was the case with Bishop. This approach was intentional on the part of the specialist nurses as there was an expectation that patients would be involved in the ERAS programme postoperative mobility requirements as a matter of course during their hospital care, so the rationale was that there was no requirement to highlight this in any detail during pre-assessment.

"I'm very easy with the whole thing [...] I'm a big believer in trying not to stress the patient out [...] To me, (ERAS) is the least of their worries when they've had as massive an operation as they've had. [...] Other people might disagree with that and think I should be making it this mega massive thing. To me – and it's worked so far – if you play it down it just becomes part of what they're going to be doing anyway."

[Case A: SNP]

The approach taken by Albany in relation to expectation management also took into consideration the potential anxieties and concerns patients' may be harbouring in the time leading up to an operation in relation to their diagnosis, their ongoing treatment and their

prognosis. It was clear from the comments made by the SN that ERAS related information, including patient involvement in patient safety through mobilisation, were not considered to be the priority for these pre-assessment appointments.

“This really isn’t a big deal compared to what they’ve been through to this point. And what they’re gonna be going through in the operation. [...] They have their initial diagnosis. That blows them out of the water. Then they go through this long staging process [...] and then they come back and they’re told ‘yes’, they’re going to have an operation [...] Don’t make it such a big deal because they’ve had so much trauma before they get to us. [...] What on earth would they want to be sat there worried about enhanced recovery for? It’s the least of their worries. They just want to be alive. They want to get through that operation. They want to live for a few more years.” [Case A: SNP]

Another nurse also commented on the seriousness of the diagnosis patients’ had most likely been presented with and described how, in light of this, many patients’ focus was most likely to be on their treatment and the associated prognosis.

“And they’ve had a devastating diagnosis as well. And prognosis. So they’ll be dealing with all that fear as well [...] As well as being a huge operation which is – they’re only having it because it’s potentially curative. But they must have had the information that it might not be and it could be recurrences. And if they’ve looked it up, it’s not fantastically successful in the long term.” [Case A: RN3]

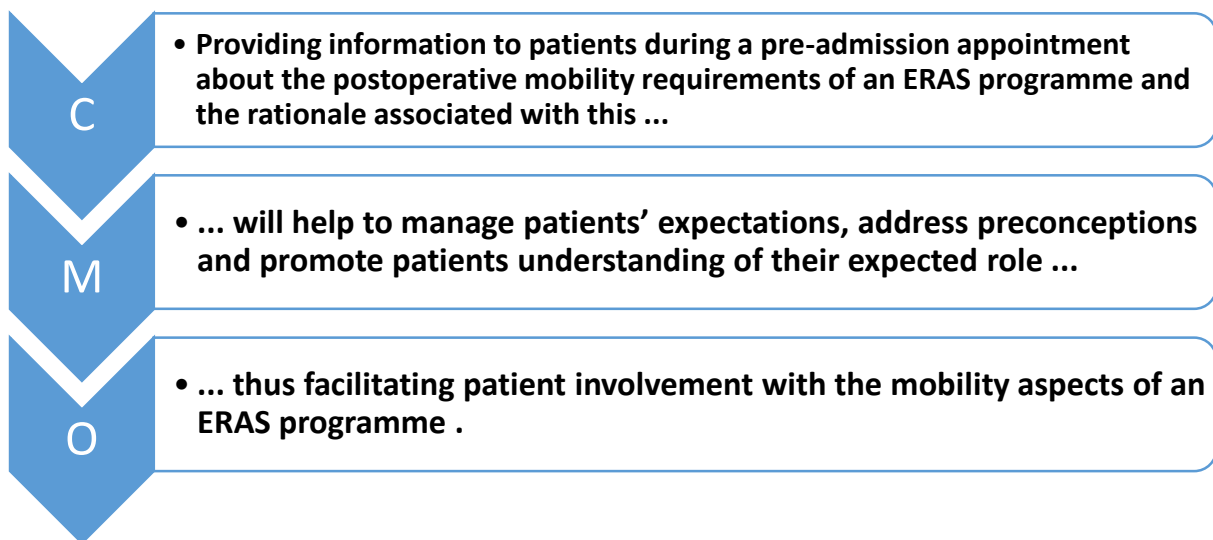
It was also acknowledged that patients would likely be anxious and nervous about their upcoming operation.

“They’re nervous about coming in, you know. Anxious about the operation and they’ve got a lot of things on their mind anyway.” [Case A: RN1]

During my observations of pre-assessments appointments on Albany it was not the case that there was no reference made to ERAS in relation to the postoperative mobility requirements, rather that this was afforded a relatively low priority and there was less attention paid to this than was the case during the Bishop pre-assessment appointments. As with Bishop, there was a lot of information being imparted to patients’ during the pre-

assessment appointments on Albany and a relatively large amount of information being collected from patients, who were also expected to engage with interventions relating to their fitness for surgery. However, there appeared to be more flexibility and autonomy from the SN during the pre-assessment appointments, in comparison to the nurses on Bishop and this has been demonstrated by the earlier quotes from the SN referring to how ERAS was not patients' main concern at this juncture of their treatment. There was, however, still a requirement by the SN to complete the required documentation in an accurate and timely fashion.

7.3 Columbus: Evaluating CMO2



7.3.1 Columbus: Providing information during a pre-assessment appointment

Patients on Columbus were invited to an optional patient education session, during which those who attended were provided with information about their upcoming treatment and hospital care. Although the format of the sessions was different to the pre-assessment appointments delivered by Bishop and Albany, the information provided during the Columbus sessions in relation to managing patients' expectations for an active role and reduced length of stay was similar to that provided in those other cases. As I have discussed in the implementation section, there was a deliberate strategy by the team delivering the sessions on Columbus not to make specific reference to an ERAS programme. However,

patients described how they were made aware of the 'active' approach to postoperative care and discussed how attending an education session helped to manage their expectations.

"I (was told) I wouldn't be, sort of, you know, taking a lot of bed rest particularly. [...] I didn't mind the thought of that because for me [...] the sooner I was up, the better."
[Case C: Patient 2]

"I just found that bit (patient education session) very useful, because it was all literally, 'This is what's going to happen. This is what you're going to do [...] I found the education day really, really good from the point of view that it started to put things into pockets for me, that me understand what was coming my way and what was happening". [Case C: Patient 3]

Attempts to manage patients' expectations during the education sessions also included information in relation to the specific goal-focused orientation for their hospital care and one patients described how this prepared them for early postoperative mobility.

"I remember the physio telling us that on the day of the operation, if you have your op in the morning, that they would have you out of bed and standing by sort of late afternoon". [Case C: Patient 3]

There was evidence from Columbus that attending the education session raised patients' awareness of the potential benefits of taking part in the required mobility, along with the rationale for this in relation to reduced length of hospital stay and reduced risks.

"They told us things like DVT's, you know? Obviously the more movement you have, the less likelihood there is of a DVT development. [...] It was all part of the recovery programme, they get people up and mobilise as quickly as possible [...] because the sooner you get up and are moving, the quicker your recovery is going to be." [Case C: Patient 3]

"It was all to do with infections and blood clots and all the rest of it. Oh yes, that was all explained to me very clearly [...] I knew exactly what they were doing and why it was important" [Case C: Patient 7]

ERAS patients admitted to Columbus were scheduled for a TKR with a predicted length of stay of between two and five days, which was conveyed to patients during the education session. In the following data extract, a nurse explains how this approach helped to address any inaccurate preconceptions patients may have in relation to their length of hospital stay.

“A lot of people are shocked when they say ‘How long will I be in hospital?’ especially with a knee or hip I’m like ‘Four days. Five days maximum.’ They’re quite shocked by that. ‘Oh, I thought I’d be out in about two weeks’”. [Case C: RN4]

There was also evidence from a patient respondent in relation to this, who described how the discharge related information was successful in managing expectations in respect of changing what turned out to be inaccurate preconceptions in regard to their anticipated length of hospital stay.

“You’re in hospital for about four or five days at the most. And it’s an everyday operation. Basically. So that calmed the nerves a lot, that did help.” [Case C: Patient 6]

7.3.2 Columbus: Patient receptiveness to information

So far, we have seen examples of when conjectured CMO2 relating to the provision of information to patients during the patient education session is successful in managing patients’ expectations and addressing their preconceptions. However, as discussed, the success of this programme theory requires that patients are receptive to this information and education. The voluntary nature of the education sessions on Columbus resulted in a relatively low uptake from patients and this is clearly a relevant and important contextual influence on this conjectured CMO in relation to Columbus. Put simply, if patients are not exposed to information, then it cannot have any influence. This low level of attendance was largely a consequence of providing specific patient education sessions, rather than combining these elements within a wider ranging compulsory pre-assessment appointment, as was the case with Bishop and Albany.

In addition to this, each education session lasted approximately two hours and those patients who did attend were exposed to a considerable volume of information and

education. The specialist nurse who led many of the education sessions told patients they may feel ‘*overwhelmed*’ and ‘*bombarded*’ by the amount of information provided during the session [Case C: Field notes patient education session], which covered topics about the entire patient journey including pre-admission and post-discharge information. One patient suggested that sitting through the entire education session was quite a feat of endurance, noting that some participants left during the break provided midway through the session they had attended, as detailed in the quote below. Whist another patient referred to how they ‘*might have felt a bit overloaded*’ [Case C: Patient 2] during the education session they attended.

“But that education session flipping ‘eck, it goes on forever and a day [...] I went for this one. And I thought, I’d better go and have a look like [...] it was going on and on and on for hours. When we went for tea break [...] a lot of people didn’t come back. Yeah, they went. I went back, I thought I might miss something interesting”. [Case C: Patient 1]

A further contextual factor which could affect the receptiveness of Columbus patients to information was the variation in time elapsed between patients attending an education session and the date of their operation. National policy (NHS Wales HTG 2011) defines the optimum time between attending an education session and having elective orthopaedic surgery as four to six week. However, these time-frames were not being achieved consistently for Columbus and those patients who were attending education sessions were sometimes doing so at what was considered inappropriate times, potentially rendering the information less effective (or ineffective).

“The one I was invited to was actually the day before my surgery. So that was probably a bit unusual. And, in fact, I left at the halfway through point because I felt that actually I needed to sort of be physical preparing [...] And so, um, although I felt that the information that was being given to me was very useful, I felt that probably the priority for me was actually sort of physically getting ready to come in (to hospital) [...] because it’s gonna be, you know, to prepare you mentally and emotionally really, for what you’re gonna go through. And I think really that was a little bit too late for me.” [Case C: Patient 2]

This lack of consistency as to when patients attended education sessions was supported by observations. For example, one patient in an education session commented they were booked for surgery two days following the session, whilst another was booked for four weeks hence. This was recognised by nursing staff as an issue which was having a deleterious effect on attempts to provide information to patients in an effort to manage their expectations.

“We just need to capture the patients at the right time for that clinic [...] you don’t want to invite someone who’s coming in the next day. It’s just getting the balance right, but it’s hard [...] we need to get a process in place to get those patients in at the right time.” [Case C: RN7]

In addition to this, although during the sessions, participants in the group were actively encouraged by staff to make the sessions ‘interactive’ and encouraged to talk to staff and ask questions, there was an expectation from staff that these questions were couched within certain parameters. That is, they needed to relate to the specific predetermined themes of the education session. However, during my observations of education sessions there were several enquiries raised by patients which did not fit these parameters and in these cases patients were advised by staff to redirect to the ‘pre-assessment nurse’ or surgeon. These queries related mostly to patients’ individual treatment and individual medicine management queries, rather than the more general information presented in the education session and patients were informed that any decision relating to this lay with their respective surgeon. However, patients were provided with an opportunity to raise these specific issues with staff during the scheduled break provided at the mid-stage of the session and staff also made themselves available at the end of the sessions for any patient enquiries that fell outside the remit of the generic education session. However, these interruptions and tangential interludes were a source of frustration for the staff running the sessions and it was clear these distractions were deflecting the sessions from the main purpose of providing general education and information to patients and also contributing to the lengthy duration of these sessions. These issues were clearly related to the scheduling of the patient education appointments in relation to the patients’ pre-assessment appointment and operation dates.

“It’s tricky for us because I was just there last week (education session), the majority of our time was just explaining stuff about pre-ad (the fitness for surgery pre-assessment appointment). And it’s just a bit disheartening that this is not the purpose. Getting them in to education, that’s fine. But getting them in at the right time, that’s the key” [Case C: RN7]

To summarise my analysis and evaluation of conjectured CMO2 in relation to Columbus, as with the other two cases there are clearly successes in relation to the programme theory aspirations about patient involvement in patient safety. The main contextual influence relating to patients’ receptiveness to this information appears to be whether or not they attend an education session. However, as with Bishop and Albany, some patients on Columbus reported being overwhelmed with information and this was corroborated by staff. This is despite the fact that, unlike the other cases, there was no ‘fitness for surgery’ or biographical type information collected by staff in these sessions and the focus was solely on managing patients’ expectations for their upcoming care. The organisation of the education sessions was also an influential factor, with seemingly no clear pattern as to when patients attended in relation to their date of surgery or ‘fitness for surgery’ appointment. ERAS patients scheduled for surgery on Columbus were all scheduled for a TKR and in contrast to the other two cases patients would not have the underlying anxiety relating to a cancer diagnosis, although there would be anxieties associated with a hospital operation. The patient education sessions for Columbus were focused on the potential positive outcomes of the treatment, which if successful would invariably be a source of relief for patients. It should be noted that a review of waiting times for this health board in relation to these procedures reveals that many patients had been waiting some months for their operation, which in itself may be a source of some anxiety.

7.4 The reconfigured CMO2

The data presented across the three case studies demonstrate that the provision of information relating to mobility goals and predicted date of discharge can be beneficial to patients in terms of creating a goal-orientated focus and it was evident that the provision of this type of information was also related to the programme theory in relation to managing patients' expectations. Patients across all three cases reported receiving information about goals in relation to early and continuing postoperative mobility and predicted dates of discharge and I also observed this information being delivered. Many nursing staff across the three cases demonstrated an understanding of the theory associated with providing this information to manage patient expectations and create a 'goal-orientated' focus. During interviews patients from across all three cases corroborated this element of the conjectured programme theory, describing how the information they were provided during the pre-admission appointment had helped to manage their expectations and encouraged them to consider mobility goals and discharge goals.

Although there were variations across the three cases in how information was presented to patients in relation to ERAS and patient involvement in patient safety, the content was similar across the three cases (even though no direct reference was made by staff on Columbus to the ERAS programme). Across all cases the provision of this information during pre-admission was demonstrated to be beneficial in managing expectations and addressing inaccurate preconceptions for some patients in relation to their postoperative care and rehabilitation. When patients claimed to have no preconceptions regarding their treatment, data shows that this information can still prove to be beneficial in setting patients' expectations, rather than managing expectations. For all three cases there were data demonstrating that some patients' understood the rationale for aspects of the mobility requirements of an ERAS programme in relation to the improved outcomes and reduced risks associated with early rehabilitation. There were also data which demonstrated some patients were aware of the risks associated with hospital care and that their exposure to adverse events would be reduced by a shorter hospital stay.

However, there were also contextual factors identified for all three cases which had an influence on the outcomes of conjectured CMO2. Firstly, there was a considerable amount

of information provided to, and collected from, patients during the pre-assessment appointments on Bishop and Albany, whilst on Columbus a lot of information was provided to participants in the education sessions. There was evidence from all three cases that some patients felt that too much information was provided during these sessions and there was also acknowledgement from some nursing staff across the three cases that different patients will have varying informational needs. The priority for staff involved in the pre-assessment appointments on Bishop appeared to be to ensure that patients were exposed to the pre-determined information, with far less credence given to whether patients were receptive to this information, whether patients understood the implications associated with this information, or whether their wider information needs were being met.

On Albany, in comparison to Bishop, there was a more relaxed approach taken by the specialist nurses in relation to the provision of information during pre-assessments. The specialist nurses had an extended role and would have met with ERAS patients at least once prior to the pre-assessment appointment, which ensured that the nurse was more informed about each patient's treatment plan. This was not the case with Bishop, where the nurses involved in pre-assessment would not have met patients previously and would have little insight into patients' treatment plans or history. This also reflects the different status of the nursing staff in the respective cases, where those staff nurses delivering pre-assessments on Bishop are likely to be more rule-bound than the specialist nurses in Albany.

In addition to these factors, some patients were not as receptive to information provided during the pre-assessment appointment due to anxieties and concerns relating to their diagnosis and prognosis, ongoing treatment and upcoming operation. In all three cases there were patients who sought specific information about their operation, however it was explained to patients that this all this type of information would be discussed at a later date.

Following my analysis and evaluation of conjectured CMO2 (patient preparation) across the three case studies, I now present a reconfiguration of this CMO to take into account the contextual factors necessary for successful outcomes in this aspect of the ERAS programme theory relating to patient involvement in patient safety.

[C] Staff provide information to patients during a pre-admission appointment about the postoperative mobility requirements of an ERAS programme and the rationale associated with this.

[C] Patients are exposed to the information (through a mandatory appointment)

[C] Information is delivered during an appropriate time-frame in relation to the patient's surgery

[C] Patients are receptive to the information being provided

[C] Consideration made of patient's potential anxieties and concerns in relation to their illness and upcoming treatment

[C] Staff recognise and acknowledge patients' informational needs and have the opportunity to tailor / personalise patient information

[C] Opportunity to address patient concerns or questions outside the predetermined scope of the appointment

[C] Patients provided with access to information about other elements of their treatment – a coordinated approach to care, with guidance and support for patients to seek further information

[M] Will allow patients and staff to explore preconceptions and manage patient expectations

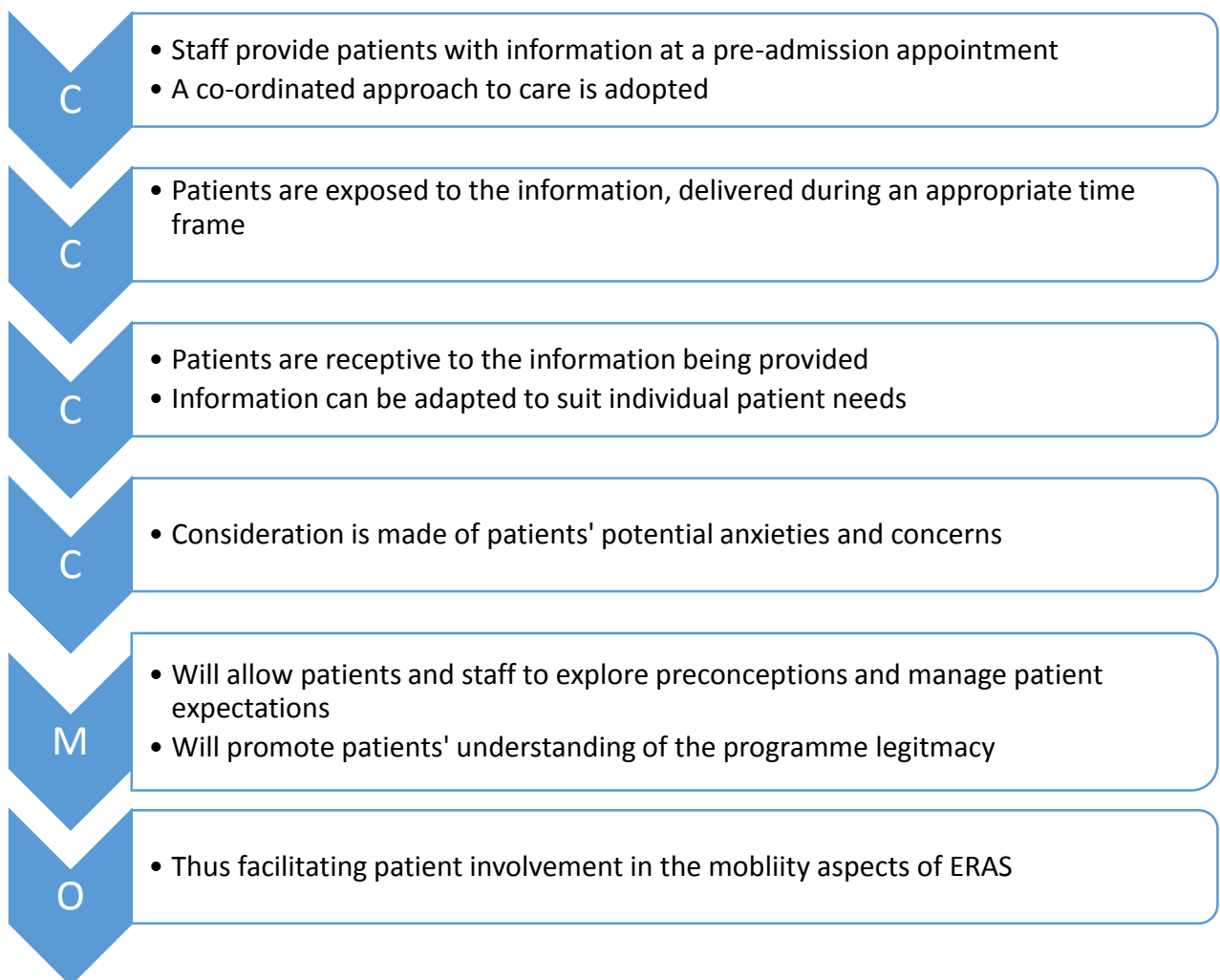
[M] Will promote patients understanding and the programme's legitimacy

[O] Thus facilitating patient involvement in the mobility aspects of an ERAS programme

An important observation to be made from the findings in relation to conjectured CMO2 is the lack of individualised care for patients during the pre-admission appointment. We can also see from the findings and the subsequent reconfiguration of the conjectured CMO that a key issue in relation to this programme theory is the receptiveness of patients to the information that is being presented to them. It is likely that a compulsory appointment for all patients enrolled onto an ERAS programme, with consistent timing of this appointment in relation to patients' date of surgery would resolve some of the issues associated with this. However, there also seems to be a requirement for several other considerations to be made in relation to how receptive patients are to the information, and indeed what sort of information is provided and whether this information can be tailored to match the needs and wants of individual patients. Staff also need to be consistently alert to any anxieties patients may have and any concerns they may harbour and work with patients to address

these issues. This may require consideration being made to the potential of ‘overloading’ patients with information and though should be given to how much of the information patients have taken on during this appointment. To support the requirements of patients’ there should also be opportunity for patients to request information which, in the current format of pre-admission appointments, is often restricted. This would require a more coordinated, ‘joined-up’ approach to patient care, which could also direct patients to sources of support and information in addition to that being provided during pre-admission appointment.

Reconfigured CMO2



Chapter 8: Evaluating CMO3 - Sustaining Patient Involvement

This chapter will consider conjectured CMO3 relating to healthcare staffs' efforts to reinforce the information provided to patients during pre-admission, with a focus on the postoperative mobility requirements of the ERAS programme. As with the previous two chapters, I will present conjectured CMO3 for analysis and evaluation, again asking questions relating to the contextual factors that influence this conjectured CMO. Once more, this involved me generating and subsequently analysing various sources of data to allow the 'testing' of this conjectured CMO in terms of the identified outcomes and the contextual influences involved. As with the other CMOs I have presented, I will also take into consideration relevant data from my implementation chapters and synthesise this into my finding.

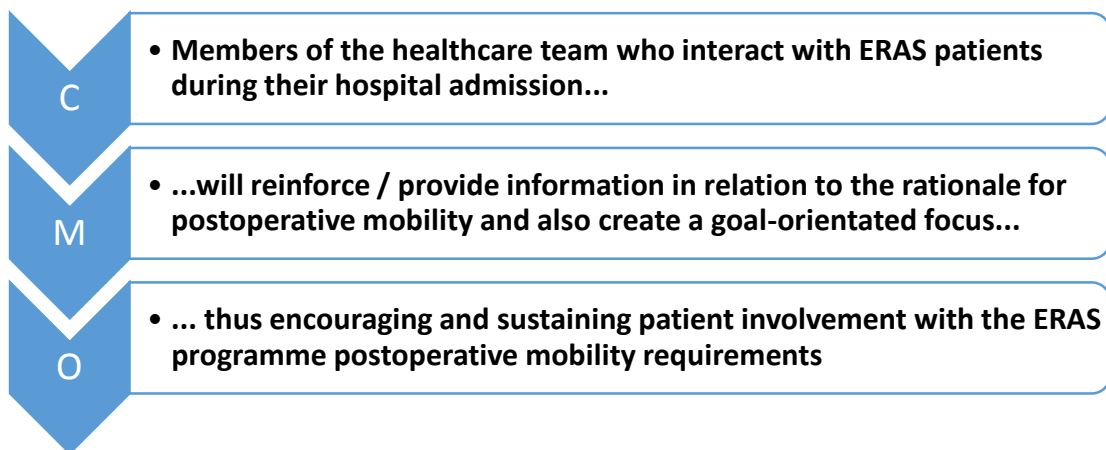
In accordance with the conjectured CMO3 there is an expectation that information provided during a pre-admission appointment will be reinforced by members of the healthcare team who engage with patients during their time on the respective hospital wards. The theory being that this approach will help to support and sustain patient involvement in the appropriate postoperative aspects of ERAS. Ward based staff are also expected to provide goals for patients and encourage and support patients to achieve these goals with the underlying programme theory being that encouraging and maintaining goal orientated behaviour in patients can help set the context as being one of 'active recovery' from surgery, rather than 'traditional' convalescence.

It has already been demonstrated across the three cases that some patients were receptive to the information provided during a pre-admission appointment, whilst other patients were less receptive to this information due to a variety of issues impacting on their particular informational needs at the time of the pre-admission appointment. There were also many patients on Columbus who had not been exposed to the pre-admission information. It is important to note that, as a result of this, for many patients on Columbus ward their first encounter with the information described was when it was presented to them by ward staff. Similarly, for those patients on Bishop and Albany (and to some extent Columbus) who were not receptive to the information when originally provided, this may

appear to them as ‘new’ information presented by the ward staff. In this sense the ward staff would act as a proxy for provision of patient information and thus in these instances, this element of the programme theory was not so much about reinforcement, but about providing new messages to patients.

Again, I begin with Bishop before proceeding to Albany and Columbus and then present a ‘re-modelled’ CMO, which will take into consideration the contextual influences at play in the respective cases, thus demonstrating what conditions were necessary in this study to support attempts to involve patients in their safety through postoperative mobility.

8.1 Bishop: Evaluating CMO3



8.1.2 Bishop: Sustaining Patient Involvement

Reinforcement of the ERAS programme requirements for patients on Bishop took place as a matter of course by virtue of the fact that the ‘active’ approach to care and early and continuing postoperative mobility outlined in the programme theory was a standard approach to patient care on Bishop ward. It was also clear from my observation and interview data that ERAS patients on Bishop were involved in early and continuing postoperative mobility and were supported and encouraged in this by members of the ward staff including the physiotherapist, HCSW and other nursing staff, while some patients would also carry out their ‘laps’ of the hospital ward independently. For those patients who required support, it was more likely to come from the HCSW or physiotherapist, but this did

not detract from the fact patients enrolled on ERAS were receiving the necessary support for their involvement in ERAS.

“They did get me out of bed and start saying, ‘you’ve got to do this and you’ve got to do that’ [...] they did follow it through and make sure I was up and doing as soon as I could possibly be.” [Case B: Patient 2]

There was also evidence that patients were aware of the rationale for the mobility aspects of ERAS and patients who were involved in this aspect of postoperative care also demonstrated an understanding of the of the benefits associated with this. This in turn acted as a form of motivation for patient involvement during their surgical recovery.

It was complete determination to get out. Cos I knew the longer I was in there, the more at risk I was with hospital acquired infection. [...] The physio came round and said to me, ‘Well do you want to come for a walk round? And I almost leapt out of the bed, she had to hold me back” [Case B: Patient 3]

“I did have a walk around with a nurse [...] they told me it was important, naturally you know yourself [...] if you can get out and move, get your muscles going and get the blood flowing. Otherwise, you don’t want to be lying in bed all the time. So as soon as I could I would get out and sit on the seat.” [Case B: Patient 4]

In accordance with the programme theory relating to providing a goal orientated focus, patients were also provided with specific goals in relation to their discharge and the efficacy of this approach to encourage patient involvement was supported by nurses on Bishop.

“I think it’s great for them to have a target, isn’t it? A lot of people area keen to come in and have their surgery and go and I think it gives them something to aim for.” [Case B: RN3]

There were also data that demonstrate this goal-orientated approach was successful in encouraging patient involvement in ERAS, although this next quote refers to goals relating to discharge planning rather than postoperative mobility.

“They gave me a proposal, a discharge date. I had it done on the Wednesday and I was expected to be out on the Saturday. [...] And I really worked hard at it and got

out on the Friday. [...] I knew being the kind of person I am, that I would go whole hog and get out.” [Case B: Patient 3]

It was also apparent that there was a reliance on patient compliance as an enabler for successful patient involvement in the mobility elements of ERAS and in support of this one patient indicated they were prepared to do what was required if it supported their recovery, even though this ‘compliant’ approach was not something they would ordinarily be comfortable with.

“I just basically had told myself that the only way I can get better quick is to be totally compliant. Which goes against the grain for me. But in this instances I decided whatever they tell me to do, I’ll do.” [Case B: Patient 3]

In this section we have seen data supporting conjectured CMO3 relating to the reinforcement of previously delivered information on the hospital ward. This is in relation to patients’ adopting an ‘active’ role in their postoperative recovery, and there are also data to support the programme theory of providing a goal orientated focus to patients. Further to this, there are data to support the programme theory that this type of approach to patient care will encourage and motivate patient involvement with the ERAS programme postoperative requirements. I have also presented data which demonstrates that this approach by staff has been successful in facilitating and sustaining patient involvement in the ERAS programme. It should be noted that, although there were no specific examples in my data of staff reinforcing the rationale for early and continuing postoperative mobility, there are examples of patients discussing their involvement in the activities whilst also describing the associated rationale in relation to patient safety. However, the programme theory presupposes patients will take part in these aspects of their postoperative care as a matter of course and in relation to this, there are clearly influential contextual feature relating to these theories which emerged during analysis of the data on Bishop. These relate to patients’ willingness and ability for involvement, which I will now present in more detail.

8.1.3 Bishop: Patient willingness and ability for involvement

In relation to patients' willingness and ability for involvement in the postoperative mobility requirements of an ERAS programme, one nurse described how there was no obvious discernible pattern evident to them as to why particular patients on the ward were more, or less, likely to become involved in these ERAS programme requirements.

"You can even split down ERAS patients to the ones that want to be involved and want to engage in it and the ones that aren't particularly concerned about it and just want to come into hospital and have an operation." [Case B: RN4]

This nurse also commented that, despite providing all patients with the same information and managing their expectations, there would still be a variation in patients' ability to follow particular requirements of the ERAS programme.

"You do get people that despite all the information still don't quite follow the pathway as you'd hope. And then somebody else that gets the exact same information, flies ahead and does everything that they're asked of." [Case B: RN4]

There was an emphasis on the importance of treating each patient 'individually' and one nurse described factors associated with patients that could influence patients' willingness and ability to take part in postoperative mobility. These different factors were also variable during the course of the patients' admission.

"You always have to take everybody as an individual. And that's kind of almost like the type of mood they're in at the time. Because you'll get a better response from some than others. Depending on if they're uncomfortable, if they're in pain anyway or if they're just tired" [Case B: RN5]

There was also the potential for postoperative complications to occur with patients on Bishop which could have a deleterious effect on their recovery and it was apparent that these complications could occur with any patient, regardless of whether they were enrolled on ERAS.

"You still get, um, the people that don't do as well. But then I think you're always going to have those even if they weren't done on the ERAS programme. [...]"

Sometimes ileuses (a blockage of the intestines caused by a lack of peristalsis). But then you can have that if you're not on ERAS. It's just something that happens." [Case B: RN3]

The previous quote is supported by comments made by the ERAS Nurse. However, there is some contradiction here as although there is acknowledgement of the need for flexibility, ERAS is also referred to as 'standardising care'. In this respect, there was clearly a tension between striving to achieve the aspirations of standardisation whilst also being 'flexible' and allowing variances.

"A pathway is a plan of care, but it's not a rigid plan [...] there are variances and we accept that not everyone is going to follow that plan of care and that's fine as well [...] it's not a tick list. [...] It is about standardising care, though." [Case B: RN7]

In order to sustain patient involvement in the desired elements of the ERAS programme, a nurse described how there was a need to be flexible in their approach to the ERAS goals and to 'pace' patients' recovery, acknowledging that individual patients recover at different rates. This demonstrates that nurses were alert to the varying willingness and ability of patients and that there was a degree of flexibility with the goals associated with the programme, which nurses had some influence over.

"We are flexible, yeah. And I think it comes with experience with (ERAS). 'Cos when it was first introduced, I think that was one of the difficulties, was staff understanding the pathway is just that, it's a pathway, you know? It's not set in stone. It's there as a guide, it's not there to be rigid [...] Because some people are quicker than the pathway would anticipate you going and some are slower and you just have to judge that on the patients' recovery." [Case B: RN4]

Other nurses also described how it was important that patients were 'paced' through the postoperative mobility requirements to prevent patient over-exertion, which could lead to a setback in recovery. In this respect, the role of the staff was not only to encourage and motivate, but also to monitor patient progress to avoid patients' experiencing any adverse effects from early rehabilitation. This approach from staff would also help ensure that patients were achieving the desired outcomes of the programme in relation to patient

safety through early and continuing mobilisation and again this can be seen as a form of compliance.

“It’s in moderation, isn’t it? Be sensible. All they’re supposed to do is four sixty metre walks. And if they try to do more than that, they are gonna be sore. [...] It’s getting that happy medium. Knowing that if you overstep the mark you could be doing damage.” [Case B: RN2]

“We’ve had a few patients who are brilliant after their surgery, you know? No pain at all, no sickness or anything. So they get on, they just push it so hard [...] which is not bad, and then the day after that [...] everything wears off and they start being sick, they start to be in pain, um, and then as an effect of that they don’t want to walk around as much as they should be doing. But you know, again you just pace it out, you just take it slow really. It’s better to start slow and build it up, rather than go big time straight away and then you eventually fall flat.” [Case B: RN1]

Nursing staff from Bishop described how they were alert to the needs of patients who may not be able to carry out the postoperative mobility requirements of the ERAS programme. Nurses also explained how they would encourage patient involvement in this aspect of care but would not push patients, recognising that some patients were unable to take part.

“Some patients just feel awful after surgery and [...] they just can’t do what we’re asking them to do. And if they can’t, it’s not about pushing people. We encourage, but we don’t push people. So if you really can’t, that’s fine.” [Case B: RN7]

“The mobilisation, I think if somebody can’t do it you’re not going to make them do it.” [Case B: RN3]

In the next data extract, a patient from Bishop described how they felt involved in the planning of aspects of their postoperative care, rather than this plan being imposed on them. This is important in the context of patients’ willingness and ability to engage in postoperative mobility and does lend support to the data from nursing staff which highlights a ‘flexible’ approach to postoperative goals.

“It wasn’t like, ‘this is the plan and on day one you’ll be able to do this, day two’. It was, ‘Well, this is what we’re working towards and how to get you there’ [...] I didn’t feel like it was their plan”. [Case B: Patient 2]

However, there was evidence to suggest it was not always the case that patients on Bishop were given the opportunity to tailor the ERAS mobility goals to suit their individual willingness or ability. One patient commented that although they had experienced postoperative complications, initially, they believed they were ‘pressured’ to take part in ERAS mobility.

“I picked up a water infection [...] and you know, I felt really rough in the morning, I didn’t need nagging. I knew it was important [...] I felt a little pressurised [...] to get on and do what I was supposed to do even though I was feeling dreadful”. [Case B: Patient 7]

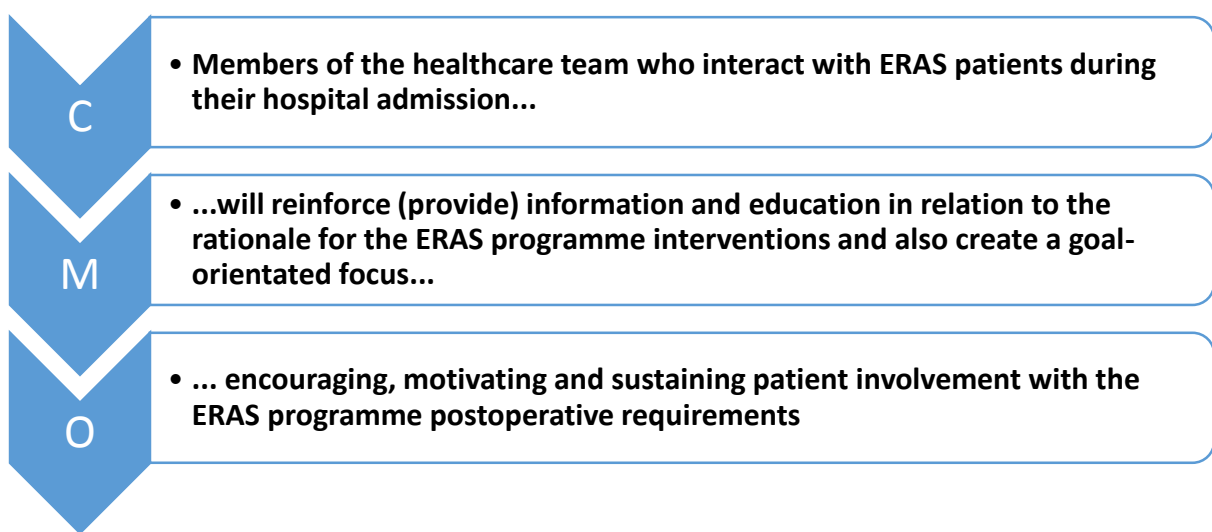
This patient went on to describe how eventually healthcare staff ‘allowed’ them to carry out rehabilitation at their own pace, but it was evident that this patient’s experience did not initially correspond with nurses’ description of a flexible approach to postoperative care.

“But I think, you know, it should be tailored to individuals rather than, ‘yes, everybody will do this no matter how they are feeling”. [Case B: Patient 7]

To summarise, during my analysis and evaluation of conjectured CMO3 in relation to Bishop we have seen that, although there were successes in relation to the programme theory aspirations, this was often reliant on patients’ willingness and ability for involvement. There were also obvious variations in each patients’ postoperative recovery journey and contextual influences that affected these variations and patients’ level of involvement. This included postoperative complications and illness, pain and discomfort, and fatigue. The data also shows that nursing staff were alert to individual patients’ needs and made reference to ‘pacing’ patients through their postoperative recovery and the mobility requirements of ERAS. However, there was also an apparent tension between the programme requirements and patients’ willingness and ability take part in these programme requirements. This was particularly evident in the remarks made by the ERAS Nurse in relation to the conflict between the need for standardised care versus individual patient variances. In this respect, there is some limited data that shows that although nurses were aware of the issues relating

to patients' willingness and ability for involvement, sometimes the requirements of the programmes and the related goal-orientated focus took precedence and this could be to the detriment of the patients' recovery. As with the pre-admission aspects of ERAS, these contextual factors made patient involvement in patient safety elements of ERAS more complex than presented in the programme theory.

8.2 Albany: Evaluating CMO3



8.2.1 Albany: Sustaining Patient Involvement

There was evidence from my observational and interview data that ERAS patients on Albany were involved in the mobility requirements of the ERAS programme and they were supported and encouraged to do so by staff on the hospital ward. However, unlike Bishop, this postoperative mobility was not enacted as a matter of course for all patients, and was instead focused specifically on ERAS patients. As reported previously, this support was more likely to come from the physiotherapist rather than nursing staff, but this does not detract from the fact that patients enrolled on the ERAS programme received the necessary support for their involvement in postoperative mobility. Although the primary responsibility for the postoperative mobility aspects of care for ERAS patients lay with the physiotherapist, nursing staff described how they monitored the mobility goals and encouraged and

supported patients to achieve these goals, and this was supported by my observational data. Patients' enrolled on the ERAS programme on Albany also described how they were aware of the programme requirements in relation to postoperative goals, which supports elements of the conjectured CMO. In the following data extracts, although patients don't talk specifically about 'goals', this was implicit in their comments as they demonstrate a clear goal orientation, with progress being measured.

"They'd walk me. I only went about four yards the first day or two. But then, you know, twice a day. Then I'd got that bit further." [Case A: Patient 1]

"I was out of bed more than I was in it. From the very first day I was out [...] I started exercising as soon as I was conscious. [...] And wanted to do it. And the nursing staff were very complimentary [...] by that time I was walking, must have been walking three hundred metres a day to start off with. Up and down the wards." [Case A: Patient 2]

"The first day I had to walk the ward. Er, the second day I had to walk actually down all of it. All down the corridor." [Case A: Patient 4]

In accordance with the programme theory relating to providing a goal orientated focus, patients on Albany were also provided with a predicted date of discharge, which was based on their planned surgical procedure.

"They know when they're coming in they're expected to be in for ten days on the ERAS programme. Whereas before we had that they wouldn't, they didn't know how long they would be in for." [Case A: RN2]

Again in support of conjectured CMO3, patients on Albany who were involved in the postoperative mobility aspects of ERAS demonstrated some understanding of the rationale associated with this and the potential benefits, which acted as a motivation for involvement. There were also data which demonstrate the goal orientated approach to discharge was successful in encouraging patient involvement in ERAS as it can act as a means of incentivising and motivating patient involvement in ERAS postoperative mobility requirements.

“I was for it straight away ‘cos they said, ‘oh you won’t be in here long’. So it’s an incentive straight away [...] so they give you this, like, you’ll be home within six to eight days. And that is a really big thing. [...] So I was driven to get up [...] that’s what worked for me was, I’d go ‘Well I might as well be at home. I wanna be at home!’”

[Case A: Patient 4]

Some patients on Albany also regarded their ‘involvement’ more as ‘compliance’ and one patient explained how they were prepared to do what was necessary to enhance their safety and expedite their discharge from hospital. There were echoes of the comments made by a patient on Bishop in relation to compliance, as this patient went to describe ‘doing whatever the staff say’. In this case, the patient viewed being compliant as a positive thing because it would expedite discharge and recovery. In this sense it is not compliance for the sake of it, or because the patient is indifferent; rather, it can be seen as compliance with a definite and self-serving purpose.

“I went into it thinking, well this is gonna get me out of here quicker [...] if I do whatever they say.” [Case A: Patient 4]

There were some data to support the notion that ERAS patients perceived themselves as part of the clinical team and one patient explained how the approach taken by staff had given them a sense that they had some control over their hospital admission experience, and that their efforts during postoperative care could make a positive difference to their recovery.

“I don’t like going to hospital, because of being helpless. You’re there, you’re not in charge of your own destiny [...] what impressed me was that I did feel involved [...] and that I could have some control over what happened to me. Not a lot, you know? But my effort would help [...] and you think, well I’m part of a team. I did feel as if I was part of a team.” [Case A: Patient 2]

In this section I have presented data which supports conjectured CMO3 in relation to the reinforcement of ERAS information to patients on the hospital ward. Patients described how they were aware of the postoperative mobility requirements and associated goals and there were also limited data that demonstrates patients’ understanding of the rationale of this activity. As with Bishop, some patients viewed their involvement more as compliance, but

this did not have a negative impact on the required outcomes in relation to postoperative mobility. There was also limited data from one patient who referred to being part of the clinical team and some evidence that patient involvement in patient safety through an ERAS programme could give patients a sense of control over their hospital admission. As described, the programme theory presupposes patients will take part in these aspects of their postoperative care as a matter of course and in relation to this, there are clearly influential contextual features relating to these theories which emerged during analysis of the data on Albany. Again, these predominately relate to patients' willingness and ability for involvement, which I will now present in more detail.

8.2.2 Albany: Patient willingness and ability for involvement

Analysis and evaluation of data from Albany shows that a contextual factor influencing patients' willingness and ability to take part in ERAS mobility requirements was each individual patient's physical reaction to their operation. Although attempts were made to prepare patients for this during the pre-assessment appointment, the ward based nurses emphasised that it was major surgery and therefore it was extremely likely that ERAS patients would experience postoperative complications.

"You have to remember what huge surgery they've had. [...] Even though you may have had all the pre-assessment and information in the world, but at the end of it, when you've had that surgery it's a huge thing". [Case A: RN1]

"I don't think anybody pulls any punches with telling them how, how major the surgery is, though. And what complications can occur. Almost everybody has a complication." [Case A: RN3]

Due to the severity of the surgery, it was sometimes the case that patients who were motivated and keen for involvement in the time leading up to the operation would find themselves adversely affected by the operation and unable to take part in their postoperative rehabilitation to the extent they would have hoped

"We've seen some people who are really motivated, really keen you know, when they come in and then they go bounding on the ward. And then they have the operation and it hits them for six [...] and it may not be that they don't want to, to um get going

and do the things, they just don't feel like it. And that can be hard to motivate them as well." [Case A: RN1]

This same nurse went on to describe how these postoperative complications could have a negative impact on patient's morale as it can have an adverse effect on patients' recovery goals.

"With a patient on enhanced recovery, when they do get a complication, and that may be an anastomotic leak [...] they really take it quite hard. 'Cos they've got this expectation that [...] I'll be doing this on this day and I'll be out on day fourteen and I'll be going home. If they don't reach that and they've got complications they really, really take it badly." [Case A: RN1]

All ERAS patients on Albany would have undergone open surgery and were likely to have an epidural (an injection of local anaesthetic or other pain-relieving medicines into a space that surrounds the spinal cord) as part of their postoperative pain management. The effectiveness of this epidural was critical for pain management and was a pre-requisite for ERAS patient involvement in early and continuing postoperative mobility. Analysis of the data from Albany showed that there was variability in the effectiveness of the postoperative pain management and in the cases where this was not effective, it could have severely debilitating effects on the patient which, in turn, would prevent their involvement in mobility. Aside from the potential complications associated with the type of surgery being carried out on ERAS patients on Albany, it was also the case that although patients were given specific goals to aim for in relation to postoperative mobility and discharge, the recovery journey of each individual patient was often unpredictable.

"Even though, yeah, we've got this programme to say you're gonna do this on this day and that on the other, people are different [...] and sometimes it's hard to predict." [Case A: RN1]

Although there were no individualised care plans for ERAS patients on Albany as they would all be expected to follow the plan of care as outlined on the ICP, which may suggest a rigid and standardised approach, interview and observational data show that when it was required, staff could take a more individualised approach to patient care, allowing for the unpredictable nature of each patients' postoperative recovery.

“ERAS works for the majority of patients. [...] But you have got the minority of patients that won’t fall into that category and will improve quicker or improve [...] not according to the pathway. So, I think, you’ve got to allow for that as well. [...] Sometimes patients’ progress quicker than the pathway allows [...] so sometimes the pathway’s too stringent for them and other times it’s not. You can’t predict a patient, can you?” [Case A: RN4]

In relation to these attempts at a more individualised approach, nursing staff were aware there was opportunity for flexibility in the goal setting aspects of the programme in relation to discharge and mobility should this be deemed necessary. As one nurse explained, these goals would be regularly reviewed and could be adjusted if deemed necessary.

“Predicted discharge is known from the beginning. But sort of on a day to day basis we’d be looking at whether that was something we can aim for. Whether they may go a little bit earlier, or it’s gonna be a little bit later [...] we’re looking at the pathway as well, every day. So we’re seeing that it’s day five, you should be achieving this. [...] Although they know that things might change as we go along [...] we can add another day or two on the ERAS pathway.” [Case A: RN3]

This flexible approach to the pathway based care and goal orientated focus of ERAS is also demonstrated in the following data extract in which the same nurse comments about not feeling pressurised about goals. This is indicative of the attitude of nursing staff on Albany toward the ERAS postoperative mobility requirements and discharge goals. However, although nursing staff reported a reasonably relaxed attitude towards the ERAS patients’ postoperative goals, there were also instances where staff reported using these goals to encourage patients to mobilise. An example of this is also provided in the following data extract where a nurse describes how they would not ‘force’ patients to engage with postoperative mobility, although this nurse also explained there was a stage during postoperative recovery where it may be necessary to remind patients of the requirements of the ERAS programme and the associated goals to encourage them to mobilise.

“They know when they’re coming in they’re expected to be in for ten days on the ERAS programme. [...] There’s a goal. [...] That’s not always accurate though. [...] Just cos it states discharge doesn’t mean it’s that particular day [...] it’s not set in stone.

You can't expect someone to come in, have big major surgery and expect to be out then because ERAS says fourteen days or ten days. It doesn't work like that. But I never feel pressurised about it." [Case A: RN2]

In this sense, enrolment of patients on an ERAS programme gave nursing staff a rationale to encourage patient mobility and some nurses appeared to make a distinction between those patients who *couldn't* engage with postoperative mobility and those patients' nurses believed *wouldn't* take part.

"If they don't want to do it, you can't force the issue. Just document that they've declined to do it. And then the following day they might be in a better frame of mind [...] But then we wouldn't be doing our jobs properly if, like for three or four days, if we didn't have ERAS and they were reluctant to be moved out of bed [...] we've documented that he's reluctant to move. Where with ERAS we say, you know, 'It's four days now, you should be doing this, this and this'. You give them that bit more encouragement". [Case A: RN2]

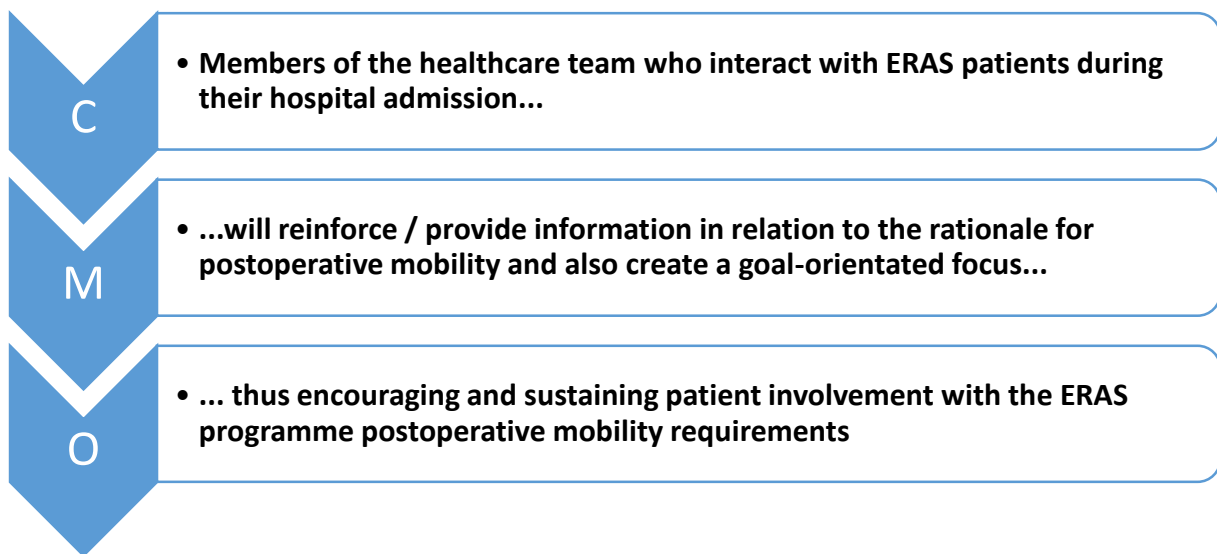
This nurse went on to describe how they would also use the risks associated with non-compliance of ERAS requirements to further encourage patient involvement, which on a fundamental level is in alignment with the programme theory I have presented.

"When there's no reason for them not to be completing the ERAS, there's no reason to leave them in bed [...] sometimes you have to be assertive and say, well you know, 'out of bed now'. [...] if you just lay down you can end up with a chest infection, a pressure sore. And that soon gives them a bit of motivation." [Case A: RN2]

To summarise, during my analysis and evaluation of conjectured CMO3 in relation to Albany there were data which supported the effectiveness of patients' involvement in patient safety in relation to the programme theory. On Albany, as with Bishop, this involvement was often reliant on patients' willingness and ability, which was influenced by certain contextual factors such as the variation in each patients' postoperative recovery. An important contextual factor on Albany was the effect of the surgery on ERAS patients and according to nurse respondents, many patients were likely to experience some form of postoperative illness or complication which could potentially delay their recovery. As was the case on Bishop, nursing staff on Albany were alert to the individual needs of patients and it was

apparent from analysis of interview and observational data that ERAS patients' on Albany were afforded quite a degree of flexibility in terms of their postoperative mobility goals, for example one nurse commented they did not feel 'pressurised' by the ICP targets. However, reference to the mobility goals associated with the ERAS programme did provide nurses with a rationale for encouraging and motivating patients. There were also occasions where nurses would use their clinical judgement to assess whether patients' could or should be more involved in the programme requirements. These contextual factors again demonstrate that patient involvement in patient safety through an ERAS programme is more complex than that presented in the programme theory, particularly in relation to individual patients' recovery and physical state.

8.3 Columbus: Evaluating CMO3



8.3.1 Columbus: Sustaining Patient Involvement

It was apparent from my data analysis that there was little to distinguish in the differences in care given to ERAS patients compared to 'non-ERAS' patients on Columbus, certainly in relation to early and continuing postoperative mobility. In view of this, although patients on Columbus who were enrolled on ERAS were involved in the required mobility elements of the programme and were supported and encouraged with this by staff on the hospital ward, this was something that applied to all patients and in this sense was similar to the approach

taken by Bishop. As reported earlier, the support for patients' mobility on Columbus was primarily the responsibility of the physiotherapy staff, but there was also some level of involvement from nursing staff. Although all patients were expected to be involved in this 'active' approach to postoperative recovery, it was interesting that some of the nurses I spoke with from Columbus stated that patients who had attended education classes were likely to be more prepared for their hospital experience. This supports the programme theory relating to managing expectations.

"I always find that patients that have been (to education class) are the ones that come in and know what's gonna happen. [...] They'll say things to me like, 'Oh, I know that I'll be getting up' [...] and it's nice to see them quite mentally prepared for it. And they come in knowing what's expected." [Case C: RN2]

"I think they're more prepared on the ERAS programme." [Case C: RN4]

As with the other two cases it was clear that patients enrolled on the ERAS programme, and others, received the necessary support for their involvement in postoperative mobility and there was evidence that patients taking part in the programme requirements in relation to mobility goals.

"I was literally up the next morning" [Case C: Patient 5]

"They started giving me exercises the same afternoon. [...] This was the same day that I'd come down from theatre." [Case C: Patient 7]

There was also evidence that some patients were aware of the programme rationale associated with the mobility aspects of ERAS. For example, in the next data extract a patient demonstrates an understanding of the rationale associated with this approach, which they described as being a motivating factor in their involvement.

"I think if you need encouraging and pushing, that's what they'll do. But you've got to go in there with a mind-set of that you've just got to get on with it. And the sooner you can do these things the sooner you'll come home and two, the sooner you'll get over it" [Case C: Patient 1]

However, as has been seen in some instances with Bishop and Albany this data also suggests that some patients on Columbus regarded this 'involvement' more as 'compliance' and were

prepared to do what was necessary to expedite their discharge from hospital. As with the other cases this demonstrates a reliance on patient compliance as a driver for successful patient involvement in postoperative mobility. In support of this, in response to whether they felt as though they were part of the team in their rehabilitation plan two patients responded that they felt they were having things 'done to them', rather than being involved, for example, as part of a team.

"I did feel mostly that I was being done to. [...] Yes. I would take my own, you know, responsibility for certain things. Um, but in the main, I would say I felt, sort of, I felt done to." [Case C: Patient 2]

"I think I was having things done to me mainly." [Case C: Patient 5]

Another patient described how nursing staff 'didn't expect much' from patients, suggesting nurses expected patients to comply with instructions provided, analogous to the more traditional 'passive' role than the ERAS programme aspires to.

"I think I just felt mostly that they had so much on their plates in terms of getting everything done with everybody that, um, although their manner was very good [...] they wouldn't expect that much from the patients." [Case C: Patient 2]

In this section I have presented data that supports conjectured CMO3 in relation to the reinforcement of previously delivered information on the hospital ward and the requirement for patients to adopt an 'active' role in their postoperative recovery. There are also data to support the programme theory of providing a goal orientated focus to patients. I have also presented data which demonstrates that the approach taken by staff on Columbus to patient care was successful in facilitating and sustaining patient involvement in the postoperative mobility requirements associated with an ERAS programme. There was, however, also a suggestion from patients that the postoperative requirements were imposed upon them, rather than being 'co-produced'.

As we have seen, the programme theory presupposes patients will take part in certain aspects of their postoperative care as a matter of course. However, there were influential contextual features which emerged during analysis of the data on Columbus relating to

patients' willingness and ability for involvement and the general approach of the staff on Columbus ward to patients' postoperative care, which I will now describe.

8.3.2 Columbus: Patient willingness and ability for involvement

As was the case in Bishop and Albany, nurses on Columbus also referred to the importance of 'pacing' patients through postoperative mobility requirements in order to avoid patients' over-exerting themselves, which could potentially cause a set-back in their recovery.

"It's a balance really [...] we don't want them to do too much. [...] We like to get them up just to, they don't have to go far, just bed to chair. [...] It will help their chest. It will help for the next day to make sure they're not restricting the movement in their leg [...] so that the next day they'll be able to progress faster" [Case C: RN1]

One of the nursing staff reported that if patients did not want to carry out the ERAS mobility requirements, then they would be supported in this decision and would not be forced into anything they were not 'comfortable with'.

"It's being open to the fact that if they don't want to do it, they don't want to do it. [...] You can't force anyone to do anything and if they wouldn't feel comfortable with something, then they wouldn't feel comfortable with it. I would never have a problem with that. I would just document it and say they're not happy to do that, and that's the reason why." [Case C: RN2]

This was supported by a patient from Columbus who described how sickness had restricted their ability to mobilise and how their postoperative goals were modified to support this. Although this particular patient was able to dictate the pace of their own recovery, it was evident from the following data extract that this had required the patient to challenge staff to some extent.

"For this knee it was within hours (mobilising). They said 'We're going for a walk'. I said, 'That's nice, who's carrying the sick bowl then?' So they had a little discussion, stood back, they said 'How about you just get out and put weight on it?' Not a problem!" [Case C: Patient 1]

However, there was also data that demonstrates it was not always the case that patients were given the opportunity to influence the pace of their postoperative recovery. For

example, one patient explained how although they were feeling unwell and not ready for involvement in the postoperative mobility, a member of staff involved in their care appeared determined that the patient should take part.

“When I was feeling ill I felt that I was being perhaps pushed unnecessarily to be doing the physio. [...] And I couldn’t get him to understand that actually I wasn’t really feeling well enough. [...] I felt that he had been given a set of instructions, or a set of what to expect from patients, and didn’t, didn’t trust that if I was able to do it, I was going to be doing it.” [Case C: Patient 2]

The same patient also commented that the approach to postoperative mobility didn’t always seem to be adapted to individual patients’ needs. However, the patient did emphasise that this did not apply to all staff and that some had allowed this patient to recover at their own pace.

“But different ones had different approaches, it seemed. And some of them were very much, you know, sort of encouraging me at my pace. But in this instance, I think he just thought I was malingering. [...] I wasn’t well for the first two days. And I needed actually to be treated as though I was not well for the first two days”. [Case C: Patient 2]

Overall, it was apparent from analysis of the data that the approach of staff on Columbus was one of strongly encouraging patient involvement in postoperative mobility. For example, nurses described how there were definite expectations regarding patients’ length of stay which required that staff were assertive and encouraged a goal-orientated focus to ensure these expected goals were being met.

“If they’re two or three nights’ post-op and they still haven’t – we usually expect them to be walking – but if people can get up we kind of encourage it because that’s part of rehab really. [...] They should be up and about ‘cos obviously it’s part of your rehab.” [Case C: RN4]

“I think to get the best results from our services we need to be seen to be, I’m saying assertive, but some patients do need to be pushed. And some patients need to be reminded that the average length of stay [...] for perhaps a hip and a knee are sort of

anything from three to five days. If somebody's seven or eight days down the line [...] then we need to be asking ourselves questions as to why we've failed in relation to that patient." [Case C: RN5]

The same nurse went on to explain how nursing staff would identify patients who they perceived would require a 'push' in relation to mobility goals. This nurse also acknowledged that some patients may require support in relation to the expectations as they may be anxious or in pain.

"We try to sort of bring them along [...] some patients who actually need that little bit of a push. So yeah, patients have the knowledge of what they need to do but sometimes they have anxieties themselves about, sort of when they mobilise. The pain. The swelling. The anxiety of maybe falling, or not being steady on their feet. [...] And really just trying to alleviate the anxieties that the patient may bring." [Case C: RN5]

It has been demonstrated that staff on Columbus were alert to the need for pacing patients during their postoperative care and the risks associated with 'pushing' patients too much. There were data that supported this, with one patient reporting on their opportunity to negotiate postoperative goals. However, there were also data which suggested that not all patients were afforded this opportunity, with another patient commenting on how they felt forced into activity they did not feel physically well enough to do. In general, it was apparent that the approach of staff on Columbus was one of forceful encouragement, with a particular focus on trying to ensure a timely discharge for patients and this had resulted in a less flexible approach to postoperative mobility goals than demonstrated on Albany and Bishop. This can be considered in the context of the overall approach to patient care on Columbus, where nursing staff described how ERAS patients who attended the unit for a TKR were already likely to be motivated about their operation and subsequent postoperative rehabilitation. In the following data extract, a nurse from Columbus connects this patient motivation to the fact that these operations were elective and that patients would be more willing to involve themselves in attempts to retain independence following surgery. This nurse also makes reference to the general expectation of staff on Columbus that patients will be motivated about their postoperative recovery.

“I think it’s because it’s elective. They opted to come here and have this done. [...] They’ve been quite independent till they come in. So I think they would want to carry on their independence and that’s what we really advocate as well. [...] Our expectation is that the patients will want to get up and I think everyone thinks that.”

[Case C: RN2]

Other nurses on Columbus described how their approach to patient care was based on the premise that patients had undergone a procedure that was designed to improve their quality of life. Nurses emphasised that patients’ who were admitted to Columbus were not ‘ill’ in the conventional sense (although ERAS patients were usually diagnosed with osteoarthritis of the knee) and thus it was important to avoid stigmatising these patients or allowing them to be defined as ‘sick’. It should be noted that this approach to patient care applied to all patients on Columbus, not just ERAS patients.

“I think someone should invent a card that says ‘congratulations on your surgery’, or something like that. ‘Cos you’re not ill. I think it’s a stigma attached to hospital. [...] So it’s trying to get across to the patient that you’ve come to have elective surgery, you’re not ill. You wanted to have this. [...] It’s trying to reinforce to patients, you know, you’re not sick.” [...] It’s a different type of hospital stay.” [Case C: RN4]

“This is them coming in healthy and getting a new knee and going out healthy. I would hope, anyway. [...] You’re healthy. [...] it’s getting rid of the sick role [...] our main aim is to get them back to their independence way before the pain they had.”

[Case C: RN7]

“Cos the reason they have the new knee [...] is to be better than what it was before. And sometimes patients need reminding of that ‘cos they feel pretty ill. I think it’s the stigma of coming into hospital. You feel ill as soon as you come in don’t you, sometimes. [...] And I’m like, no, it’s a brand new knee [...] you’re gonna be, you know, better hopefully than what you were before. That’s the idea here.” [Case C:

RN3]

Another nurse described how staff would motivate patient involvement in postoperative mobility by reminding them of the curative nature of their treatment and the potential

improvements in quality of life. This approach appeared to have some success in motivating patients.

“I try to say this is your new start to life, really. You’re having a new hip or new knee that could make you, you know, be up and mobile a lot better than you are now. [...] I think they appreciate that bit of extra sort of encouragement. [...] They’ve been quite independent till they’ve come in. So I think they want to carry on their independence and that’s what we really advocate as well.” [Case C: RN2

This demonstrates what can be described as a non-traditional, recovery-orientated ward culture, which is certainly in line with the ERAS programme theory that describes active patient involvement and there was an expectation on Columbus that patients would engage with the required postoperative mobility to improve patient safety and expedite discharge.

To summarise analysis and evaluation of conjectured CMO3 in relation to Columbus, there were data which supported the effectiveness of patients’ involvement in patient safety in relation to the programme theory. As with the other cases, this involvement was reliant on patients’ willingness and ability, which was influenced by certain contextual factors such as the variation in each patients’ postoperative recovery. Similarly, staff on Columbus were also seemingly alert to the individual needs of patients, however unlike the other two case studies, patients were not afforded much flexibility in the expected goals and there was much more a target focused approach on Columbus in relation to patient discharges, which worked in alignment with the recovery-orientated ward culture I have described. These contextual factors again demonstrate that there is more complexity to the realities of clinical practice, compared to the programme theory I have presented in the form of conjectured CMO3.

8.4 Summary of CMO3 and Cross Case comparison

In this chapter I have presented findings which demonstrate that across the three case studies information provided during a pre-admission appointment was reinforced by healthcare staff during patients’ hospitalisation. I have also presented findings which demonstrate that each of the three cases adopted a goal orientated approach to

postoperative care for ERAS patients to support and sustain patient involvement in mobility elements of the programme. Drawing on the empirical data generated during the study I have also provided examples from each of the three case studies which demonstrate successful outcomes of conjectured CMO3 in relation to sustaining patient involvement in patient safety.

Further to these successful outcomes of the programme theory as presented in conjectured CMO3, as the main purpose of this study is to consider what works for who, in what circumstances and why in relation to patient involvement in patient safety, I have also identified specific contexts that were influential in the outcomes of the CMO. In respect of this, firstly there were a variety of surgical procedures associated with the ERAS programme on Bishop and Albany and an inevitable consequence of this was the varying expectations in regard to each patient's predicted length of stay. In addition, patients on Albany and Bishop Ward were informed that there was a degree of flexibility in the expected goals relating to mobility and discharge. This was particularly evident with Albany where patients were made aware of the 'severity' of their operation and the potential effects of this on their postoperative mobility endeavours. This was not the case for Columbus Ward, where all patients attended the education session were informed of the same postoperative mobility goals and length of stay and there was no discussion observed relating to potential flexibility of these goals.

Another influential contextual factor across the three cases was the actual ability of individual patients to be involved in the mobility requirements of an ERAS programme. There were examples where patients had experienced postoperative complications which prevented them from taking part, or where patients were simply too unwell for involvement. In these instances, there was the opportunity for deviations to the postoperative goals and in view of this, patients' individual recovery rate is identified as an important contextual influence in relation to CMO3. Another influential contextual factor was patients' willingness to take part in the mobility requirements of ERAS, which may relate to physical aspects of the patient, but can also relate to psychological aspects.

From the patients' perspective, the opportunity for involvement was a way of ensuring they got the necessary treatment to expedite their recovery and hospital discharge and to reduce their chance of adverse events and this is analogous with 'compliance'. Another important

point for consideration is that once patients were enrolled on an ERAS programme, there was an expectation they would involve themselves in the programme mobility requirements unless there were specific reasons why they could not do so. These reasons were usually linked to the physical condition of the respective patient, although as I have demonstrated previously there were some patients who were encouraged (pushed) to take part, even though they did not feel capable or prepared to do so due to physical restrictions.

In conclusion, considering the data across the three case studies created an interesting line of analysis in regard to what involvement in safety actually means in the context of this thesis. The ERAS programme aspires to a form of co-production and to an extent this was taking place with staff supporting patients' in their attempts to achieve the prescribed goals. However, there was also a significant reliance on patient compliance to achieve these goal, rather than a partnership approach to care and it was apparent that there were occasions when patients were not able or willing to cooperative with staff. The consequences of 'non-involvement' or 'non-compliance' were reiterated to patients by staff in terms of the potential risks patients could expose themselves to.

8.5 The reconfigured CMO3

Following my 'testing' of the conjectured CMO across the three case studies, I now present a reconfiguration of the original CMO to take into account the contextual factors necessary for successful outcomes in this element of the programme theory.

[C] Healthcare who staff interact with ERAS patients during their hospital admission understand the rationale of the mobility aspects of ERAS and are supportive of this

[C] Healthcare staff use clinical judgement to evaluate each patient's ongoing willingness and ability for involvement

[C] Healthcare staff acknowledge that individual patients recover at different rates and allow for variances in the ICP

[C] Healthcare staff are alert to postoperative complications, sickness and illness and support and reassure patients in these circumstances and tailor goals accordingly

[C] Healthcare staff recognise and acknowledge variation in patients' motivation for involvement and respect patients' preferences for different levels of involvement

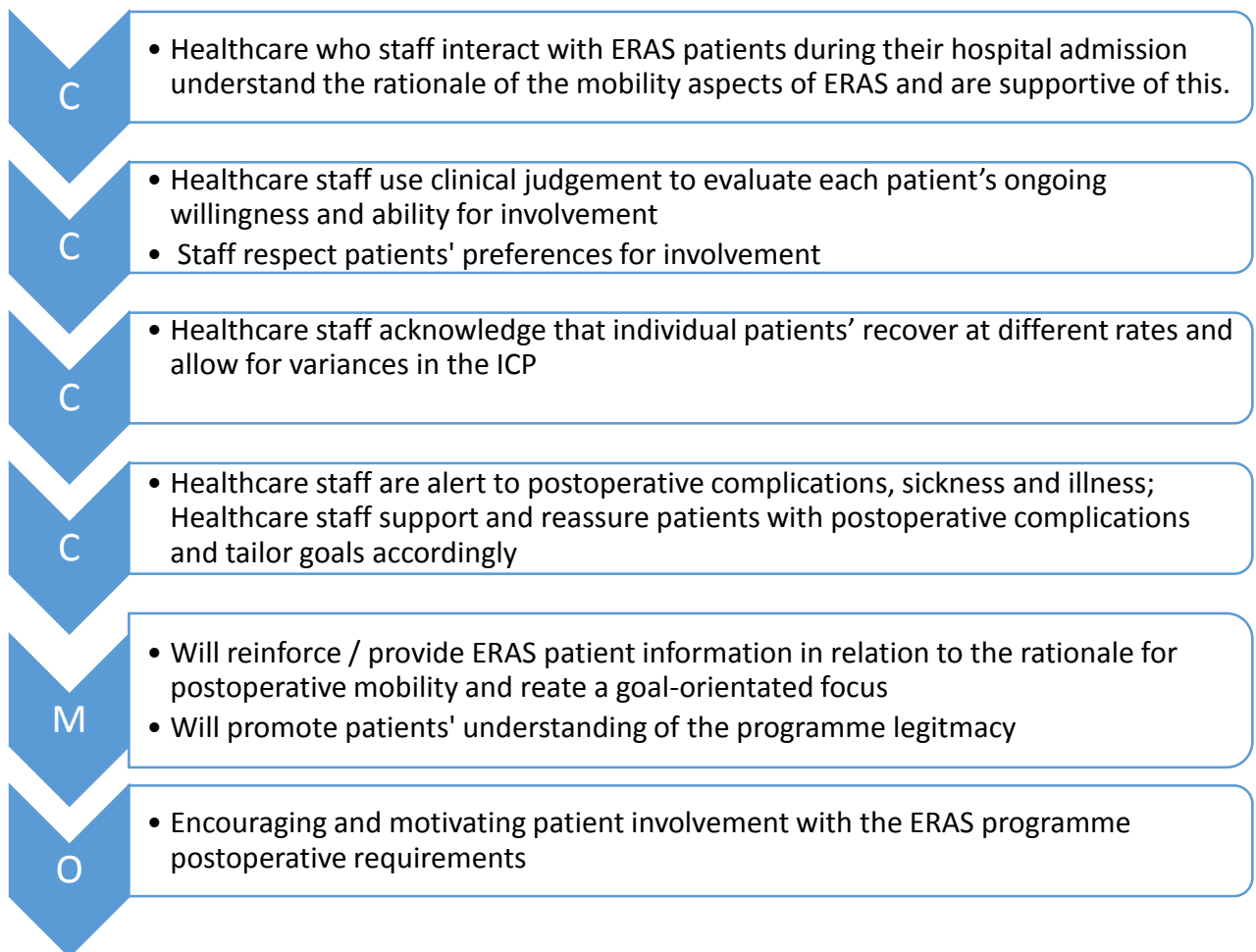
[M] Will reinforce / provide patient information in relation to the rationale for postoperative mobility and also create a goal-orientated focus

[M] Will promote patients' understanding of the legitimacy of postoperative mobility

[O] Encouraging and sustaining patient involvement with the ERAS programme postoperative mobility requirements

The first requirement for the successful outcome of CMO3 is the understanding of, and engagement with requirements of the programme by healthcare staff. We can also see from the findings and the subsequent reconfiguration of the conjectured CMO that a key issue in relation to this programme theory is the willingness and ability of patients to take part in the ERAS programme mobility requirements and this is often related to patients' physical capabilities. As with the previous CMO, an important observation to be made from the findings in relation to conjectured CMO3 is the lack of individualised care for all patients during their hospital care in relation to postoperative mobility. There is a need for staff to use clinical judgement to monitor, guide and support patients safely through the programme requirements. However, in the spirit of 'co-production' of safety, there is also a requirement for staff to be alert to the individual requirements of patients and staff should also respect the wishes of each patient in terms of their desired level of involvement. There could also be a formalised process of information and education provision at ward level, as it is difficult to ascertain how much information patients will have retained from the pre-admission process.

Reconfigured CMO3



Conclusion to Part III of the thesis

In conclusion to this third part of the thesis, 'patient involvement in ERAS – the interaction of context-mechanism and outcomes,' I have presented my interpretation of the programme theory relating to patient involvement in patient safety through an ERAS programme, drawing on policy and the wider literature. In accordance with a realist evaluation approach, I have presented this programme theory as a series of conjectured context-mechanism-outcome configurations (CMOs), which relate to staff involvement, provision of information during pre-admission, and encouraging and sustaining involvement on the hospital ward. I have then 'tested' these conjectured CMOs, drawing on the empirical data generated during my study to identify what contextual factors are required for the successful outcomes of the programme theory. I then presented reconfigured CMOs, with suggestions as to what are the required contexts for successful patient involvement in patient safety through early and continuing postoperative mobility as part of an ERAS programme. In the final part of the thesis, I will discuss these findings in the context of the wider literature and provide an overall conclusion with reflections on my learning throughout my PhD candidature.

Part IV: Summary, Discussion and Conclusion

In this fourth and final part of the thesis I provide a summary of my findings, and a discussion chapter which thematises my findings and considers these themes in the context of the wider literature. I also present a section outlining the limitations of this study followed by my methodological reflections with a consideration of the learning I have achieved during my PhD candidature which I will take forward into my future research endeavours. I then provide a brief conclusion to complete the thesis, making consideration of this thesis as a foundation in relation to ideas for my future work.

Summary of findings

The findings of this thesis have highlighted the relevance of the involvement of staff in a quality and safety improvement initiative such as ERAS. The findings have also addressed the provision of information and education to manage patient expectations and encourage patient involvement, and the subsequent attempts by healthcare staff to involve patients in their safety at hospital ward level. Throughout the thesis I have focused on the early and continuing postoperative mobility requirements of ERAS to support and expedite patient recovery and hospital discharge, whilst also reducing the risks of certain adverse events, for example hospital acquired chest infections.

Overall, the findings show that there are many contextual factors relating to the successful outcomes of the programme theories I have postulated. The main areas for consideration from these findings are the importance of the role of healthcare staff in attempts to involve patients in patient safety, along with the obvious tensions between standardisation of care versus the aspirations of providing person-centred, individual care for patients. This is considered in relation to the ongoing standardisation of healthcare through an increasing reliance on protocols and pathways, such as the ERAS programme. The concept of empowerment came through strongly in the literature and this was mirrored to some extent in my findings, where there were clearly aspirations with policy and programme documentation to 'empower' patients to take a more active role in their care.

It was also clear in my findings that relationships between healthcare professionals and patients are critical to the success of involvement initiatives. In this sense, any attempts at co-production between these parties requires a trusting relationship to support a move to a new type of professionalism in which the imbalance of power between patients and professionals is re-aligned to some extent. I will consider these themes in more detail in the course of this next chapter.

Chapter 9: Discussion

In this discussion chapter I will consider, in the context of the wider literature, some of the key themes that have emerged during my thesis in relation to patient involvement in patient safety through an ERAS programme. This will begin with a consideration of the role of the healthcare staff in attempts to involve patients in their patient safety. Following this, I will discuss the apparent tensions between the aspirations of healthcare service providers and policy makers to provide individualised ‘person-centred’ care. I then consider the notion of ‘empowering’ patients to take a role in their hospital safety and following this I discuss the relationship between patients and healthcare professionals, with a focus on trust within these relationships. To complete this chapter, I present a section outlining the limitations of this study followed by my methodological reflections with a consideration to the learning I have achieved during my PhD candidature which I will take forward into my future research endeavours.

9.1 Involving healthcare staff

It is widely accepted that an essential requirement for any quality improvement strategy is the active involvement of staff (for example, Watt et al 2009). From a policy perspective, the NHS Wales quality improvement programme (NHS Wales 2012) refers to engagement of the workforce as being integral to the key actions and aspirations outlined within this programme. Considering specifically patient involvement, the NHS Wales quality programme cites the provision of formal and informal education to healthcare professionals to support their efforts to engage with, inform and involve patients in their care (NHS Wales 2012). Commentators have also noted that if patients are to make a valid contribution to improvements in patient safety, healthcare professionals need to move beyond recognising the benefits associated with patient involvement and begin to actively encourage this type of behaviour in patients (Watt et al 2009; Ward et al 2010). Further to this, Watt et al (2010) call for a focus on a broadly supportive environment for patient involvement in patient safety where patients are routinely encouraged to take part in safety-related behaviour and activities. This is supported by the NHS Wales quality plan, which states that healthcare staff should encourage patients to raise their expectations of involvement and express their

preference to staff (NHS Wales 2012). Another, crucial, observation from NHS Wales is that professionals, patients and policy makers need a better grounding in the evidence base that supports any strategy to engage or involve patients in their care (NHS Wales 2012).

Findings from my study reveal there were varying experiences across the three case studies in relation to staff involvement with ERAS. There was little attempt made from an organisational level to engage with the ward based staff on Albany and Columbus and this resulted in some scepticism toward the perceived quality improvements associated with ERAS from the participants in these respective case studies. Albany and Columbus were also the two cases where those nursing staff on the hospital ward who were intended to engage with the ERAS programme were involved to the least extent with the implementation and development of ERAS. Conversely, staff on Bishop were supported throughout the implementation of ERAS and beyond, and displayed a sense of engagement and 'ownership' with the programme. On Albany, it was clear that the ward based staff did not feel 'connected' to the ERAS patients and saw them as something different to the normal routines of work and were more than prepared to delegate responsibility for postoperative mobility to the physiotherapy staff. As discussed, the roles of nursing staff on Columbus were largely unaffected by the introduction of ERAS onto the unit, as there was little change to standard practice in relation to the postoperative care of patients.

Ongoing organisational change in the NHS has been widely acknowledged as have an impact on healthcare workers' readiness to engage with any quality improvement initiatives, resulting in 'change fatigue' and reactive, rather than proactive approaches to service improvement (Wilkinson et al 2011). There is a risk that an approach such as this is characterised by organisations (and workers therein) 'surviving', rather than developing and improving and this is likely to have a considerable influence on any centrally planned quality improvement initiatives (Wilkinson et al 2011). This was something that was apparent on Albany, due in some part to the number and diversity of patients being cared for on the ward at any one time, but was not so apparent to me during my observations of the other cases. However, it was also apparent that there were staff across the three cases that remained sceptical in regards to the innovative nature of certain elements of the ERAS

programme, commenting that early and continuing postoperative mobility was something that was standard practice regardless of the ERAS programme.

In conclusion to the level of staff involvement in my study, what was evident across the three case studies was that there was a certain scepticism associated with how innovative the postoperative mobility elements of ERAS actually were. This raises an interesting point in relation to ERAS and the improvement agenda overall, in as much as several staff I observed and spoke with across the three case studies commented that the actions required by the ERAS programme were standard procedures for them already. A common theme reported back to me by nursing staff was that 'it's what we've always done'. There was also feedback that suggested certain staff saw this 'improvement initiative' as an additional level of paperwork with no real added value for patient care, with some staff viewing the improvement agenda as creating more work for them. However, in terms of innovations to practice, I would comment that what ERAS does introduce is a formalisation and standardisation of this approach to care along with a goal orientated focus which is designed to encourage patient involvement.

9.2 Standardisation or individualised care?

Almost twenty years ago, the Institute of Medicine (IOM) called for standardisation and simplification within healthcare organisations, relating this to fundamental human factors principles which, at the time, were widely used in other 'safe' industries (such as aviation), but virtually ignored in healthcare (IOM 1999). Immediately, there is a potential for conflict with the goal of patient-centred care, which calls for the customisation of care to the specific needs and circumstances of each individual (IOM 1999; IOM 2001). Recognising a conflict between a systems approach and individual care, the IOM recommended that healthcare institutions, clinicians and patients work together to balance competing or conflicting objectives (IOM 2001). Further to this, the IOM also advocated for the patient as a source of control, claiming that health systems should be able to accommodate differences in patients' preferences. The task for clinicians and managers is to understand when standardisation is appropriate and when it is not (IOM 2001). It would appear that healthcare services are caught between a continued drive for efficiencies through

standardisation and reduced variability and the continued call for more individually focused, patient-centred services.

ERAS is part of the developing trend for elective surgery to be increasingly governed by practices associated with the streamlining and standardisation of care through integrated care pathways, in conjunction with reduced patient stay associated with minimal access surgical techniques and improved anaesthetic management (Goode and Harley 2009; Mitchell 2011; Bernard and Foss 2014). This has resulted in surgical nursing being increasingly fragmented into pockets of nursing interventions based largely on these protocols (Mitchell 2011). Other risks associated with the implementation of such ICPs are that they could lead to 'mechanistic' nursing care, with less value placed on nursing knowledge (Foy and Timmins 2004; Mitchell 2011). There was some evidence of this in the findings of my study, where there was an ongoing tension between the individual needs of the patients' and the expectations and 'goals' of the ERAS programme (and wider organisational objectives, such as length of stay). There is little research investigating patients' experience of an ERAS programme but a study carried out by Norlyk and Harder (2011) reports that although some patients praised ERAS for providing them with motivation in their postoperative recovery through a goal-orientated focus, others suggested that the fixed regime of ERAS and the focus on meeting goals distracted them from listening to their bodies signals. This is clearly an important issue in relation to patient involvement, as to truly practice patient-centredness, we must be alert to the patients' perspective.

9.2.1 Pre-admission and Standardised Care

When considering standardised versus personalised care in relation to the pre-admission aspects of this study, findings showed that there was a lack of individualised information during the appointments, and that the receptiveness of patients to this information was not taken into account during appointments. Eldh et al (2006) state that for effective patient involvement in the education process, nurses need to view each patient as an individual and information should not be given solely by standardised procedures, but based on individual needs. Further studies of patient education have reviewed issues such as preferences and

attitudes towards education and evidence from the literature suggests that educational interventions, such as those in an ERAS programme, should be individualised, taking into account each patient's skills, knowledge abilities and need (Eldh et al 2006; Lingerfelt and Thornton 2011). These strategies need to be adopted for more effective provision of patient information and education during the ERAS programme and Aasa et al (2013) suggest that patients and nurses can work together in this respect, identifying the information necessary for patients to optimise their healthcare. In this sense nurses' can still make a significant contribution to the care and wellbeing of ERAS patients' during pre-admission appointments through communication, information support and psychosocial support (Mitchell 2011). In support of this, Swart and Houghton (2010) recommend that each ERAS patient is provided with information that takes into account their particular social and cultural background and requirements.

Patients need to be receptive to the information and education as it is hypothesised (Louw 2013) that if a patient fully understands the operation and postoperative routines, and their psychological well-being and physical recovery are promoted through preparatory information, they will be less anxious and have a shorter hospital stay. This type of preoperative education may also reduce the risk of postoperative complications such as pulmonary embolism from deep vein thrombosis (Brady 2000). However, it is interesting to note that McDonalds et al's (2014) Cochrane review of 18 trials (1463 participants) was unable to establish whether preoperative education reduces anxiety or leads to improved surgical outcomes or reduced adverse events over and above usual care (McDonald et al 2014). One possible reason cited for this by the authors' was the education they evaluated as part of the review is not targeted at individuals and so is not adapted to the person's psychosocial factors and so recommend that future research should investigate how a 'stratified' approach could be used to assess each individual's requirements in relation to their physical, social and psychological needs and thus tailor education accordingly (McDonald et al 2014).

There were also findings from the case studies which demonstrate that patient anxiety was a mitigating factor in patients' receptiveness to information and education during a pre-admission appointment. Many studies have recognised patient anxiety prior to surgery

(Walker and Smith 2009) and several studies have established that effective preoperative education and information can decrease anxiety (Kahokehr et al 2009). However, as Kahokehr et al (2009) note, these types of consultations contain large amounts of critical information and can be limited by temporal, spatial and personnel barriers. As Bishop et al (2015) point out, patients are often at a disadvantage when attempting to acquire new information in such circumstances as their primary concern is usually their illness. A study by Kessels (2002) discovered that between 40% and 80% of information presented to patients is forgotten immediately and patients' memory is often affected by the perceived importance of the information being relayed to them and as such, patient safety information may be lost in the myriad of other information presented. However, it should be noted that patients' who experience anxiety prior to surgery do not necessarily have a worse outcome, or find it harder to recover from their surgery, but anxiety may have an effect on a person's ability to retain and understand information during a pre-admission appointment (Bastian 2002).

9.2.2. Hospital wards and Standardised Care

When considering standardised versus personalised care in relation to the hospital ward aspects of this study, Allen and Hughes (2002) considered the rationale for standardisation in healthcare and the challenges associated with this approach, and it was apparent from my research that the tensions that existed when this work was published still existed to some extent. Allen and Hughes (2002) referred to hospitals as people processing organisations which bring together a wide variety of individuals with varying needs and wants, providing 24-hour care, seven days a week to a continuous throughput of biographically distinct individuals. They also remark that each of these patients will be at a different stage of their illness, with their own unique biology and their own unique concerns, rendering the type of 'people-work' undertaken in hospitals inherently unpredictable. This has provided hospitals with particular challenges in their attempts at organisation and one of the ways these organisations have dealt with this is to order patients in both space and time, and this requires standardisation (Allen and Hughes 2002). In reference to the standardised pathway approach to care, as personified by an ERAS programme, the literature informs us that these ICPs are most effective in contexts where

patient care trajectories are predictable. As a logical extension to this, the value of ICPs in areas of care in which recovery pathways are less predictable, with more potential for variation is less clear (Allen 2009). There was an obvious distinction here between Albany, where there was a diverse range of procedures and variable recovery, compared to the other two cases under study which had a more predictable patient trajectory, particularly Columbus.

We have also observed through the findings I have presented that, as identified previously by Allen (2014), nurses can play a central role in the coordination of care and nurses on the three wards in my study generated and kept in play a working knowledge of the evolving status of patients' trajectories and this required an oversight of individual patients' developing needs, wellbeing and physical. What Allen (2014) refers to as 'trajectory narratives' function to sustain a working knowledge of each individual patient's ongoing care and this forms part of each nurses' everyday work. This was observed to lesser or more degrees depending on the case study under observations, and interestingly, although nursing staff on Albany were seemingly the least engaged in the ERAS programme, they were also the most alert to developing patient trajectories. This was also observed to some extent on Bishop, but, conversely, nurses on Columbus were not so concerned with this, as we have discussed previously in relation to the quite fixed expectations for patients' postoperative care on this ward.

Allen and Hughes (2002) also refer to 'regularities' as a means of allowing hospitals to accommodate the multiple and varying needs of their patient population and this can be achieved through a common timetable and set routine for hospital staff and patients. This was most clearly observed on Columbus in relation to the postoperative care being provided. As Allen and Hughes (2002) note, it is an inevitability that these routines are going to be out of synchronisation with individual patients' personal routines, which will also be disrupted due to their illness and associated treatment. In addition to this, during their systematic review of preoperative education for patients undergoing elective hip or knee replacements, McDonald et al (2014) make an interesting observation in relation to early postoperative mobilisation noting that established ward routines may determine when patients are mobilised. They go on to say that, although a patient's level of anxiety and

knowledge may determine how much time staff spend with them, it may not deter hospital staff from mobilising the patient on the prescribed day (McDonald et al 2014). This is something that was observed during my study, particularly so on Columbus, which again highlights the tensions between standardised and individualised, patient-centred care.

There is a sense from the literature that this issue of standardisation versus patient centred individualised care may be what could be referred to as a 'wicked problem'. For example, Waring et al (2015) reported on a study by Weiner (2000) which looked at efforts in US hospital to increase the quality of care through standardisation. Weiner (2000) observed that there were many aspects of care which defied any attempts at standardisation and would remain elusive to this. McDonald et al (2005) examined attitudes towards standardisation by clinicians and managers in the English NHS and concluded that these groups had entirely different world views with the medical perspective opposing standardisation and advocating clinical judgement, whilst the managers sought standardisation through adherence to guidelines.

Another issue to consider in relation to the standardisation of healthcare through programmes such as ERAS is the potential for approach to create what West (2000) refers to as a 'diffusion of responsibility' within healthcare organisations in which potential problems are seen as somebody else's responsibility and therefore are not always adequately addressed. This can also be considered in the context of the 'division of labour', which West (2000) refers to as a rigid demarcation of responsibility and occupational role that can run counter to the type of integrated working that is said to be integral to the success of an ERAS programme. Allen (2014) notes that in relation to quality improvement there is a tendency for healthcare professionals to rely on designated teams, or named lead individuals for particular issues, citing examples such pain management and infection control. This can render quality in relation to specific aspects of care as the responsibility of these designated individuals or teams (Powell et al 2009), and in this respect it has been observed that many extended nursing roles have been developed to assist enhanced recovery programmes (Bryant 2010). This was the case with Albany and Bishop during my study and the implications of this have been discussed in the findings, essentially that this resulted in some confusion of roles and responsibilities, analogous with West's (2000)

concept of diffusion of responsibility. However, specialist roles that have developed in relation to ERAS can be problematic in this sense, as there was some confusion among staff and patients in relation to nursing responsibilities for ERAS patients.

To conclude, there is clearly an ongoing tension between attempts to standardise healthcare, whilst also aspiring to provide patient-centred, individualised care. This was the case during my study, although there were several examples of when nurses were able to circumvent the expectations of the ERAS ICP and use their nursing skills and judgement as a basis for care. For future programmes, it would be prudent to consider individualised patient information, which takes into account their requirements and receptiveness to this information in relation to their psychosocial needs.

9.3 Empowering patients

One of the main policy aspirations of the ERAS programme is to 'empower' patients to take a more active role in their healthcare and rehabilitation. An empowering approach to patient involvement is intended to work on the basis of addressing the power differentials between healthcare providers and patients and increasing self-determination. However, empowerment is a multifaceted and complex concept, the definitions and meanings of which vary in the healthcare literature. Clearly it is a concept linked to 'power' and Freire (1973) defined 'powerlessness' [cited by Kieffer 1984] as occurring when an individual assumes the role of an object acted upon by the environment, rather than a subject acting in and on the environment. Wallerstein (1992) identified powerlessness as a determinant of ill health, whilst others (for example, Jones 1993; Bergsma 2004) consider empowerment as a health enhancing process. As Frankenberg (1992) noted [cited in Allen and Hughes 2002], in hospital patients are placed in a space where their uncertainties are reinforced by the professionals' certainties and the time view of others is imposed on them, which in turn creates a situation in which patient autonomy is reduced while at the same time the power of healthcare professionals is enhanced. This will immediately restrict attempts at genuine empowerment and, as one of the respondents in my study commented about hospital care, *"it's not normal"*.

Aujoulat et al (2007) carried out an extensive review to examine how the term 'empowerment' has been used in relation to the care and education of patients with chronic conditions. Although their review did not consider 'acute' patient care, and so should be treated with caution in relation to the transferability and generalisability of their findings, I believe there are certain fundamental principles which can be considered in the context of all patients, including those who took part in my study. Aujoulat et al (2007) contend that there are two dimensions to the process of patient empowerment – what they refer to as an intra-personal dimension and an inter-personal dimension - with the former seen from the point of view of a provider-patient interaction and the latter seen from the point of the view of the patient alone. The inter-personal dimension of empowerment is of most relevance to this thesis, as there were clearly attempts from healthcare providers across the three case studies to communicate with, and to some extent educate, patients in an attempt to share to varying degrees, knowledge, values and power. There is evidence that attempts to empower patients through this type of education strategies can result in patients' adopting a more active role in their care (Chang et al 2012). As Aujoulat et al (2007) state, this approach views empowerment as an interactive process in which the healthcare provider 'gives' power to the patient, which on a fundamental level is what the ERAS programme aspires in relation to patients' roles in their care and safety.

An empowerment approach is also intended to develop and reinforce certain abilities in people in relation to their care, for example the ability to determine personal goals and define strategies to achieve these goals, to develop and encourage patient motivation, to seek information and to ask questions and express preferences for healthcare (Aujoulat et al 2007). The importance of self-efficacy in relation to health behaviours has been well documented in the literature and although it is most often associated with long-term conditions, it is a useful concept to consider in the context of patient involvement in patient safety. Essentially, patients are more likely to become involved in their care if they believe they can influence the behaviour of the healthcare provider and this is supported by empirical evidence, for example Schwappach et al (2012) and Bishop et al (2015). These studies demonstrate that an increase in patient involvement in patient safety can be achieved if healthcare providers educate patients about the benefits and risks associated with their healthcare and reinforce positive patient behaviours, thus increasing self-efficacy.

Again, to some extent it can be argued that the approaches taken to patient care across the three cases under study were striving to achieve some, or all, of these outcomes with varying degrees of success.

However, the 'empowerment' approach observed during my study was seemingly some distance from that described in the literature in relation to long-term illness. For example, McWilliam et al (1997) view empowerment as the result of both an interactive and personal process, which is facilitated by a caring relationship and results in the emergence of a person's (patient's) potential in an act of co-creation and true partnership. McWilliam et al (1997) continue by suggesting the empowerment process will occur when both provider and patient share an understanding of the patients' story, creating meaning to the patient's experiences. It seems unlikely from the findings of my study that this was something that could take place within the boundaries of an ERAS programme attending to acute surgical patients with a view to reduced length of stay and minimisation of risks. However, as we saw, there were attempts by some nurses on Bishop during pre-assessment appointments to talk with patients about their lives and experience.

One of the guiding principles of empowerment is self-determination, which can also be framed as patients' being provided with choices and subsequently taking responsibility for these choices (Aujoulat et al 2007). However, Anderson and Funnell (2005) note that empowerment has been presented as an alternative paradigm to compliance. It is clear the specified outcomes are often necessary for the healthcare provider, as is the case in the ERAS programme, which does appear to relate more readily to a model of compliance, rather than an attempt to empower patients. As we have discussed previously, not all patients see involvement in their care as desirable and similarly not all patients want to be empowered and Anderson et al (1991) argue that patients who choose to delegate responsibility for decision making and hand over responsibility for their care to professionals should be considered empowered as they are expressing self-determination. Further to this, Steel et al (1987) warn against just considering empowered patients as just those who are 'active' in the sense that they have rejected the sick role associated with passivity and compliance. Patients may also be empowered by being provided with information about their treatment regimens and satisfied with and committed to those regimens (Steele et al

1987) under the guidance of healthcare providers. This is something that we have seen during the course of this study, with patients accepting a position of compliance from the perspective that this will result in them receiving the necessary treatment and required outcomes.

Research by Anderson and Funnell (2005) found that although healthcare professionals agreed in principle with efforts toward patient empowerment, their observed behaviour in practice reflected what Anderson and Funnell refer to as a traditional acute care paradigm. They argue that any endeavours towards patient empowerment would require a paradigm shift from this traditional approach, which is likely to be resisted by professionals. Anderson and Funnell (2005) also comment that patients in acute settings are more inclined to surrender control to care providers and cede to their clinical expertise. These patients are also likely to be passive in relation to their involvement and patient safety, as the acute care paradigm is inconsistent with the empowerment approach and Anderson and Funnell (2005) argue that this paradigm is usually embedded in the minds of healthcare professionals and is the basis for most policy and procedures in healthcare organisations. The findings from my study demonstrate that this 'acute care paradigm' was evident in the three case studies.

To conclude this section, I will refer back to the work of Allen (2000) who has previously discussed the role of patients in their care, drawing on the work of Hughes (1984) [cited in Allen 2000] and sociological theories of the division of labour, which is concerned with how activities within a society are divided up, to make an analytical distinction between the 'role' and 'task' components of what Allen refers to as 'lay participation'. On this basis, Allen (2000) argues that a failure to distinguish between these two components has led to a tendency with healthcare policy and practice to equate patient involvement with their empowerment. However, as Allen (2000) goes on to suggest, patient involvement can take place without being empowered in any real sense, whilst conversely patients may be empowered without direct or active involvement in their healthcare. Allen also provides a note of caution in that, although there may be contexts in which the traditional patient-professional relationship is appropriate, this should also always be negotiable.

9.4 Relationships between healthcare professionals and patients

The relationship between healthcare service users (in this case, acute surgical patients) and healthcare service providers has been identified by Donabedian as forming the core of good quality care and his conceptualisation of quality in healthcare highlighted the importance of the social and psychological aspects of the interactions between service users and providers (Donabedian 1980; 1988). It should be noted that, as Pederson et al (2013) have commented, relationships in healthcare do not exist in isolation and are strongly influenced by the contexts in which they take place. This will include many of the factors we have already considered in the course of the findings of my thesis, including the policies and guidelines governing these interactions and the abilities and beliefs of the individual patients and healthcare professionals towards, in this case, patient involvement in patient safety.

As we have seen, empowerment can be defined in a healthcare context as an established relationship between patients and clinicians (Aasa et al 2013). In this sense, a distinction can be made between an empowerment approach which is intended to work through the provision of patient information, such as ERAS is, and an empowerment approach which is considered as a process that emerges from a particular type of relationship or set of interactions between patients and healthcare professionals. McWilliam et al (1997) suggest that this type of approach requires a change not just to the patient, but also implies that the professional should relinquish some control, or unlearn being in control. However, at a fundamental level some level of inequity of power between patients and healthcare providers is unavoidable, for example, patients may be disempowered to some extent by their illness which will restrict certain abilities (Kleinman 1988).

Alongside this, we have also previously considered the discourse which considers patients as passive and healthcare professionals as authoritarian, along with the environmental factors which can also delimit patient involvement. In this respect, Hor et al (2013) describe how power cannot simply be removed from relationships between patients and healthcare professionals, nor can it be resolved by the sharing of clinical expertise. Instead, Hor et al

(2013) argue that power inequalities can be disrupted and managed through attending to the dynamics of these relationships at a local level.

Therefore, truly empowering patients and encouraging self-determination may also require a transformation of interpersonal dynamics between patients and healthcare providers (Rathert et al 2011). In this case, healthcare professionals should consider the patients' priorities and concerns, allow patients to express their emotions and provide emotional support (Aujoulat et al 2007). This all points to the need for a shift in the role of the healthcare professional from that of a skilled clinician to a facilitator. This will also require that scientific knowledge is balanced against individual patients' values and priorities (Aujoulat et al 2007), whilst still ensuring safe, effective and efficient treatment. However, counter to the notion of developing relationships between healthcare professionals and patients in an attempt to improve quality and safety, Potter and McKinley (2005) argue that the term 'relationship' in the context of contemporary professional-patient interactions can be misleading. Further to this is the work of Gutek et al (2000) who believe that these 'relationships' would be more appropriately described as 'encounters', in the sense that the service provider and the user do not expect to interact with each other again in the future. In a consumer type relationship, the customer expects to interact again in the future with the service provider, which can result in the two becoming interdependent, however as Pederson et al (2013) highlighted in their review, conceptualising healthcare service users as customers would result in the 'seller' (service provider) aiming to move this relationship towards a long-term exchange. Obviously, this is not the aspiration of the healthcare service providers in my study, who aim to treat and discharge patients as efficiently and safely as possible, and in which a 're-admission' for any complications is viewed as a failure on the part of the service provider. It is also the case that the silo-based nature of the healthcare organisations observed in my study would compromise any efforts to develop this type of relationship.

9.5 Relationships and power

It seems that the notion of power is inescapable when considering interactions between patients and healthcare professionals and Pederson et al (2013) note that power is a core

component of several models that have attempted to conceptualise relationships between patients and providers, with the majority of these arguing that the professional status of the doctor determines the role of the patient. This links back to the important work of Parsons (1951) who formed the notion of the 'sick role', rendering patients' passive and compliant to medical instruction and advice, and Freidson (1970), who discussed the potential 'conflict' between the doctors and patients due to their different agendas, which we have already covered earlier. However, as this is of central importance to the thesis, it would be prudent to revisit this as part of my discussion. In these conceptualisations, there is competition between formal medical 'expert' knowledge and the lay knowledge of patients and developments in medical technology has further increased the imbalance between healthcare providers and patients (Pederson et al 2013). Whilst the vast majority of the literature considers the doctor-patient relationship, this can be extended to the wider healthcare professions and the overall relationship between patients' and their healthcare provider and the NHS in general.

There appears to be a continuing dominance of healthcare professionals and the relevance of the power dynamics between patient and provider is still obvious. For example, as patients' health and wellbeing improves during their treatment, the relationship could change from a passive one, toward a more active role. This is something which we witnessed during the cases under study, and was particularly relevant to Albany where the patient recovery trajectories tended to be longer and more unpredictable than patients' in the other two cases. Pederson et al (2013) also highlighted the importance of compatibility between patients and healthcare providers in terms of the level of involvement patients should and could take and in their review they identified congruence in this area as an important factor in relation to the quality of relationships and patient satisfaction.

Although the work of writers such as Illich, Parsons and Freidson has retained an importance place in our overall understanding of interactions between patients and healthcare providers, there is more recent work by the Health Foundation (Christmas and Millward 2011) which has explored the role of the medical profession in relation to a 'new professionalism'. This work explores the changing roles of doctors, which the authors' view as being a result of major contextual changes to how medicine and healthcare is practiced in

relation to political, societal and generational change, along with continuing advances in medical technology and changes in how healthcare is delivered. The growing accessibility of evidence for all parties has also had an effect on this, with patients now able to access a wide variety of information to support their own 'lay knowledge'. Another theme which emerged from the review by Christmas and Millward (2011) was that of trust, which is seen as being an important element of professional-patient relationships. However, some contend that professionalism in healthcare is no longer bound by trust, but rather it has become regulation based (Heath, I. cited in Christmas and Millward 2013). This brings the discussion back to the evidence tensions between standardised care and aspirations toward patient centred, individualised care. As Iona Heath, president of the Royal College of GPs at the time succinctly put it, *"No-one is prepared to adjust to individuals because you have to follow rules"* (cited in Christmas and Millward 2013).

9.6 Relationships and trust

There is a consensus emerging in the literature that trust is an important element of clinical encounters between patients and healthcare professionals, regardless of the role patients assume (Kraetschmer et al 2004; Entwistle and Quick 2006; Thompson 2007; Christmas and Millward 2012). Entwistle and Quick (2006) suggest several factors which may be considered as indicators of trust in the relationship between healthcare providers and users of healthcare services, the first of which is patient involvement in efforts to improve patient safety. This includes open communication about safety issue, making patients aware of potential and recognised threats and a commitment to any strategies in place to reduce the risks of these threats, including the implementation of established safety-protocols and procedures. It has been demonstrated in my findings that patients' were provided with information in relation to the risks they may be exposed to during their hospital care, and what patients' could do to reduce the risks of potential harm, although this was presented to varying degrees across the three case studies. This can be cited as an example of attempts to healthcare providers and healthcare professionals to develop trust.

Growing awareness of the problem of adverse events has prompted concerns that patients' trust in healthcare providers may be threatened and contemporary understanding of

patient safety suggests that in order to be deemed trustworthy healthcare providers should make their efforts to improve safety visible to patients and be honest about potential safety issues (Entwistle and Quick 2006). Rathert et al (2011) comment that making patients' aware of these problems and asking them to become more involved in attempts to prevent adverse events may erode trust that patients' have in their healthcare provider and others have expressed concerns there is a risk that awareness of healthcare errors will undermine public trust (Leape and Berwick 2005). Another concern is that patients' may continue to trust healthcare providers and professionals despite patient safety issues, and this trust may be inappropriate as it may preclude patients from being vigilant when they use healthcare services, which may render them more vulnerable to harm (Quick 2006). However, as Entwistle and Quick (2006) point out, providers trust in patients' to be alert to patient safety issues may in turn strengthen patients' trust in them and help build relationships which facilitate safety improvement (Entwistle and Quick 2006).

As Coulter (2002) has stated, failure to provide patients with full and balanced information about the risks and uncertainties of healthcare encounters may create unrealistic expectations. However, it is also the case that even if patients do receive full disclosure in relation to potential safety risks, they may not always completely understand the implications of this in relation to their care. Even if healthcare providers make efforts to identify and address such limitations, this does not necessarily mean they will be able to help patients' overcome them, or indeed that patients will be responsive to support of this nature (Madison 2010). This can be traced back to the acute care paradigm described by Anderson and Funnell (2005) in which patients were deemed more likely to cede control to healthcare professionals in order to receive their expert care. In relation to this, in the study by Kraetschmer et al (2004), patients who had more trust in their doctors wanted less involvement in decision making. This trust in healthcare professionals has traditionally resulted in patients letting professionals do whatever is needed and it is this traditional view of the passive, compliant patient role that may lead some to express concerns that trusting patients may be less safe patients as they will be less likely to check, challenge or question their treatment.

Entwistle and Quick (2006) also cite honesty from healthcare providers about safety issues as being an important factor in garnering patient trust. It should be noted at this juncture that, in response to certain recommendations from the Francis Report (2012), new joint guidance from professional regulators focuses on the need for doctors, nurses and midwives to be open and honest with patients when things go wrong, and this is set out as a duty of candour in their respective professional standards. This approach is designed to encourage and support a culture of openness and transparency in healthcare (Dix 2015) although it is too early to say whether this has been the case or not. However, clinicians may influence patients' decisions to engage with safety issues through the nature of their disclosures (Madison 2010). This candour could also extend to informing patients about significant risks they may be exposed to in relation to certain safety protocols, for example if there is a shortage of nursing staff on wards.

Another important factor identified by Entwistle and Quick (2006) in relation to trust is the need for healthcare professionals to enable and support patients' contributions to patient safety, which we have already considered in some detail during the course of this thesis. Entwistle and Quick (2006) conclude that trust can serve to facilitate and strengthen co-operation between patients and healthcare professionals and this is in alignment with the work of Hor et al (2013) who have stated that safety is co-produced between patients and professionals. This co-production of safety can be achieved by attending to the ongoing patient-professional interactions, which can be built on a basis of trust. This is supported by the work of Iedema et al (2011) and Mesman (2011) who discuss how safety is performed on an ongoing basis not just from the professional skills and expertise of clinicians, but from all actors in healthcare services, including patients. It should be acknowledged this potential will not always be achieved in practice, as the disparity in power dynamics in relationships may continue to present barriers to patient involvement in patient safety, despite there being a trusting relationship. The success of these endeavours toward co-production is also contingent on the capacities and capabilities of patients' and professionals to support this type of work.

To conclude this discussion, I have considered the findings of my thesis in relation to the respective roles of patients and healthcare professionals and the different dimensions of the

relationships between these two groups, along with the intertwined tensions relating to the standardisation of care versus the aspirations of individualised patient centred care.

Ultimately, it is for individual patients and practitioners to enter into ongoing negotiations regarding their respective roles within the healthcare encounter, in the context of patient involvement in patient safety. Again, it is about relationships – but the question that may need to be asked is how do healthcare professionals avoid being rule bound and regulation based in the face of evidence based practice. If these boundaries are circumvented, does this produce additional risks to patients' or compromise the effectiveness of their healthcare.

9.7 Study Limitations

During the course of this research I needed to recognise, confront and make decisions about key research issues and try to ensure these decisions were informed and strategic, rather than reactive (Mason 2002) (although, as I will describe in the course of this section some of these decisions could well be described as reactive). To support this, I have recorded a clear decision audit trail for this project and kept a personal reflective journal, which has been described as an essential part of qualitative research (Porter 1993). Reflexivity is the way in which researchers strive for reliability and validity, and the development of one's reflexive skills is the keystone of what Coffee (1999) calls 'The Ethnographic Self'. These beliefs and values are made explicit and taken into account so that 'rather than engaging in futile attempts to eliminate the effects of the researcher, reflexive researchers try to understand them' (Hammersley and Atkinson 2007).

Ultimately, the pursuit of rigour in my research rested on me spending enough time at the field sites to understand what is going on, recording data meticulously and attempting to develop theory iteratively as emerging data is analysed (Stake 1995; Pawson 1997). However, for a range of reasons which I will describe during the course of this section, my study did not progress as I would have ideally liked. The compromises made to the study design reflect in part the challenges of 'real world' research and I think it is also reasonable to suggest that this also reflects the learning curve of a novice researcher. These issues have been key learning points for my development as a researcher during my doctoral studies,

however they have also introduced some potential limitations to the study. In the interests of preserving rigour, I have striven to only make assertions on the basis of the data I have generated and equally I have been clear and transparent about where there are gaps, or higher levels of uncertainty in my analysis and evaluation.

As I will describe in the course as my research progressed it was necessary for me to make some diversions from, and adaptations to, my original research design. These diversions did result in some limitations to the research study which I will describe in detail during the course of this section.

9.7.1 Sequential case studies / Concurrent case studies

Firstly, ideally I would have carried out the three case studies concurrently. However, due to the nature of my research, which relied on myself as a single researcher, I believed it would have been impractical for me to attempt to manage field work and data analysis simultaneously in three cases in terms of time and resources. As my fieldwork and analysis progressed, it became apparent that this decision had implications for my research as it was only when entering the field for my case study fieldwork that I was able to make sense of the complexities of the various approaches to an ERAS programme that had been taken by the respective case studies.

In relation to the sequencing of the case studies, it was my initial intention to explore the four specific elements of patient involvement in patient safety through an ERAS programme that were described in chapter three of the thesis in relation to prehabilitation, dietary advice, discharge planning and early and continuing postoperative mobility. I had a proliferation of conjectured CMOs which I took into the first case study, but it became evident during the course of my fieldwork that there were significant variations in each of the case studies in relation to their use of the ERAS programme. These inconsistencies in implementation of ERAS across the respect cases made data generation and subsequent analysis challenging, particularly in terms of cross-case comparisons.

Although developing an array of conjectured CMOs relating to these elements of ERAS prior to my fieldwork was a useful exercise in helping me to develop an understanding of the

programme theory behind patient involvement in patient safety aspects of ERAS, of the four identified, only the mobility element was implemented consistently across the three case sites. I believe that if I had undertaken concurrent case studies, rather than considering each in isolation, I would have been able to identify the most relevant programme theories to test across the three case studies and this would also enabled me to develop and refine the CMOs across the three cases simultaneously.

Toward the later stages of my fieldwork and analysis it became apparent that of the distinct ERAS interventions I had identified, early and continuing postoperative mobility was the most appropriate of these to enable me to robustly examine the programme theories in the form of a realist evaluation. Using mobility as a 'tracer' element, rather than a more diverse range of patient safety related interventions allowed me to test the related theories which I had developed in the form of conjectured CMOs were tested, with a focus on those activities and behaviours related to mobility. As this was common across all three case studies, it also allowed me to make cross-case comparisons in relation to the contexts required for patient involvement in patient safety through an ERAS programme.

In a sense, this relates to the essence of my realist evaluation approach which aims to identify contextual factors that affect patient involvement in patient safety and reflects the nature of the theory driven approach. What I have been able to do is provide rich data and an in-depth analysis of patient involvement in patient safety using early and continuing postoperative mobility as a 'tracer' issues to ensure effective and useful cross-case comparisons in relation to the overall aims of my research.

9.7.2 Multi-stage case work

I had originally intended for my fieldwork in each of the case studies during the stage of data generation designed for testing the conjectured CMOs to take place in two stages. Firstly, I planned to explore and examine the pre-operative aspects of the respective cases; that is, pre-assessment clinics and patient education sessions. I then intended to analyse the data generated during this exercise to help further develop my conjectured CMOs before then revisiting each of the case sites on the respective hospital wards for more data generation resulting in further refinement of the conjectured CMOs in light of this empirical

data. I think it is reasonable to suggest that if I had taken this approach, as originally planned, the issues relating to the variation in the implementation of ERAS across the three cases would have become apparent much earlier in my research and provided me with an opportunity to further explore which elements of the ERAS programme were most amenable to investigate in relation to patient involvement in patient safety. Unfortunately, delays in access to the case sites under study led to reduced availability of time for me fieldwork and forced me to abandon this strategy and take advantage of the access that was available to me in each of the respective cases.

There were further issues in relation to access to the study sites which impacted on my original research design. Specifically, in anticipation of access being granted to the case study sites I had arranged to meet with representative from the sites. I had originally planned to carry out my first set of fieldwork on Bishop as this was the University Health Board's 'flagship' site for ERAS and I felt this would provide the richest data in terms of developing my theories about patient involvement in patient safety. I then planned to take these more developed CMOs to Albany and Columbus to examine how they played out in these contexts, further refining and developing the CMOs.

However, following a meeting to discuss my research with a specialist nurse and consultant surgeon who were involved with ERAS on Albany, I was invited by the consultant to start my research on the unit immediately. I felt a sense of urgency by this stage that I should begin my data generation and was concerned that if I did not seize this opportunity I would face further delays which would have an adverse impact on my research timetable, which had already slipped considerably by this stage. I was also concerned that I might offend the consultant who thus far in our encounter had been very supportive and encouraging and was confident that Albany would provide me with ample opportunities for my research focus. In light of this, I agreed to start my fieldwork on Albany and was engaged in this within 48 hours of the meeting. Again, this decision had implications for my study, as it became clear as my research progressed that my original decision to begin fieldwork with Bishop would have lent itself to a more coherent set of fieldwork and a more solid foundation to base the subsequent case studies on.

9.7.3 Selection of participants

Another limitation of the study was the lack of interview data from physiotherapy staff. When originally planning the study I had identified that nursing staff should be the main focus on my research observations as they were the group most likely to be involved in activities which related to areas of interest. However, it became apparent during my fieldwork on Albany that physiotherapists played a significant role in relation to the mobility aspects of ERAS. This was also the case during my subsequent fieldwork on Bishop and Columbus. Unfortunately, due to the constraints of my ethical and access approval I was not in a position to interview physiotherapy staff and although I was aware there was an opportunity to generate potentially insightful and relevant data from such interviews, I was reluctant to revisit ethical approval and access negotiations, based on my experiences thus far and the amount of time remaining to carry out my study.

Another potential area of weakness of my study is that I did not choose to recruit patients' families and carers as part of my interview process. It has been contested that companions should be part of a patient centred team (Clayman and Morris 2013) and a recent meta-analysis found that roughly half of adult patients were accompanied in routine medical visits (Wolff et al 2011). During my fieldwork it became apparent that these companions played an important role in the journey of the patient and recruiting companions as part of my interviews would have added another dimension to my study. However, there were clearly resource limitations and there was a requirement for boundedness in the research.

Written information complements verbal information and enables the patient to refresh their memory of the information when needed (Walker 2007) and in this respect, another limitation is that, although I generated data in relation to the written patient information aligned to the ERAS programme, I elected not to include the written information components in my findings, choosing to focus instead on the verbal interactions between patients and nurses in pre-admission and during hospital care. This decision was based on the inconsistencies in the quality of data available from the booklets and leaflets that were provided to patients during pre-admission and / or during their hospital admission. In addition, a restriction with word count and a requirement for an element of boundedness in

the thesis meant that I had to make some concessions in relation to whether I included this information.

9.7.4 Policy 'architects'

I have also described in the methods chapter my not entirely successful attempts to engage with programme authors. In this sense, I had an expectation that interviews with programme originators and authors would enable me to further develop the conjectured theories I had developed. These programme originators (what Pawson and Tilley referred to as 'policy architects') would be able to present underlying theory and their vision or expectations of what patient involvement in patient safety through an ERAS programme should look like in practice, and this would help guide my fieldwork. This, in turn, would allow me to further develop my conjectured CMOs and test them across the three case studies.

This necessitated a change to the original research design, but this is in line with other studies in the literature that have been published as realist evaluations, but do not make reference to this element of the process as originally cited by Pawson and Tilley (1997); namely, Tolson (2007); Rycroft-Malone et al (2010); and Tolson and Schofield (2011). There is also a chapter in Pawson's recent book in which he provides an examination of some published examples of 'realist evaluation' in order to diagnose potential weaknesses and to consider how these interpretations of the approach might be strengthened. These cases were chosen to represent examples of common drawbacks, including 'absence of an explanatory focus' (Pawson 2013). Reviewing the criteria applied by Pawson (2013), this study certainly stands up to scrutiny in that respect.

This altered approach required that I took a more inductive approach to my research, developing a looser amalgam of conjectured CMOs to take into the case studies, with a view to refining these as my study progressed, drawing on empirical data. This inductive approach was designed to complement the theory I had already developed and this was in lieu of any interventions from policy makers or programme authors. In this respect, it was always my intention to test and refine my conjectured CMOs using case study data, and this is what I have done.

9.7.5 Compressed fieldwork

The process of data generation was compressed due mostly to time restrictions relating to access issues, as I have described and this did not allow as much time for systematic analysis and theoretical work as I had initially planned, with the result that much of my data generation was progressed on the basis of hunches and intuition. This relates particularly to observational data and, as I have discussed in the methods chapter, I would carry out preliminary analysis of this observational data and sort into preliminary themes which I would then match to my conjectured theories. However, the compressed nature of my fieldwork did mean that this was not ideal.

However, in practice my analysis of fieldnote data was mainly based on hunches rather than through ongoing analysis as circumstances dictated there simply wasn't the time available for me to achieve the progressive narrowing of focus that should have resulted from these efforts. These 'hunches' I refer to are where activities were taking place and I would consider how these activities related to the conjectured CMOs – what could be referred to as 'hunch-hypotheses'. I had to make certain assumptions about the activities taking place on an acute surgical ward at any one time and my 'hunches' would help guide me to where activity was taking place which could inform my research.

Overall, I am confident my original research design and methodology were generally fit for purpose, although there were some adaptations and modification based on circumstances during the course of my studentship and there are also some areas of the design which, on reflection, may not have been ideal. Although there are variations in the volume and quality of data to support each of the case studies, which reflects some of the limitations I have described, I am confident the quality of the data is of a good standard throughout the study. As I have noted previously, the data for all three case studies is rich and has depth and this has enabled me to successfully answer the research questions and address the research aims.

One of the main strengths of the study is that I have considered the perspective of patients and healthcare professionals and augmented and triangulated this data with my own observations. Choosing to select three case studies was also a strength of the study in terms

of the richness and volume of data that also enabled cross-case comparisons through a myriad of organisational contexts.

I chose to use an approach to my research, realist evaluation, which when I started this process some five years ago would probably still have been considered nascent. It is debatable whether this is still the case, although as I have continually reviewed the literature and engaged with members of the realist evaluation community during my candidature, it is not unreasonable to suggest that this approach has not evolved or matured to the extent that I, or indeed the research community, anticipated. There are clear benefits to the realist evaluation approach and I am confident that this was suited to my research project.

I have developed as a researcher through this process and at times it has been a steep learning curve. The issues relating to access were a particular shock to me, as I had been forewarned by peers and colleagues that 'ethics' was the difficult process to get through. I think, on reflection, it may well be that people have conflated 'ethics' with 'access', as for me the ethical process was useful and allowed me to focus on the ethical dimensions to my study, particularly in view of the fact that I would be accessing and working with vulnerable patients who were experiencing personal crisis. It also allowed me to consider the work I was proposing in 'lay' terms, rather than the somewhat abstract and jargonistic language I seemed to be developing during the early stages of my candidature. However, the access process, as I have outlined in my methods chapter, was disheartening and I will most certainly relate back to my experiences with this study for future research project and have contingencies in place should I experience similar challenges.

9.8 Reflections on methodology

9.8.1 Gatekeepers

During the first case study, I developed what I considered to be a good relationship with the Specialist Nurse (SN) and spent quite a lot of time with this individual during my fieldwork on Albany. The SN was based in an office close to the ward and I often popped in for a chat or a catch up on my way to and from the hospital ward and I found she provided a

fascinating insight and perspective to the unit and was a good sounding board for me to discuss my thoughts and ideas.

On reflection, I became over-reliant on this one person and allowed our discussions to influence the nature of my field work, rather than the conjectured CMOs. Neyland (2008) comments that often gatekeepers are charismatic and well-connected and particularly useful in providing access to the group being studied. This was very much the case in this instance, however it became apparent to me that I was potentially becoming over dependent on this one person and although the SN had a wealth of knowledge, information and connections, I realised it was important to make sure I was acting independently in my research and that my field work was guided by the aims of the study. As the research study progressed over the three cases, I again developed relationships with gatekeepers, but I was alert to avoiding becoming over-reliant on any of these individuals. However, as Mason (2002) comments, it is unrealistic to assume the researcher can maintain a completely neutral stance in the development of such relationships and for me it was striking the right balance, without risking becoming over-reliant on any one individual.

9.8.2 Reflections on observations

I had previously worked as a staff nurse in the UHB under study and so the physical environments and routines of the wards did seem quite familiar to me. However, I was not quite so comfortable with my position as a researcher within this environment. I often felt quite self-conscious when I was 'just' standing around observing, while others were busying themselves and it took me some time to get used to watching people working. I was able to restrain myself and did not pursue my powerful instinct to rush around the hospital wards making beds and cleaning commodes and I also became aware that, much like the dog in Pavlov's famous experiments, I was reacting to patients' call bells and found myself seeking out the source of these bells on more than one occasion in the early stages of my observations. On another occasion I found myself chatting with a healthcare support worker and without any prompting, attempting to justify and explain why I couldn't help with the bed she was making at the time. 'We'll soon have you mucking in!' was the response, so I realised it would be prudent in future to avoid drawing attention to my lack of participation.

This was something that I became used to as the first case study progressed, and although it was an issue with subsequent cases, it was not quite so acute for me. I reflected on whether I would have been better placed as a participant observer, it would certainly have been more comfortable to me, but I recognise that this would have made it difficult for me to focus my observations on my specific areas of interest for the research aims as I may instead find myself with 'work' commitments distracting me from this.

Following the initial orientation period on the respective cases, I recognised that I needed to present an impression of being 'purposeful', as staff would question what exactly I was doing, or what I hoped to gain from 'hanging around' the hospital ward. Nursing staff would occasionally comment on how much time I would spend on the ward, or what time I would arrive or leave. To counter this, I would say that I was making specific observations in regard to, for example, physiotherapy, discharge planning, handover and so on, which seemed to satisfy my enquirers.

Another issue of note was that during my first case study observations it became evident that my use of a small book to take notes was potentially affecting the behaviour of those people I was observing. For example, one healthcare support worker developed quite an interest in my notebook and would follow up any remark or comment she made to me with "Put that in your book!" On another occasion a nurse asked what I was writing in my book and I explained they were notes and prompts for further enquiry and offered to show it to him, or read out the notes I had just written, but he declined this offer and joked that I was writing down how many chocolates he had been eating. Another incident of note was when a senior nurse told me that, even though she was used to being observed, my taking of notes when observing her interaction with a patient had made her "a little flustered" and "self-conscious". These events, along with other remarks made by staff members, drew my attention to the fact that people were obviously aware of my note taking to the extent that they were interacting with me about it and I wondered what effect this was having on their behaviour in my presence. Specifically, my use of a note book was contaminating further any attempts of mine to observe 'natural' behaviour and I developed a new strategy so my note taking was less obvious, which involved me locating various spaces on and around the respective units which would enable me to write my notes out of view of study participants.

Being a novice at observational methods, I also found it helpful to use my first few periods of observations to practice and develop my observational methods and techniques. My attempts at getting to know participants and allaying any fears or suspicions they may have had of me did not always prove fruitful, as there were instances in each of the case studies where staff believed I was employed as some form of 'spy' for the health board, with a couple of suggestions that I was engaged in a 'time and motion' study of the nursing staff. A particular example of this suspicion was when I entered a ward area and a nurse was sat on a patient's bed filling in a form. On seeing me she exclaimed 'I thought you were going to tell me off!'

On reflection I believe I was somewhat self-indulgent in my observational fieldwork on Albany and I should have started focused observations earlier in the case study. However, I was keen to take advantage of all the opportunities on offer, even though this was not in tune with my theory-led approach to the research design. This was something that I was alert to and attempted to address in the subsequent case studies. Reading the theory and text books about observational methods and discussing them with experienced researchers is one thing, but until I actually began my fieldwork I didn't appreciate the complexities and demands of this type of research method. Identity issues can be draining, as is the constant requirement to stay alert and mentally prepared for whatever or whoever came my way. I had a sense of not being able to let my guard down early on during my field work, although I did relax somewhat as my confidence grew. It is difficult to know how others perceived me or judged me. Mason (2002) advises that the researcher should ensure they continually analyse themselves and their actions with others, as this will help the researcher to make judgements about these issues. I was mindful of this in my observational fieldwork and I tried to remain self-critical and reflexive during the course of my study.

I kept a reflective journal throughout the entire process and this was useful in alerting me to issues such as my over-reliance on one informant, thus allowing me to be reflexive in my approach and gradually withdraw from the relationship.

9.8.3 Reflections on interviews

There was an incident of particular note in relation to timing issues with my first interview on Albany which had repercussions for the case study and subsequent recruitment. This interview ran over the predicted time and although I reminded the interviewee (who was also the deputy ward manager), on several occasions of how long we had been away from the ward she was keen to continue and I was also reluctant to terminate the interview. This interview took 62 minutes and this proved to be significant, as when the interview was finished and we returned to the main ward area, we were approached by a nurse who had initially agreed to carry out an interview saying that she was no longer willing to do it because of the time we had spent in this interview. She was visibly annoyed and quite abrupt and this was quickly followed by another nurse who also withdrew her agreement to take part in an interview as she was too busy. Allowing this interview to overrun was a naive mistake on my part and the nurses' reaction to this did negatively affect my confidence and was also detrimental to my attempts to gain trust and acceptance from the staff on the ward. I was careful to try and ensure that no further interviews ran over the allotted time and this was something that I took into future case studies. This was an important event in the course of my fieldwork because it demonstrated the importance of field relations and trust.

Methodological discussion about interviewer conduct discusses rapport as an ideal of interviewer practice, inferring that if the interviewee feels comfortable, they will find it easier to talk to the interviewer (Stake 2005). However, although many of the interviewees appeared relaxed and seemed to welcome the opportunity to talk with me, as has been documented previously by Hammersley and Atkinson (2007), it was also the case that some nursing staff I interviewed seemed wary of my objectives, despite my attempts to reassure them and put them at ease. In reality, I question whether rapport was something I could achieve with many of the interview participants in what was essentially an artificial and contrived encounter.

Further to this, Rapley (2004) reveals the danger of assuming that interview talk is only about the official topic of the interview as it may also reveal what he refers to as identity

work in which the talk in an interview may be as much about the person presenting themselves as an 'adequate interviewee'. This was apparent during some of my interviews with nurses and occasionally it appeared to me that nursing staff seemed concerned to present the 'right' answers when it came to patient safety and patient involvement and the utility of ERAS and it sometimes required some digging on my part and hopefully I was able to demonstrate some degree of guile at times to get beneath these answers and encourage interviewees to express themselves more freely. In an attempt to support this, I would draw on my observational data and use examples from this where there may appear to be some counter examples of nursing practice to those which were being presented. I was mindful to present this in a naïve way, so as not to question the veracity of the participants' responses. However, it was sometimes a bit of a verbal wrestle to encourage staff to 'open up' about certain topics particularly in relation to patient safety, or to be critical about ERAS or the organisation and I was alert to boundaries to ensure I was not coercing staff into making comments they may have regretted. Conversely, many of the staff I interviewed were frank and candid in their responses. I was always sure to thank the interview participants and assure them they had provided useful and interesting information.

I had developed an interview schedule for patients and I was anticipating interview participants providing a narrative of their experiences, telling me about their 'journey' and I was careful to allow the patients to talk freely, trying to avoid interruptions or interjections if possible. I was particularly mindful of this for those patients who had received devastating and life-changing diagnoses. However, it was necessary on occasion for me to steer and re-focus interviews with patients. There were also specific issues which needed to be addressed with my interviewing technique for the first case study, Albany. On reviewing my data from interviews with patients from Albany, I noted that although there was fascinating and insightful in relation to the patients' overall experience, these interviews were lacking in focus in relation to my conjectured CMOs, which made it quite challenging for me to identify the elements of data which could inform my research questions. There were several issues connected to this. Firstly, I think my inexperience as a qualitative researcher was evident and I was overly keen to explore the unexpected turns that followed the informant's interests or knowledge that Hammersley and Atkinson (2007) refer to. I would then often find it difficult to be assertive enough to be able to control the interview when required and return the

interview to the required course when necessary (Hammersley and Atkinson 2007). It was often the case that many of my CMO related themes would be squeezed into the end stages of an interview, as I attempted to recover these interviews. I was certainly alert to this in future case studies and tried to be more focused during my interviews with patients, although often patients' would share such compelling stories that I would allow these to run their course, before attempting to steer patients back to the topics at hand.

In relation to the issues identified in my interviewing technique, this was the case for early interviews, and review of my interview technique and data early on through transcription and journal reflection allowed me to identify and correct this. This was also a reflection of the fact that there were limited ERAS related activities taking place on Albany, as discussed in the methods and findings chapters.

An issue identified through reflection on my technique in the first case study (Albany) was my tendency to talk too much, rather than listening. This was certainly the case with staff interviews, where I had a tendency to be overly concerned with trying to establish my credibility as a nurse and trying to create this identity which I hoped would forge a stronger bond with the interviewee. I was sometimes overly keen to demonstrate knowledge or understanding of a subject or demonstrate my insight into the interviewees' talk, rather than listening and considering how the comments related to my research aims. In earlier interviews, I also had a tendency to sometimes interject and express my opinions on matters under discussion, rather than developing the ideas and themes with the participant. When reviewing my interview recordings and transcripts I recognised this was not the best way to go about these interviews and I made a concerted effort to change my approach to interviews, my interview style, in the latter stages of Albany and for the subsequent cases. This was not so much of an issue for patient interviews, although as I have mentioned, on some occasions I allowed these interviews to meander too much, rather than keeping a clear focus on the research aims.

To conclude my reflections on my learning, in future I will be more alert to the realities and practicalities of carrying out ethnographic research in a busy, modern hospital and will give more consideration to access issues in future studies. I will also ensure I carry out a pilot

study of some sort and give more credence to initial scoping exercises and consider engaging with a wider range of informants in relation to this. If I were to undertake further realist evaluations, I would cast the net wider in terms of who I could and would speak with to try and ascertain programme theory from a policy perspective and augment and develop my own theories. Again, there are issues here in relation to whether it is a prospective or retrospective evaluation – Pawson and Tilley talk about the iterative process of evaluation and this could be achieved through prospective realist evaluation.

Conclusion to the thesis

This thesis was presented in four distinct parts the first two of which provided a background to the study and a methodological description of the study. Part three presented the findings of the study and the final part provided a discussion of these findings and some of my personal reflections.

The broad aim of this study was to explore the extent to which patients are involved in attempts to improve their own healthcare safety through enrolment in an enhanced recovery after surgery (ERAS) programme. Recognising that patient safety is just one aspect of the ERAS programme theory, this research evaluated those elements of the programme that see patients taking a role in their own healthcare safety. This was achieved by considering in realist terms the mechanisms of effect by which patients might contribute to their healthcare safety and investigating the conditions and circumstances (contexts) that are required to enable this involvement. The overall aim of this research was to seek out regularities in the patterns of these contexts and mechanisms which result in patient involvement in patient safety. The emerging theory will help explain implementation variations, and the experiences of the programme participants in the different cases provided an opportunity to make comparisons with initial programme theories, the objective being to better understand when and why patient involvement in patient safety works in an ERAS programme.

In line with the aims of the study I have explored patient involvement in patient safety through an ERAS programme using a realist evaluation approach and I have identified some of the contextual features necessary for patient involvement in patient safety. This was done using early and continuing postoperative mobility as a 'tracer' intervention for the ERAS programme, which allowed me to provide cross case comparisons across the three surgical units under study.

Within the thesis I have considered policy context and also engaged with the wider literature in relation to patient involvement in patient safety, allowing me to present a rationale for why patients should be involved in patient safety, and the relevance of my study in relation to this. I have also presented details about the ERAS programme and considered this in the context of the wider literature in relation to patient involvement in patient safety. Following this, I

have used a realist evaluation approach to build theories about when and how patients can be involved in patient safety through an ERAS programme. These theories were developed from national policy documentation, local, national and international guidelines and the wider literature and were expressed in the form of three distinct conjectured CMOs, which related to staff involvement, the provision of information and education to patients and sustaining patient involvement during hospital care.

I then used the data generated across the three case studies during my field work to 'test' these conjectured CMOs, thus enabling me to identify certain contexts which were required for successful outcomes for patient involvement in patient safety. Based on this analysis of my empirical data and consideration of the wider literature, I have presented re-configured CMO configurations, which express the contextual conditions required for effective patient involvement in patient safety through an ERAS programme. As described, this is specifically related to the early and continuing postoperative mobility elements of an ERAS programme. I have then presented a discussion based on these findings, using what I consider the main themes derived from my study. These themes related to the role of healthcare staff in attempts to improve quality and safety in healthcare through patient involvement and how healthcare professionals can work with patients to 'co-produce' patient safety. I also considered the tensions between the ongoing standardisation of healthcare and the requirement for patient-centred, individualised care. I then discussed the concept of 'empowering' patients in their healthcare, and how this might be enacted in light of the obvious power differentials at play between patients and healthcare professionals. Finally, I considered the concept of a new professionalism which is based on trusting relationships and candour between patients and healthcare professionals.

Original contribution to knowledge

To recap, I believe this thesis sits at the interface of a number of health policy and quality improvement trends including patient involvement, patient safety, standardisation, patient centred care, co-production and the growing interest in healthcare with the implementation and embedding of interventions.

The main areas for consideration from these findings are the importance of the role of healthcare staff in attempts to involve patients in patient safety, along with the obvious tensions between standardisation of care versus the aspirations of providing person-centred, individual care for patients. This is considered in relation to the ongoing standardisation of healthcare through an increasing reliance on protocols and pathways, such as the ERAS programme. The concept of empowerment was also identified, where there clearly aspirations with policy and programme documentation to 'empower' patients to take a more active role in their care, which proved more complex in reality.

I have identified elements within an ERAS programme which can be considered in terms of patient involvement in patient safety. This involvement takes the form of monitoring and ensuring safe delivery of treatment by helping to ensure treatment is given as planned and according to the appropriate protocols, specifically in relation to the requirements for early and continuing postoperative mobilisation at the level of direct care.

Patient involvement in patient safety through an ERAS programme can also be viewed in the context of patients' receiving information about what actions they can take to reduce their risks in hospital, and making decisions about this information in respect of managing their own health and postoperative recovery.

Patient involvement in ERAS also represents an attempt to encourage a form of 'co-production' between patients and clinicians, with clinicians' expertise guiding the patient experience to help improve patient safety. An enhanced recovery programme tackles what can be realistically expected for many patients to do in relation to their own care, whilst avoiding a complete shift of responsibility onto patients. It was also clear in my findings that relationships between healthcare professionals and patients are critical to the success of

involvement initiatives. In this sense, any attempts at co-production between these parties requires a trusting relationship to support a move to a new type of professionalism in which the imbalance of power between patients and professionals is addressed.

Pawson (2006; 2013) also makes reference to the contextual layers that shape and influence attempts to introduce and sustain innovations such as ERAS. These consist of the individual capacities of the key actors and the interpersonal relationships involved. The institutional setting and wider infra-structural systems also have an influence on attempts to embed programmes into practice. This thesis demonstrates the effects of some of these layers of context on the attempts by healthcare policy makers and providers to involve patients in patient safety.

At an individual level, patients may be affected by a range of factors, such as illness, fatigue and the effects of analgesia and anaesthesia, which can affect their ability and willingness to take part in their own safety and care. In these cases, patients should be supported to ensure their safe care and recovery, allowing them to recuperate to the stage where they can take more responsibility during their care, should they so wish. The days following an operation can be critical in terms of a successful long-term outcome, so nursing staff, and others, must be alert to this and ensure that patient safety and welfare is not compromised by 'pushing' patients too hard, or conversely, ensuring that patients do not push themselves too hard. It has also been demonstrated that patient involvement in patient safety related activities is more likely if patients receive direct instructions to do so from a clinician.

In terms of the interpersonal relationships involved in attempts at involving patients in safety, we have seen there are issues of power imbalances between patients and healthcare providers, and in acute settings such as those I have studied here, it is questionable how much power or control patients could have in such a relationship. Certainly, aspiring to true partnerships and patient empowerment as these concepts are expressed in the literature, will be difficult in light of the technical and clinical expertise required for many aspects of surgical care. Also, it has been established that different patients may desire different levels of involvement, depending on their circumstances, and this can change as the patient progresses through their healthcare journey. We have also seen that some patients are prepared to

adopt a 'compliant' role with little involvement, with the expectation that they will receive the required treatment. This has also highlighted some of the tensions associated with the standardisation of care through protocols such as ERAS, against the aspirations of patient centred care that is espoused in the policy literature and embedded in the ideology of many healthcare professionals.

We have also seen that patients are presented with very little opportunity for decision making during their pre-admission appointment or subsequent hospital care. The real choice patients are faced with is whether they choose to act on the information provided to them and actively engage with the ERAS programme, although as we have seen, not all patients will be able to take part, even if they so wished, whilst others are strongly encouraged to 'comply'. This has highlighted that patients 'compliance' may be considered at one end of the continuum of involvement, in the sense that this is an informed compliance, with a rationale associated with improved outcomes and safer care.

In terms of expected impact, this research highlights the importance of contextual factors when considering the implementation of standardised, evidence based practice across diverse healthcare units and patient groups. The results will add to current understanding of the workings of patient safety and quality improvement policy in Wales and beyond and will be of direct relevance to NHS service providers, service users, managers, policy makers and educationalists.

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Gwasanaeth
Moeseg
Ymchwil

RES

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Ethics
Service

South East Wales Research Ethics
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17 Churchill Way
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South East Wales Research Ethics Committee Panel B

02 July 2012

Mr Dominic Roche
Doctoral Student
Cardiff University
School of Nursing and Midwifery Studies
Eastgate House, Newport Road
Cardiff
CF24 0AB

Dear Mr Roche

Study title: Patient Involvement in Safer Surgery: A Realist Analysis
REC reference: 12/WA/0192

Thank you for your letter of 01 June 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair, Mrs A. Dowden.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science
Collaboration is hosted by Powys Teaching Health Board

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of insurance or indemnity	Cardiff University	06 July 2011
Investigator CV	Mr D Roche	02 June 2012
Letter from Sponsor	Cardiff University	31 May 2012
Other: CV	Dr A Jones	
Other: Letter from Cardiff University SONMS RRESC		22 May 2012
Other: Timeline for PhD		
Participant Consent Form	1.0	01 May 2012
Participant Information Sheet: Patient - Outpatients Department		01 June 2012
Participant Information Sheet: Staff - Surgical Ward	2	01 June 2012
Participant Information Sheet: Patient - Surgical Ward	2	01 June 2012
Participant Information Sheet: Patient - Patient Education Session	2	01 June 2012
Participant Information Sheet: Participant - Pre-Assessment Clinic	2	01 June 2012
Protocol	1.0	01 May 2012
REC application	3.4	06 June 2012
Response to Request for Further Information	2	01 June 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/WA/0192

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

P.P. Dowden

**Mrs A Dowden
Chair**

Email: jagit.sidhu@bsc.wales.nhs.uk

Enclosures: "After ethical review – guidance for researchers" [SL-AR2]

Copy to: R&D Office, Cardiff and Vale University Health Board
R&D Office, Cardiff University



Consent Form

Cardiff University, School of Nursing and Midwifery Studies, Eastgate House, Newport Road, Cardiff, CF24 0AB

Title of Project: Patient involvement in Safer Surgery: A realist analysis.

Name of Researcher: Mr. Dominic Roche (e-mail roched1@cf.ac.uk)

Contact Telephone Number: 02920 917 727

Participant Identification Number for this study:

Please initial box

I confirm that I have read and understand the information sheet dated _____. I have had the opportunity to consider the information, ask questions, and have had these questions answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I agree to the interview I participate in being audio-taped and notes being taken by the researcher

I agree to take part in the above study

Name of researcher

Date

Signature

Name of participant

Date

Signature

Patient Participant Information Sheet (Surgical Ward)

Patient Involvement in Safer Surgery

My name is Dominic Roche and I am a PhD student at Cardiff University and I would like to invite you to take part in my research. Before you decide whether or not to take part, I would like you to understand why the research is being done and what it will involve for you. If you are interested in taking part, I will go through this information sheet with you and answer any questions you have, which should take about five minutes. Please talk to others about the study if you wish. Please ask me if there is anything that is not clear.

What is the purpose of the study? The main purpose of the study is to explore the extent to which patients are involved in attempts to improve their own healthcare safety. If you agree to take part in an interview, I will be asking you questions about your current healthcare experience. This information will be used to help find out how patients can be more involved in their healthcare.

Why have I been invited? Your personal experiences will provide valuable information for the research project.

Do I have to take part? No. Taking part in the research is entirely voluntary, and it is up to you to decide to join the study. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part? If you agree to take part you will be asked to take part in a face to face interview with me, which will last no longer than sixty minutes. The interview will be taped and you will be asked to sign a form to say you agree to this. Unfortunately, if you do not wish to be tape recorded you will not be able to take part in the interview. I will ask you questions about your experiences relating to your hospital admission. I will also ask you to provide information about your age, education and ethnic background. You will not be asked to



provide any other personal details, and your name will not be used in the study.

What are the possible benefits of taking part? Agreeing to take part in an interview will not provide you with any direct benefit. However, I believe that this study will provide useful information which could benefit others in the future.

What if there is a problem? If you do have a concern or complaint about any aspect of this study, please speak to me and I will do my best to answer your questions. If you remain unhappy and wish to complain formally, you can do this. Details of how to do this can be obtained from a member of staff.

Will my taking part in the study be kept confidential? All information that you provide during this study will be strictly confidential and all documentation held in accordance with the data protection act and in agreement with the data Protection Officer at Cardiff and Vale University Health Board. All information will be stored within a locked cabinet in a locked room, to which I have access, in Cardiff University.

Recorded interviews will be transcribed the day following our interview, after which the recording will be erased. The transcriptions will be kept by me for five years, on behalf of Cardiff University in accordance their policy on data storage and disposal policy. Direct quotations from our interview may be presented in the final research report, which will be anonymous.

Please note, I cannot guarantee confidentiality if I perceive that participants, or others, are in any way deemed to be at serious risk of harm. If such an occasion should arise, I will act through the appropriate reporting channels which exist within the University Health Board.

What will happen if I don't want to carry on with the study? If you wish to withdraw, any information I have collected relating to your interview will be destroyed. Please contact me using the details at the bottom of this form should you wish to do this.



What will happen to the results of the research study? The results will be published in academic journals, presented at conferences and shared with patient groups. If you agree to an interview you will not be identified in any report or publication.

Who is organising, carrying out and funding the research? I am carrying out the research as part of a full time PhD in Nursing at Cardiff University. The research is being funded by the National Institute for Health and Social Care Research in Wales, part of the Welsh Government.

Who has reviewed the study? To protect your interests all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the South East Wales Research Ethics Committee, who are happy for it to take place.

What do I do now? If you are willing to participate in an interview, please let a member of staff know, or contact the researcher on the following details below.

You will be asked to sign a consent form agreeing to take part in a tape recorded interview with me. You will have at least 72 hours between signing the consent form and the interview taking place. If you change your mind at any time, you are free to withdraw your consent.

Contact for further information:

Mr. Dominic Roche (Researcher) Cardiff University, School of Nursing and Midwifery Studies, Eastgate House, Newport Road, Cardiff CF24 0AB

Telephone: 02920 917 727 or e-mail roched1@cf.ac.uk



Staff Participant Information Sheet (Surgical Ward)

Patient Involvement in Safer Surgery

My name is Dominic Roche and I am a PhD student at Cardiff University and a registered nurse and I would like to invite you to take part in my research. Before you decide whether or not to take part, I would like you to understand why the research is being done and what it will involve for you. If you are interested in taking part, I will go through this information sheet with you and answer any questions you have, which should take about five minutes. Please talk to others about the study if you wish. Please ask me if there is anything that is not clear.

What is the purpose of the study? The main purpose of the study is to explore the extent to which patients are involved in attempts to improve their own healthcare safety. If you agree to take part in an interview, I will be asking you questions about your involvement in the ERAS programme and experiences you have had with involving patients in their healthcare and safety.

Why have I been invited? The selection criteria for the study require that you are a member of nursing staff involved in the ERAS programme. Your personal experiences will provide valuable information for the research project.

Do I have to take part? No. Taking part in the research is entirely voluntary, and it is up to you to decide to join the study. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part? If you agree to take part you will be asked to take part in a face to face interview with me, which will last no longer than forty five minutes. The interview will be taped and you will be asked to sign a form to say you agree to this. Unfortunately, if you do not wish to be tape recorded you will not be able to take part in the interview. I will ask you questions about your experiences relating to patient involvement in healthcare and healthcare safety. You will not be asked to provide any other personal details, and your name will not be used in the study.

What are the possible benefits of taking part? Agreeing to participate in an interview will not provide you with any direct benefits, but the information from this study may provide useful information which could benefit others in the future.

What if there is a problem? Any complaint about the way you have been dealt with by the researcher will be addressed. If you do have a concern about any aspect of this study, you should ask to speak to me and I will do my best to answer your questions. If you remain unhappy and wish to complain formally, you can do this. Details can be obtained by contacting Cardiff University.

Will my taking part in the study be kept confidential? All information that you provide during this study will be strictly confidential and all documentation held in accordance with the data protection act and in agreement with the data Protection Officer at Cardiff and Vale University Health Board. All information will be stored within a locked cabinet in a locked room, to which I have access, in Cardiff University.

The recorded interview will be transcribed the day following our interview, after which the recording will be erased. The transcriptions will be kept by me for five years, on behalf of Cardiff University in accordance their policy on data storage and disposal policy. Direct quotations from our interview may be presented in the final research report, which will be anonymous.

Please note, I cannot guarantee confidentiality if I perceive that participants, or others, are in any way deemed to be at serious risk of harm during. If such an occasion should arise, I will act through the appropriate reporting channels which exist within the University Health Board.

What will happen if I don't want to carry on with the study? If you wish to withdraw, any information I have collected relating to your interview will be destroyed. Please contact me using the details at the bottom of this form should you wish to do this.

What will happen to the results of the research study? The results will be published in academic journals, presented at conferences and shared with patient groups. If you agree to an interview you will not be identified in any report or publication.

Who is organising, carrying out and funding the research? I am carrying out the research as part of a full time PhD in Nursing at Cardiff University. The research is being funded by the National Institute for Health and Social Care Research in Wales, part of the Welsh Government.

Who has reviewed the study? To protect your interests all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the South East Wales Research Ethics Committee, who are happy for it to take place.

What do I do now? If you are willing to participate in this research, please let your ward / line manager know and your details will be passed on to me and I will contact you to arrange a suitable time and place for the interview.

You will be asked to sign a consent form agreeing to take part in a tape recorded interview with me. If you change your mind at any time, you are free to withdraw your consent.

Contact for further information:

Mr. Dominic Roche (Researcher) Cardiff University, School of Nursing and Midwifery Studies, Eastgate House, Newport Road, Cardiff CF24 0AB

Tel: 02920 917 727 or e-mail roched1@cf.ac.uk

Appendix 5: Sample of search strategy

1 Consumer Participation/(3886)

2 exp Patient Education/(25965)

3 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 involv\$).ti,ab. (2414)

4 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 participat\$).ti,ab. (1808)

5 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 view\$).ti,ab. (1232)

6 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 attitude\$).ti,ab. (673)

7 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 role\$).ti,ab. (1278)

8 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 contribut\$).ti,ab. (78)

9 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 reporting).ti,ab. (286)

10 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 aware\$).ti,ab. (822)

11 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 concern\$).ti,ab. (1664)

12 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 check\$).ti,ab. (154)

13 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 as partners).ti,ab. (28)

14 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$

or user\$) adj2 partnership\$).ti,ab. (325)

15 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 engag\$).ti,ab. (300)

16 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 encourag\$).ti,ab. (538)

17 (promoting adj (patient\$ or inpatient\$ or outpatient\$or consumer\$ or citizen\$ or public or carer\$ or caregiver\$ or user\$)).ti,ab. (118)

18 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 empower\$).ti,ab. (612)

19 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 complain\$).ti,ab. (730)

20 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 educat\$).ti,ab. (6498)

21 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 opinion\$).ti,ab. (452)

22 exp Patient Safety/(17291)

23 Risk Management/(3579)

24 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 adverse).ti,ab. (251)

25 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 safe\$).ti,ab. (3911)

26 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 harm\$).ti,ab. (334)

27 ((patient\$ or inpatient\$ or outpatient\$ or consumer\$or citizen\$ or public or carer\$ or caregiver\$ or user\$) adj2 unsafe\$).ti,ab. (21)

28 (risk\$ adj2 manag\$).ti,ab. (1742)

29 (safe\$ adj2 manag\$).ti,ab. (277)

30 ((check\$ or monitor\$) adj2 safe\$).ti,ab. (223)

31 (adverse adj4 reporting).ti,ab. (202)

32 negligence.ti,ab. (822)

33 negligent.ti,ab. (278)

34 ((incident or error or errors or mistake\$ or safe\$ or harm\$) adj2 report\$).ti,ab. (804)

35 ((professional\$ or worker\$ or dentist\$ or nurs\$ or doctor\$ or physician\$ or surge\$ or pharmac\$ or human or practitioner\$ or psychiatrist\$ or psychologist\$ or anaesthes\$ or anesthes\$) adj2 (mistake\$ or error or errors)).ti,ab. (353)

36 ((medical or diagnos\$ or treatment\$ or medication\$ or healthcare or care or hospital\$ or system\$ or

disclos\$ or past or previous) adj2 (mistake\$ or error or errors)).ti,ab. (2303)

37 ((incident\$ or error or errors or mistake\$ or unsafe\$ or safe\$ or harm\$) adj2 (detect\$ or prevent\$)).ti,ab. (744)

38 near miss.ti,ab. (68)

39 near misses.ti,ab. (75)

40 err is human.ti,ab. (61)

41 or/1–21 (43608)

42 or/22–40 (25322)

43 41 and 42 (1254)

Appendix: Literature

Search Categories

(CINAHL)

Clinical Governance
Patient Safety
Quality Assurance
Quality Improvement
Quality of Healthcare
Risk Management

Access to Information
Accountability
Behavioural Change
Collaboration
Consumer Attitudes
Consumer Participation
Cooperative Behaviour
Decision Making, Patient
Empowerment
Health Behaviour
Information Needs
Information Seeking Behaviour
Patient Autonomy
Patient Centred Care
Patient Compliance
Patient Education
Patient Rights
Patient Satisfaction
Self Care
Self Efficacy
Teaching Materials
Teaching Methods

Adverse Drug Event
Adverse Health Care Event
Harm Reduction
Health Care Errors
Human Error
Incident Reports
Medication Errors
Treatment Errors
Truth Disclosure
Surgical Wound Infection
Wrong Site Surgery

Attitude of Health Personnel
Nurse-Patient Relations
Organisational Culture
Paternalism
Patient Advocacy
Patient Attitudes
Physician-Patient Relations
Power
Professional-Patient Relations

Caregiver Burden
Caregiver Support
Caregivers
Decision Making, Family
Family Attitudes
Family Centred Care
Family Role
Professional-Family Relations

Checklists
Intraoperative Care
Perioperative Care
Postoperative Care
Postoperative Complciations
Preoperative Education
Preoperative Care
Preoperative Period
Surgery, Operative
Surgical Patients
Surgical Wound
Surgical Wound Care
Venous Thromboembolism

Antibiotic Prophylaxis
Blood Glucose
Body Temperature Regulation
Glycaemic Control
Hair Removal
Hypothermia
Skin Preparation, Surgical
Warming Techniques

Appendix: Literature Search Categories (MEDLINE)

Adaptation, Psychological
Attitude of Health Personnel
Attitude to Health
Checklist
Checklist methods
Checklist standards
Clinical Competence standards
Delivery of Health Care standards
Health Behavior
Health Knowledge, Attitudes, Practice
Health Status
Internal-External Control
Interprofessional Relations
Locus Control Region
Motivation
Organizational Culture
Patient Care standards
Patient Compliance
Patient Education as Topic
Patient Education as Topic methods
Patient Education as Topic organization and administration
Patient Preference
Patient Satisfaction
Patient-Centred Care
Patient-Centred Care methods
Physician-Patient Relations
Postoperative Complications
Postoperative Complications etiology
Postoperative Complications diagnosis
Professional-Family Relations
Professional-Patient Relations

Social Responsibility

Surgical Procedures, Operative standards

Surgical Wound Infection prevention and control

Accidents
Consumer Product Safety
Hospital standards
Iatrogenic Disease prevention & control
Infection Control methods
Medical Errors nursing
Medical Errors prevention & control
Medication Errors nursing
Medication Errors prevention & control
Medication Errors psychology
Quality Assurance, Health Care
Quality Assurance, Health Care methods
Quality Assurance, Health Care organization & administration
Quality Assurance, Health Care standards
Quality Improvement
Quality Indicators, Health Care
Quality Indicators, Health Care standards
Quality of Health Care
Quality of Health Care standards
Risk Management
Risk Management ethics
Risk Management legislation and jurisprudence
Risk Management methods
Risk Management organization & administration
Risk Management standards
Safety
Safety Management
Safety Management methods
Safety Management organisation and administration
Safety Management standards
Safety standards

Consumer Participation
Consumer Participation psychology
Cooperative Behavior
Patient Participation
Patient Participation methods
Patient Participation psychology
Self Efficacy

Appendix: Literature

Search Categories

(PUBMED)

Patient safety	participation rates	patient education
Patient safety culture	participation stroke	consumer driven
improving patient safety	participation rehabilitation	patient satisfaction
patient safety indicators	patient participation decision making	patient centred care
patient safety climate	patient participation nursing	patient empowerment
patient safety goals	participation older adults	patient decision making
patient safety quality	famiy participation	self efficacy
nursing patient safety	social participation	patient information
clinical governance	participation outcomes	
quality assurance	patient participation	
quality improvement	community participation	
quality care		
clinical risk management		
safety risk management		
health risk management		

preventing medication errors checklist
human error
harm reduction
wrong site surgery
error disclosure
errors



NIHR CRN Workforce Development
Enabling learning and development in the Clinical Research Network



**National Institute for
Health Research**



Today's **Research**; Tomorrow's **Care**
Ymchwil Heddiw; Gofal Yfory



Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

Certificate of Attendance

Dominic Roche

attended

Introduction to Good Clinical Practice (GCP):

A practical guide to ethical and scientific quality standards in clinical research

on 19th July 2012

Sessions include:

1. The Value of Clinical Research and the role of NIHR CRN & NISCHR CRC
2. GCP: the standards and why we have them
3. Study set up: responsibilities, approvals and essential documents
4. The process of informed consent
5. Case report form, source data and data entry completion
6. Safety reporting in clinical trials

This course is accredited by the Royal College of Physicians (6 CPD points) and the Royal College of Nursing Accreditation Unit (7 study hours)



Zoe Whale

Paul Maher

Zoe Whale
Training & Development Manager
NISCHR CRC

Paul Maher
NIHR CRN GCP Training Manager

Appendix: List of study participants

Case Study A

<i>Role and Gender</i>	<i>Pseudonym</i>
Patient (Male)	Patient 1
Patient (Male)	Patient 2
Patient (Male)	Patient 3
Patient (Male)	Patient 4
Patient (Male)	Patient 5
Patient (Male)	Patient 6
RN (Surgical Nurse Practitioner) Female	SNP
RN (Deputy Ward Manager) Female	RN1
RN (Staff Nurse) Male	RN2
RN (Ward Manager) Female	RN3
RN: (Staff Nurse) Female	RN4
RN (Staff Nurse) Female	RN5
RN (Staff Nurse) Female	RN6

Case Study B

<i>Role and Gender</i>	<i>Pseudonym</i>
Patient (Male)	Patient 1
Patient (Female)	Patient 2
Patient (Female)	Patient 3
Patient (Male)	Patient 4
Patient (Female)	Patient 5
Patient (Female)	Patient 6
Patient (Female)	Patient 7
Patient (Female)	Patient 8
RN (Staff Nurse) Male	RN1
HCSW (Support Worker) Female	RN2
RN (Staff Nurse) Female	RN3
RN (Deputy Ward Manager) Female	RN4
RN: (Staff Nurse) Male	RN5
RN: (Ward Manager) Female	RN6
RN: (Staff Nurse / ERAS Nurse) Female	RN7

Case Study C

<i>Role and Gender</i>	<i>Pseudonym</i>
Patient (Male)	Patient 1
Patient (Female)	Patient 2
Patient (Female)	Patient 3
Patient (Female)	Patient 4
Patient (Female)	Patient 5
Patient (Male)	Patient 6
Patient (Male)	Patient 7
RN (Staff Nurse) Female	RN1
RN (Staff Nurse) Female	RN2
RN (Staff Nurse) Female	RN3
RN (Staff Nurse) Female	RN4
RN (Deputy Ward Manager) Male	RN5
RN (Discharge Liaison Nurse) Female	RN6
RN (Clinical Nurse Specialist) Female	RN7

Appendix: Schedule of interviews

Staff interviews

Case A	Date	Position	Band	Gender	Length
RN1	27/11/2012	Staff Nurse	5	M	28m 58s
RN1 / RN2	08/01/2013	Staff Nurse	5	M	39m 41s
RN2	27/11/2012	Deputy Ward Manager	6	F	62m 22s
RN3	03/12/2012	Ward Manager	7	F	37m 20s
RN3	17/12/2012	Ward Manager	7	F	50m 37s
RN4	10/12/2012	Staff Nurse	5	F	33m 20s
RN4	09/01/2013	Staff Nurse	5	F	30m 33s
RN5	11/12/2012	Staff Nurse	6	F	45m 35s
RN6	19/12/2012	Staff Nurse	5	F	32m 46s
SNP	24/12/2012	Surgical Nurse Practitioner	7	F	62m 25s

423m 30s

Case B	Date	Position	Band	Gender	Length
RN1	26/03/2013	Staff Nurse	6	M	51m 03s
RN2	29/03/2013	Health Care Support Worker	3	F	51m 29s
RN3	02/04/2013	Staff Nurse	5	F	55m 13s
RN4	02/04/2013	Deputy Ward Manager	6	F	94m 58s
RN5	09/04/2013	Staff Nurse	5	M	50m 11s
RB6	15/04/2013	Ward Manager	7	F	66m 08s
RN7	15/04/2013	Staff Nurse	6	F	78m 00s

447m 02s

Case C	Date	Position	Band	Gender	Length
RN1	26/06/2013	Staff Nurse	5	F	46m 20s
RN2	26/06/2013	Staff Nurse	5	F	42m 02s
RN3	27/06/2013	Staff Nurse	5	F	44m 14s
RN4	27/06/2013	Staff Nurse	5	F	45m 39s
RN5	28/06/2013	Deputy Ward Manager	6	M	84m 07s
RN6	04/07/2013	Clinical Nurse Specialist	6	F	56m 10s
RN7	10/07/2013	Clinical Nurse Specialist	6	F	41m 42s

360m 14s

Patient Interviews

Case A	Date	Gender	Length
Patient 1	27/12/2012	M	84m 51s
Patient 2	30/12/2012	M	71m 54s
Patient 3	30/12/2012	M	56m 08s
Patient 4	02/01/2013	M	85m 57s
Patient 5	03/01/2013	M	57m 42s
Patient 6	13/01/2013	M	66m 06s

422m 38s

Case B	Date	Gender	Length
Patient 1	22/04/2013	M	56m 14s
Patient 2	22/04/2013	F	43m 45s
Patient 3	23/04/2013	F	53m 39s
Patient 4	03/05/2013	F	110m 53s
Patient 5	15/05/2013	M	61m 26s
Patient 6	16/05/2013	F	55m 15s
Patient 7	17/05/2013	F	52m 35s
Patient 8	20/05/2013	F	51m 22s

485m 09s

Case C	Date	Gender	Length
Patient 1	09/07/2013	M	40m 01s
Patient 2	10/07/2013	F	47m 59s
Patient 3	11/07/2013	F	58m 24s
Patient 4	16/07/2013	F	58m 28s
Patient 5	17/07/2013	F	66m 37s
Patient 6	18/07/2013	M	40m 36s
Patient 7	22/07/2013	M	100m 51s

412m 56s

Appendix: Interviews with patients: Guideline schedule for patient interviews

Did you feel involved during your stay in hospital?

You were on the enhanced recovery programme. What did / does that mean to you? What was your understanding of it?

I am interested in how the pre-assessment, pre-operative elements of ERAS affected you in terms of involvement and opportunities for involvement. What did you make of pre-assessment?

Do you think it helped prepare you for your operation? Your hospital stay and recovery? Your discharge? In what way? Or if not, why not?

Follow up telephone call – how was this? How did it make you feel?

Patient related

Prior to admission, what were your expectations in terms of how involved you would or might be in your healthcare? Did pre-assessment change these expectations?

What are your previous experiences of hospitalisation? How does this compare in terms of how involved you were with your care?

Did you understand your condition and the recovery process prior to admission? Did pre-assessment change this understanding?

What written information were you given in pre-assessment?

How useful did you find the information provided to you in pre-assessment? The verbal information and also the written information you were provided to take home with you?

How useful, easy to understand, relevant to your condition did you find the information you were provided in pre-assessment and also when you arrived on the ward? And on discharge?

Were you aware / made aware of opportunities for involvement in your care? For you family to be involved?

How willing did you find staff were to share information with you or your family?

How much of a support network did you have during your hospitalisation? Family and friends etc. How involved in your care did they get?

How do you think that affected your involvement?

Do you think your emotional state affected your ability or desire to be involved? Did you feel anxious, vulnerable, frightened, confused, powerless or empowered? Distressed?

Did you find the nurses communication skills were of a standard that helped or enabled you to be involved in your care?

Did you question staff? Did you challenge staff? What about your family? If so, how did the nursing staff respond?

How motivated did you feel to be involved in your care? Did staff help you in terms of your motivation?

What about your relationships with nursing staff? Was there continuity – did you see the same staff or were there many different staff caring for you? Do you feel you had an opportunity to develop relationships and for staff to find out about you and your needs, particularly how involved you wanted to be in your care? Did they feel like a series of ‘one-off’ encounters?

Did you experience any language or other communication barriers with staff?

How satisfied were you during your stay with the level of opportunity for involvement?

Illness related

Did you feel that the amount of involvement you wanted or were offered changed over time? Did your condition affect your ability to be involved? Were staff aware of this?

What sort of involvement and information did you want before your operation? Before admission? After your operation? On discharge?

What do you think would have improved how involved you or your family were in your care?

Healthcare worker related

Did nurses discuss involvement or safety with you?

Did nurses make you aware of involvement opportunities?

How would you rate the communication skills of nurses?

How do you feel the nursing staff interacted with you and your family?

Did the nursing staff encourage involvement?

Did the nursing staff speak to you in a way that you understood, or helped you to become involved?
Did they use jargon and medical terms?

Did the nurses have time to spend with you? Helping you to be involved?

Do the nurses appear too busy, unable to spend time with you?

What was your perception of the busyness of the ward?

Do you feel you had enough time during your interactions with nursing staff? Did you feel rushed?

Do you feel that nursing staff made any assumptions or presumptions about you and your family in terms of how involved you would like to be?

Task related

What specific things were you involved in?

Did you get involved in your medication?

Level of education

Employment status

Age

Patient Diary

Was the patient diary explained to you? In pre-assessment? On the ward?

Did you use the patient diary? Did your family complete the diary for you?

Did any of the staff review the diary entries with you?

Did any of the staff help you to complete the diary?

Did the staff discuss your diary goals with you?

Did you find the diary helpful? If so, in what way?

Do you think it helped you to be more involved in your care?

Appendix: Interviews with nursing staff (Example Questions)

What are the expectations of involvement?

Are there potential situations which you consider to be 'better' for involvement? Then try to establish why this is, e.g. is it to do with the patient, or perhaps the task, or organisational constraints, e.g. time, busyness, staffing levels. Try and tease out if there are any 'personal' reasons, i.e. "healthcare worker related".

Some of the contextual factors are visible, whilst others are hidden. I need to consider which are which and how I can introduce them to interviewees, or how indeed they could introduce them to me.

Would 'patient safety' be identified / associated by staff with a particular or discrete set of tasks? i.e. this involvement is affected by contexts which are 'task related'. How specific should I be about 'patient safety'? Should I allow staff to define it, or should I explain what I mean when I talk about the term? How likely is it that staff have not heard of it – they may 'do it', but in a different guise, or call it something different, or just not distinguish it from other tasks, activities as a 'special' thing.

Ditto with patients – however, I need to be careful of how I approach patients with the idea of patient safety.

I am also interested in family / carer / visitor involvement too. I am interested in your personal experiences and thoughts.

Questions

Can you tell me what 'patient safety' means to you?

What does patient involvement mean to you?

So, bringing this together, what does patient involvement in patient safety mean to you?

What involvement opportunities are you aware of, particularly in relation to patient safety issues?

Tell me (briefly) what you know about ERAS.

Do you think ERAS has anything to do with patient involvement in patient safety?

Do you think ERAS provides more or different opportunities for patient involvement that they would not normally have?

I am interested in how the pre-assessment, pre-operative elements of ERAS affect the patient / nurses in terms of involvement and opportunities for involvement. So, do you find that ERAS patients have different levels of expectation for involvement in safety and in their care in general than non-ERAS patients?

Do you have any (recent) experiences of patient involvement? What about in patient safety, or what you would regard as patient safety? If you don't have any, just try and answer the questions based

on what you would do if presented with the opportunity to involve a patient in a safety related matter.

What do you think are the influences on whether or not a patient is involved in their care and their safety?

What would you say are the barriers that you face in involving patients?

What do you perceive as the benefits of involving patients in their healthcare and safety?

What do you perceive as the negatives, the drawbacks of involving patients?

Patient related

Do you find that some patients have an expectation to become involved in their care and safety? Are there others who are less inclined to, or may not want to at all?

Does it depend on the patient whether you involve them or attempt to involve them?

Does it depend on the family / carers whether you attempt to involve them?

What about patients with lesser or wider support networks? Would that affect your decision to involve a patient?

What about patients with lesser or wider support networks? Would that affect your decision to involve a patient?

What do you think patients need to be involved in their care and safety? For example, some prior education or knowledge? Certain communication skills? Do you find that there are communication barriers to involvement?

What are the signs to you that a patient is willing to become involved?

What are the signs to you that a patient is able to be involved?

Do you think some patients are more approachable than others in terms of involvement, is there a certain type of personality that is more likely to be involved?

Does the patients emotional state, level of anxiety affect your attempts to involve them?

Do you think that some patients are more interested or motivated in becoming involved?

Do you find that patients preferences or expectations change during the course of their stay?

Do you think there is a particular 'type' of patient who is more likely to get involved in their safety? How would you identify them?

Illness related

Do you feel that the patient illness and condition has an effect on their willingness and ability to be involved in their care and safety?

Does a patient's perceived vulnerability to harm affect the way you involve them?

Does the type of patient change the likelihood of involvement from your point of view, e.g. elective patient, medical, trauma, emergency situations?

Healthcare worker related

How do you feel about involving patients in safety and in their care in general?

Would you say you actively encourage involvement from and with patients?

What about the relationship you have with the patients, for example how long you have been nursing them? Would this affect how you involve them in their care and safety?

How would / do you feel about being challenged or questioned by patients or their relative / carer?

How do you feel about delegating or sharing tasks with patients?

Do you feel that you have the necessary training or educational support to involve patients in their safety?

Do you always feel as though you have enough time to involve patients in their healthcare safety?

How do you prioritise who to involve, when to involve them? How do you decide how to involve patients?

What benefits do you see for yourself and colleagues when involving patients in patient safety?

Do you have a fear of repercussions if you involve a patient, e.g. what if something should go wrong, or the patient misinterprets their role?

Task related

Are there types of activities or tasks that you are more likely to involve patients in?

Healthcare setting related

Are you aware of any local policies or procedures relating to patient involvement in patient safety?

Other influences, e.g. cultural, organisational

Do you think or feel that there are expectations that you should involve patients in their care and specifically in safety matters?

Do you feel that you are encouraged to involve patients in their care and safety?

What level of priority do you give patient involvement in patient safety? Do you think it is worthwhile? Do you see any benefits in it for staff and or patients?

What level of priority do you think your ward gives to patient involvement in patient safety?

What level of priority to you think your hospital gives to patient involvement in patient safety?

Do you feel that you have enough organisational support to involve patients? Support from your colleagues, managers, the nurse in charge?

Information related

What type of information do you (or could you) provide to the patient to help them become involved in their healthcare safety? Do you think it is suitable, or a good quality, fit for purpose?

Appendix: Examples of contextual influences

Patient Safety Contextual Issues

The extent to which patients can contribute to safety improvement will depend on various factors. Successful partnerships with patients to reduce errors and improve safety can only occur in environments where patient involvement is valued and supported. If patients are to play a role in ensuring the delivery of safer healthcare, safety improvement programmes should be informed by and take account of patients' preferences, values and expressed needs. Genuine forms of patient involvement will only be achieved within a safety culture that appreciates the value of patient contributions, and is supportive of these. A culture of this kind will be developed by promoting the principles of openness and honesty, and by enhancing trust and communication between doctors and patients.

Contextual Factors which can influence patient involvement in patient safety

Patient related

Patients existing knowledge and beliefs, patients prior experiences. Patients expectations. Existing knowledge of healthcare system. Level of health literacy. Coping styles. Emotional experiences. The varied personal characteristics of patients. Socio-demographic and biographical details. Patients feelings of physical or emotional vulnerability and level of anxiety.

- (C) Patient emotional state
- (C) Patient experience of illness
- (C) Patient social circumstances
- (C) Patient habits
- (C) Patient attitude to risk
- (C) Patient values
- (C) Patient preferences
- (C) Patient personality
- (C) Cognitive skills / abilities
- (C) Social skills
- (C) Basic health knowledge: Individuals capacity to obtain process and understand basic health information
- (C) Basic skills in literacy and numeracy to be able to function effectively in a health context
- (C) Ability to read, comprehend and evaluate health information
- (C) Patient motivation
- (C) Patient interest
- (C) Level of education
- (C) Employment status
- (C) Patients emotional state
- (C) Language and communication skills
- (C) Auditory or visual impairment
- (C) Patient's interpersonal skills
- (C) Patients' confidence and willingness to directly challenge or question staff
- (C) Awareness of involvement opportunities
- (C) Willingness to share information

- (C) Patient satisfaction
- (C) Professional-patient relationships (e.g. length, continuity)
- (C) Ability to learn new skills
- (C) Patient preferences
- (C) Health status of patients
- (C) Interpersonal skills
- (C) Patients fear of consequences of challenging staff
- (C) Patients perception of staff 'busyness'
- (C) Previous experiences
- (C) Patient stage in the course of a disease / treatment episode
- (C) Severity of patient's condition
- (C) Willingness to negotiate
- (C) Knowledge of research findings

Illness related

The point on the illness trajectory, stage and severity of the patients illness. The type of illness and comorbidities. How the illness manifests itself and how symptoms affect functional status. The type of treatment plan and how much opportunity for involvement this allows. The likely impact that involvement will have on the patients' health outcomes. Prior experience of illness. Patients knowledge of their own condition.

- (C) The type of information that is sought by an individual patient is likely to change during the course of their illness.
- (C) In the initial stages following diagnosis, there is a preference for practical information to support care decisions, including information on treatment options and their likely outcomes.
- (C) More in-depth and specific information needs emerge later, when the patient's focus often turns to issues of self-care and long term prognosis.

Healthcare worker related

Healthcarers' knowledge and beliefs about safety and patient involvement. How they interact with patients. Whether staff actively encourage involvement. Nature of patient and health carer relationship. Healthcare workers personal beliefs, attitudes and behaviour. Different professional groups have different attitudes. Level of training and education. Type of patient being treated. Perceived availability of time. Desired levels of control. Willingness to delegate or share tasks with patients.

- (C) Awareness of involvement opportunities
- (C) Willingness to share information
- (C) Professional-patient relationships (e.g. length, continuity)
- (C) Knowledge and skills
- (C) Motivation
- (C) Attitude
- (C) Experience
- (C) Communication skills
- (C) Interpersonal skills
- (C) Tone and style of language used
- (C) Oversimplification of language

- (C) Physical and mental health
- (C) Fatigue
- (C) Stress
- (C) Response to question or challenge
- (C) Acknowledgement of the legitimacy of patient preference
- (C) Status, position, grade
- (C) Presumptions of patient ability / willingness for involvement
- (C) Making assumptions based on observable characteristics
- (C) Perceived vulnerability to harm
- (C) Staff response to being questioned or challenged
- (C) Patients perceived as a 'nuisance'
- (C) Previous experiences (patient / health carer)
- (C) Willingness to negotiate
- (C) Knowledge of research findings

(C) Team

- (C) Verbal communication
- (C) Written communication
- (C) Supervision and willingness to seek help
- (C) Team leadership

Healthcare setting related

The extent to which patients can be involved in their healthcare will vary according to the type of healthcare setting, i.e. primary, secondary, tertiary, and the admission process – elective or emergency. Also patients perceived 'busyness of the environment'.

- (C) Organisational constraints
- (C) Organisation of health services
- (C) Local policies
- (C) Local protocols
- (C) Availability, clarity and use of protocols and guidelines
- (C) Available resources
- (C) Available personnel
- (C) Available devices

(C) Institutional

Regulatory context

(C) Organisational and Management

- (C) Financial resources and constraints
- (C) Policy standards and goals
- (C) Safety culture and priorities

(C) Work Environment

- (C) Staffing levels and mix of skills
- (C) Patterns in workload and shift

- (C) Administrative and managerial support
- (C) Time available for consultation / information exchange / interaction

Task related

What specific actions and behaviours are required. Is specialist knowledge required. Is it problem solving or decision making. What is the perceived value of potential outcomes. Is it considered major or minor decision making. Perceived immediacy and gravity of threat to safety and wellbeing. Perceived level of challenge associated with the proposed action. Fear of repercussions.

- (C) Availability and use of protocols

Other influences

Patient involvement can reflect societal norms and depends on whether the culture of the organisation supports it. If culture dictates a passive role then it is likely that many patients are likely to not "want" to be involved.

- (C) Is involvement valued and supported
- (C) Are patients preferences, values and expressed needs taken into account?
- (C) A culture that appreciates the value of patient contributions
- (C) Promoting the principles of openness and honesty
- (C) Enhancing trust and communication between patients and staff
- (C) Cultural sensitivity
- (C) Cultural differences

Information related

- (C) Access to consumer health information is limited by disparities in both access to and ability to use computer technology.
- (C) Differences between patients and healthcare professionals in their estimation of what constitutes useful material
- (C) Information supplied by health professionals
- (C) Accessibility of printed and electronic consumer health information / patient information leaflets
- (C) Readability of printed and electronic consumer health information
- (C) Quality of printed and electronic consumer health information
- (C) Reliability of printed and electronic consumer information
- (C) Usefulness of printed and electronic consumer health information (relevance and ability to help patients understand their situation and make appropriate decisions)
- (C) Degree of personalisation of written information provided to the patient
- (C) Tailoring information to patients' needs and characteristics.
- (C) Personalised materials tend to produce better health and service-related outcomes and are more highly valued by patients themselves.
- (C) Quality of consumer health information materials
- (C) Amount of information supplied by health professionals
- (C) Information sought versus information available
- (C) Adequate information on topics of relevance to patient
- (C) Availability of relevant and accessible information to clinicians and patients
- (C) Information provision

Appendix: ERAS Potential Mechanisms of Involvement (Case B)

Pre-operative assessment – risk assessments (completed and documented in generic risk assessment book): Waterlow; Pat-e-bac; Falls and bedrails; Unified assessment (for complex discharge or social care needed). Risk assessments calculated post-operatively

Patient education record (pre-assessment): Understanding of Enhanced Recovery Programme and patient's role; Fasting instructions; Bowel prep; Pain control; Keeping warm before and after theatre; Mobilisation post-op; Carbohydrate loading; Pre-and post-operative dietary advice; Nutritional supplements; Thromboprophylaxis therapy; Deep breathing, leg exercises and preventing pressure ulcers.

Written information provided: ERAS, Anaesthesia / analgesia, CPX test, pain leaflet

Discharge plans discussed and family / social support plans for discharge discussed

Colorectal nurse: Stoma information pack provided; colorectal nurse service and aftercare explained; importance of patient participation in care reinforced; stoma bag application – taught and demonstrated; sited for stoma. Stoma appears well perfused and appliance intact; Patient observing appliance change. Patient has changed and emptied stoma bag twice today with assistance (day 1)

Pre assessment / education

The ERAS pathway requires that you remind patients of the programme requirement and reiterate the patients and families' role in the enhanced recovery process. How do you do this? Patients and relatives' roles in enhanced recovery process reiterated

Patient orientated to ward – how do you do this? Do you introduce yourself and colleagues? What about other patients? Is there a form of safety briefing for the patient and his / her family?

Patient fully aware of planned surgery and the treatment plan. Does the RN discuss this with patient? Surgery treatment / plan

Do you discuss safety or potential risks of harm with patients and their families? Do you encourage patients to “speak up” about safety issues?

Diary

Patient diary explained and given; Do you involve yourself with the patient diary? Do you use it to involve the patient? What if the patient does not want to complete the diary, is too unwell or simply can't?

Meds

Do you discuss medication with patients during their stay? How involved are patients in the administration of their medication? Do they have opportunity to self-medicate? Meds reviewed for appropriate route

Do you discuss patient allergies with them?

TTO – explained to patient, Green Card completed, explained to patient. Follow-up phone call arranged; Patient given ward contact number; Hospital discharge service

Pain / Nausea

Is the pain / nausea scale used by you as a tool to involve the patient? Are there other tools / documents that you use to monitor this? Do you discuss the importance of alerting you / nursing staff to nausea, vomiting, pain? Nausea, vomiting, Pain well controlled; Pain assessment If pain controlled remove PCEA, remove catheter; Straight leg raise 2 hourly (if epidural in place) / Epidural site checked regularly; Epidural care plan; PCA care plan; Intrathecal morphine care plan – is the patient involved in this?

Mobility

Do you discuss the patients 'goals' with them? E.g. mobility and whether they have achieved them? Do you get involved with the patients post-operative mobility? Patients out of bed 6 hours after surgery, sitting in chair for 2 hours. Patient out of bed 8 hours total (d1) The importance of mobility post-operatively, deep breathing and limb exercise; Chest (o2, breathing, coughing). Do you get involved with these with the patient (i.e. completing the diary?) Deep breathing promoted, patient able to deep breath and cough

Diet / Nutrition

Do you discuss carbohydrate loading with patients? Do you explain the pre-operative fasting requirements with them? No food six hours prior to surgery, Clear fluids up to two hours pre-op; Time at which patient must be NBM

Do you get involved with the patients post-operative nutrition? Importance of post-operative nutrition and early enteral feeding

Nutritional supplements; Encourage supplement drinks. Do patients get given a choice of nutritional supplements? Do they ask for them? Do you encourage patients to drink them? Do patients record them on the food chart? Do patients like / enjoy them?

Food chart (encourage patient to record this) Do you involve the patient and their family with food charts?

Drink and eat as tolerated; IV fluids; Stop IV fluids if oral tolerated

Do you involve patients and families with weighing?

DVT

Patients are assessed for risk of DVT, do you explain the risks to them of developing HAT / DVT, how it presents, what can be done to reduce the risk of harm? Do you discuss the use and application of AES and Clexane with them? Do patients ever self-medicate Clexane or AES? Measured for AES and stockings provided; legs, feet and heels checked all blanching and no discolouration / broken areas present.

Risk assessment

Do you involve patients in the 'Generic risk assessment book'?, e.g. Waterlow, Pat-e-bac, falls risk. Do you discuss these assessments with patients / family?

Do you discuss post-operative signs of complications to look for with patients and their families?

Do you involve patients or family in recording fluid intake / balances (including catheters, IV's) Are patients involved in catheter care / monitoring? Fluid balance completed hourly, Catheter measurements. Are patients aware of the risks of a catheter in terms of infection?

MRSA screen – this is done by RN in pre-assessment. What about results etc.?

Observations are taken frequently, do you involve patients in this? Do patients or their families alert you to deteriorations in their condition? Has NEWS made a difference at all?

Random BM recorded on obs chart

Identify band – confirm details

Discharge arrangements confirmed – do you discuss and confirm discharge arrangements with patients? How involved are patients in discharge dates? What if they don't feel ready to be discharged? Predicted and / or actual date of discharge re-assessed and entered on clinical workstation. Confirm discharge arrangements

Do you ever feel under pressure to discharge patients even if you think it may not be appropriate? Does the PDD help with safe and timely discharges? Discharge arrangements are established at pre-assessment. What if there are complex discharge requirements for an ERAS patient?

Patients temp maintained above 36°C pre-op Do you discuss normothermia with patients and the importance of keeping warm?

Patient able to walk to theatre

VIP scoring, check venflons – are patients involved in the checking of cannulas / VIP scoring?

Wound observations – do you discuss wound care with patients, e.g. looking for signs of infection? Are patients given information about wound care? Do you discuss infection control with patients? Do you encourage patient hand hygiene? Do you encourage patients to ask about your hand hygiene? If a patient has an infection or suspected infection (wound or other HAI), do you discuss it with them / explain it to them, e.g. how they may have contracted it? What if a patient is in contact isolation / barrier nursed? Do you discuss this with them? Do you discuss the use of antibiotics with patients?

Drains checked – are patients involved in the monitoring of drains?

Pressure areas checked – do you explain to patients the importance of repositioning to reduce the risk of developing pressure sores? Are patients and families involved in monitoring pressure areas, are they reminded of the importance of repositioning? Do you discuss other ways of reducing pressure sore risks? Is the SKIN bundle in use? Pressure areas checked for blanching, discolouration,

broken areas. Patient encouraged to reposition 2 hourly by day, 4 hourly by night. Patient reminded to reposition

Hygiene needs met / Independent of hygiene need, including oral care

Flatus / faeces passed

Foot exercises

Urine output monitored (without catheter?)

Passing urine without difficulty

Does ERAS help to encourage patients to do things for themselves? Does it effectively promote patient involvement?

Do you discuss handover information with patients, e.g. confirm the accuracy, or plans for treatment, investigations etc.? Do you involve patients in the updating of documentation, specifically the pathway? Do patients have access to their medical records?

Do you have documentation you give to patients? Do you discuss this documentation with patients?

Appendix: Examples of mechanisms under development

Mechanism 1 : Provide patients with a rationale for their involvement in the programme and what this means for them, provide 'evidence'

Explaining the principles of enhanced recovery

Providing written information to patients and family

Mechanism 2 : Advise patients what they can do to help ensure that they are fit and safety prepared for surgery

Pre-operative activity, exercises

Co-morbidities, smoking cessation, reducing alcohol consumption, co-morbidities

Nutritional advice, 'build up'

Mechanism 3 : Patients advised what they can expect during their admission, changing perceptions of surgery and recovery

What patients can expect of staff

What is expected of patients

Patients as part of the team, centre of the team

Giving patients control

Helping patients make informed decisions

Create a sense of ownership for patients

Empowering patients, enabling them to question and challenge staff

Orientate patient to the ward

Mechanism 4 : Patients advised how they can play an active part in their recovery

Patient prepared for his / her role

Mobilisation, sitting out, breathing exercises

Post-operative nutritional advice and support

Goals – setting and discussing

Motivating patients; Incentivising patients

Patient diary; Use of food chart

Mechanism 5 : Make patient aware of post-operative risks and what they can do to help reduce these risks

Patient aware of risks

Post operative expectations – importance of early and continuing mobility

Post operative expectations – importance of breathing exercises

Patient aware of risk of chest infection – what patient can do to reduce this risk

Patient aware of risks of DVT – what patient can do to reduce this risk

Patient role in pain management, preparing patient for post-operative pain

Discharge planning, patient role in safe discharge

Mechanism 6 : Providing consistent message, information to patient and family and reinforcing this message / information during patients journey

Mechanism 7 : The role of the RN in providing advice, support and guidance to the patient and family during their journey

Mechanism 8 : The role of the patients family / support network

Preparation for ERAS

Contexts (?) Enablers / Constraints

Pre-admission	C	<i>Education element of session is compulsory</i>
Education and Information	M	<i>Nurses engagement with implementation</i>
Changing Patient / Family Expectations	O	<i>Nurses understanding of / engagement with ERAS</i>
		<i>Who carries out pre-assessment / continuity</i>
Pre admission	C	<i>Patients receptive to information (preference, ability to interpret)</i>
Sharing 'science' of ERAS	M	
Securing understanding / legitimacy	O	

Sustaining engagement and participation

Ward	C	<i>Nurses understanding of / engagement with ERAS</i>
Use of documentation		<i>Continuity of care</i>
Reinforcing / understanding expectations	M	<i>Specialist nursing role for ERAS</i>
Agree / negotiating role expectations	M	<i>Nursing staff attitude to patient involvement / sharing responsibility (culture?)</i>
		<i>MDT working</i>

Technologies of enrolment

Normalisation	M	
Enrolling family support	M	<i>Relatives present and willing / able to take part</i>

Goal Setting	M	<i>Nursing staff attitude to patient involvement / sharing responsibility (culture?)</i>
<i>Mobility</i>		<i>Patient acuity, recovery journey</i>
<i>Discharge</i>		<i>Pain management</i>
<i>Diary</i>		<i>Other patients</i>
<i>Lap board</i>		<i>MDT working</i>

Sustaining engagement and participation in ERAS	O	
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Appendix: Examples of theory development / CMO evaluation

Case introduction outline

A short introduction to each case study describing the following areas:

Patient group - Environment – People / how are they organised – Routines / activities – Information (safety)

ERAS programme implementation at ward level

Case A

Funding / resources – Project team - Developing the ICP/ patient group – (non) Collaboration – Drivers for ERAS – Initial implementation – Ward staff involvement – Ward staff perceptions

Case B

Funding / resources – Drivers for ERAS – Project team - Dedicated ERAS nurse – Developing the ICP - Prior knowledge – Core group of staff / early adopters – Ward staff involvement – Consistency – Developing a pathway – Initial implementation / pilot – The national collaborative / implementation and development team – Measuring and improving

Case C

Funding / resources – Drivers for ERAS – Staff perception of ERAS – Staff involvement — The Collaborative / the improvement agenda – Implementation – Measuring and improving – Overlap with existing processes - Who attends education and when

Findings Chapters

The findings chapters will be divided between activity in pre-assessment, which is combined for all three cases and then ward based activity, which is divided into separate cases.

Conjectured CMOs at pre-admission (Findings Chapter 1)

[C] ERAS education / information delivered to patient at pre-assessment appointment by MDT, led by RN. **[M1]** Information as a mechanism that manages patients expectation **[O1]** = Patients 'buy in' to the programme and their expected role.

[C] ERAS education / information delivered to patient at pre-assessment appointment by MDT, led by RN. **[M2]** Information as a mechanism that encourages patient involvement / self-help pre-admission **[O2]** = Patients are better prepared for surgery, reducing risk and improving recovery.

[C] ERAS education / information delivered to patient at pre-assessment appointment by MDT, led by RN. **[M3]** Information as a mechanism that helps patients increase safety during admission **[O3]** = Patients are empowered to become involved in their safety, reducing risks / improving safety.

These CCMOs are broken down into the following constituent areas:

[C] ERAS education / information delivered to patient at pre-assessment appointment by MDT, led by RN.

[M1] Information as a mechanism that manages patients expectation [O1 = Patients 'buy in' to the programme and their expected role]

During the pre-admission process patients are provided with evidence of interventions and rationale / justification for their involvement in enhanced recovery. Patients made aware what they can expect during their admission, changing perceptions of surgery and post-operative recovery.

Explaining fundamental principles of enhanced recovery

Role of family / support network

Visiting arrangements

Orientate patient to the ward

[M2] Information as a mechanism that encourages patient involvement / self-help pre-admission [O2 = Patients are better prepared for surgery, reducing risk and improving recovery]

Patients are advised what they can do to help ensure they are safely prepared for surgery.

Co-morbidities

Smoking cessation

Pre-operative activity

Nutritional advice – 'Build up'

[M3] Information as a mechanism that helps patients increase safety during admission [O3 = Patients are empowered to become involved in their safety (reducing risks / improving safety)]

Patients made aware of post-operative risks and what they can do to help reduce these risks. Patient made aware how they can play an active role in their recovery.

Early and continuing mobility

Breathing exercises

Reducing risk of DVT

Reducing risk of HAI

Post-operative nutrition; Patient Diary, Food Record Chart

Discharge goals / planning

Patient role in pain management

These are some of the main factors identified that can affect the pre-admission:

Who?

Case A – ERAS delivered by MDT / CNS, CNS is aligned to ward and patient case and established relationship which continues on admission. All planned surgery. Patients are upper GI cancer diagnosis. ERAS only.

Case B – ERAS delivered by MDT / RN, RN is aligned to ward. RN possibility of relationship with patient on admission, will shared pre-admission information with ward based colleagues. Patients are all planned surgery. Lower GI, cancer and non-cancer. ERAS only.

Case C – ERAS delivered by MDT / CNS, CNS not aligned to the ward. One off event. All planned surgery (electives). Total knee and total hip replacements – separate session for each type of surgery. ERAS and non-ERAS.

Where & How?

Case A – takes place in OPD. May take place on ward, not purpose built. Staff concerns about environment. One on one basis as part of extended pre-assessment process. Use of pathway, ritualised, tick-box. Involvement message lost in the ‘noise’ of the pathway?

Case B – takes place on ward, opportunity to meet ward based staff, see ward environment, practice laps. One on one basis as part of extended pre-assessment process. Use of pathway, ritualised, tick box. Involvement message lost in the ‘noise’ of the pathway?

Case C – takes place in seminar room based in OPD. No opportunity to visit ward. Part of large group, peer support. Pre-assessment process takes place separately. No pathway.

What else?

When do patients attend pre-admission? Challenge for Case C, also issue for patients who have a ‘cancellation’ appointment. Issues of management of cancer waiting lists. Patient priority is operation. Case C isolates education element but variety of organisational factors mean pre-assessment / patient specific clinical issues over-spill into education session.

Findings Chapter 2

Ward based activity – this will described how the ERAS programme theory / CMOs identified in the first findings chapter fare in the individual wards.

Contexts at ward level

Patients are admitted following pre-admission with potential **[M]**echanisms (these are the **[O]**utcomes of pre-admission, that is *O1 = Patients ‘buy into’ their role* and *O2 Patients empowered*

to become involved in their safety – these may need to be fired again at ward level to create the **[O]utcome = O4 – Patient involvement in patient safety.**

I am suggesting there are two layers of context at work on the (conjectured) **[M]echanisms** [M1] and [M3]. Firstly the different contexts influencing the conjectured CMOs during the pre-admission process. Then the different contexts influencing the Mechanisms at ward level. Both these will need to fire to create the **[O]utcome = Patient involvement in patient safety.** Successful outcomes transfer to the ward, but this does not always mean these ‘new’ mechanisms are ‘fired’ at ward level.

There may also be unintended or unplanned opportunities for patient involvement in patient safety, those which are not related to ERAS. Medicines management offers opportunity for patient involvement in patient safety at ward level, but is not specifically referred to during the ERAS education.

Contexts not only ‘fire’ the mechanisms, they may also prevent the mechanisms from ‘firing’.

Context at ward level

Much of the context could be described as ‘cultural’ – ‘how we do things around here’.

Individual level (Micro)

*Patient **choice** (to be involved, to not be involved, how much choice)*

Patient expectations

Patient knowledge

Patient recovery / effects of surgery / patients physical status, pain

Patient attitude to involvement

Patient priorities (e.g. treatment)

Nurse attitude to safety and involvement

Ritualised practice

Defensive practice

RN interpretation of ERAS

Accountability

Interpersonal level (Micro)

Nurse-patient relationship, communication

Trust

Nurse – nurse relationship, communication

Patient support network

Influence of other patients

Role boundaries

Sharing of information (from PA, generally); openness; clarity

MDT working (role of RN)

Institutional level (Macro)

Ward safety culture

Ward involvement culture

Controlled environment

Patient mix

Hot topics

Use of technology

Complaints

Perceived availability of time

Use of ICP / pathway based care

Relationship / links between pre-admission and ward and ERAS