

DAY CASE LAPAROSCOPIC CHOLECYSTECTOMY –
WHAT'S STOPPING US?

By

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Abstract

Introduction: Day surgery has many benefits for patients and the NHS, but progress in this area of healthcare has been slow. A high volume procedure, laparoscopic cholecystectomy, was chosen to explore this. The aim of this study was to explore and explain the factors that influence the uptake of day case laparoscopic cholecystectomy at three trusts and whether the changes occurring at the trusts impacted on day case rates.

Methods: A mixed methods collective case study was conducted across three trusts. 34 semi-structured interviews were undertaken and 5 years of hospital activity data was analysed.

Results: Day case laparoscopic cholecystectomy rates did increase over a 5 year period at all trusts but to varying degrees. Factors that influenced activity according to qualitative data analysed were grouped into two themes: context and mechanisms.

Conclusion: Participants did not believe that the changes had any direct impact on their practice. New ambulatory care facilities alone did not lead to increased day case laparoscopic cholecystectomy rates because the trust that performed the most did not have any change to their infrastructure. Clinical attitudes towards performing day case laparoscopic cholecystectomy remained variable despite the changes that took place at the trusts. Therefore

the increase in day case laparoscopic cholecystectomy rates occurred regardless of infrastructural changes or variable clinical attitudes.

Dedicated to my mother

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List of Abbreviations

ASA	American Society of Anaesthesiology
BADS	British Association of Day Surgery
CLAHRC-BBC	Collaboration for Leadership in Applied Health Research and Care – Birmingham and Black Country
DoH	Department of Health
DTC	Diagnostic Treatment Centres
ENT	Ear, Nose and Throat
GI	Gastrointestinal
HES	Hospital Episode Statistics
HPB	Hepatobiliary
HRG	Healthcare Resource Groups
ICD	International Classification of Diseases
LA	Local Authority
LC	Laparoscopic cholecystectomy
NHS	National Health Service
NIHR	National Institute of Health Research
NOTES	Natural Orifice Transluminal Endoscopic Surgery
OPCS	(stands for) Office of Population Censuses and Statistics but refers to Classification of Surgical Operations and Procedures
PCT	Primary Care Trust
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
QIPP	Quality, Innovation, Productivity and Prevention
RCT	Randomised Controlled Trial
UK	United Kingdom
WHO	World Health Organisation

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1. Introduction

Outline of the problem

Organisations within the National Health Service (NHS) redesign services in order to provide better quality, efficient and streamlined healthcare. The redesign of health services is driven, in part, by the need to reduce variation in clinical practice (Mays 2011) and to deliver high quality care that is efficient in terms of throughput and finance (Darzi 2008). Redesign processes can take several forms, for example, the creation of integrated care pathways or new buildings. These major changes are complex and challenging and success is not guaranteed. Therefore, it is important for organisations to learn from each other about which strategies work as well as how and why. This can be achieved by evaluating the process of health service redesign and this research was undertaken to contribute to this developing body of work. As part of a study investigating health service redesign in three NHS acute trusts, the changes on day case surgery rates were examined.

The redesign of health care services involved the expansion of day surgery because expert opinion suggests that it benefits both patients and the organisation (NHS Modernisation Agency 2004). Day surgery provides patients with a streamlined and efficient service for elective procedures and is cost effective for the trusts because of the reduced length of stay. Acknowledging these benefits the Department of Health (DoH), sought to

expand day surgery services and predicted that 75% of all elective surgery could be carried out as day cases by 2005 (Department of Health 2000). The reforms that focus on this area are described in more detail in the following chapter to provide further background to the study. However, the recognition that day surgery rates vary widely (Faiz et al. 2008; Solly et al. 2007) was the starting point for this research. The historical trends in day case activity are described in the Background chapter and the literature exploring why there is a variation in day case rates is presented in the literature review. This variation existed despite support from professional organisations for day surgery (Jackson et al. 2011).

A high performing ambulatory care unit can be instrumental in enabling a trust to meet its key performance targets. Day surgery reduces length of stay, provides streamlined care and increases staff productivity, all of which are in line with Quality, Innovation, Productivity and Prevention (QIPP) requirements (Health Policy and Economic Research Unit 2010). QIPP describes the approach the NHS is using to assess its reforms in the current economic climate with the intention of providing better quality services in the most productive and cost effective way and making use of innovation and investment in prevention. The Audit Commission also reported that trusts could save £200 million a year by increasing day surgery rates (Health Briefing 2010). This suggested that the slow progress in increasing the provision of day surgery and the variation in day case rates (Aylin et al. 2005)

was an important area of service provision to examine in greater depth. It was for these reasons that the decision to explore this further was taken, along with a desire to explore the impact of redesign processes being implemented in this area of healthcare provision.

The benefits of day surgery, which include a better patient experience, improved clinical outcomes and cost savings, seem to make a compelling case for developing the service to provide opportunities for more patients to undergo day surgery. The target that was set by the DoH to deliver 75% of all elective operating as day case procedures, mentioned earlier, had not been met despite government and professional support. This made it an interesting problem to explore further. Why had the day surgery target not been met? What were the barriers to expanding the service?

The focus for this piece of evaluation research was day case laparoscopic cholecystectomy (removal of the gallbladder) and to explore how changes in three National Health Service (NHS) acute hospital trusts, which included new ambulatory care facilities, affected clinical practice. By exploring this issue, the researcher hoped to be able to explain some of the variation in day case rates. The reasons for selecting this procedure as the focus for the study are provided in the Background chapter. There were national innovations (Solly et al. 2007) that were directly aimed at increasing day case laparoscopic cholecystectomy rates because the national average was so low. This made it

an important aspect of day surgery to examine and of addressing some of the questions about day surgery stated above, which could potentially affect my clinical practice as a surgeon.

Aim and objectives

The aim of this study was to explore and explain the factors that influence the uptake of day case laparoscopic cholecystectomy, a high volume procedure, at three NHS trusts and the impact of any changes made at the hospitals to day case rates.

In order to achieve this aim, a number of specific objectives were identified:

- To undertake a literature review to assess the level of evidence for day case laparoscopic cholecystectomy and to provide an explanation for variability in day case surgery rates
- To describe the historical and current day surgery activity at each trust for laparoscopic cholecystectomy using Hospital Episode Statistics data (HES)
- To describe any changes at each trust that were planned during the study period, which may impact on day case laparoscopic cholecystectomy rates, from information gathered by theme 1 CLAHRC-BBC and during the project
- To interview clinicians performing the chosen procedure in their clinical practice in order to discover how it affected practice

2. Background

This chapter provides an account of the reforms in day surgery and the historical trends in day case rates to illustrate the problem described in the Introduction chapter. The chapter also explains the reasons behind choosing day case laparoscopic cholecystectomy as the focus for this study. Before this, it outlines the need for evaluation research in health services research and the context within which the study was conducted.

Evaluation research is a “form of applied research which aims to produce information about the implementation, operation and effectiveness of policies and programmes designed to bring about change” (Clarke & Dawson 2005, page 35). For example, is the triage system in the accident and emergency department effective in enabling staff to classify patients according to clinical need? The strength of this type of evaluation lies in its potential to examine the impact of processes, answer questions about whether goals are achieved or practice is changed or how long it has taken to achieve and whether a change has resulted in improvement or not. This makes it more than audit or monitoring and important to NHS organisations that are all striving to maximise effectiveness and efficiency through service redesign processes.

There is a recognised gap between research and practice with new interventions or technology taking a decade to be translated into clinical practice and evaluation research can help address this issue. The Cooksey

report (Cooksey 2006) led to the development of collaborations between academic institutions and NHS trusts. These are described in further detail later in this chapter and explain how health service redesign was included in this collaborative process. It was under the purview of a large project undertaken as part of one of these collaborations that the study reported here was conducted.

Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

In 2006 the government commissioned an independent review to assess how research funding in health care should be directed (Cooksey 2006). In this review, a gap in translating basic and clinical science into new interventions and a gap in implementing these into practice were identified. It was recommended that funding for translational research should be increased, particularly to address the implementation gap. Following this, the National Institute of Health Research (NIHR) funded collaboratives between academic organisations and the NHS, such as the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) to encourage the knowledge transfer between the two. Nine CLAHRCs were established in various regions (Appendix 1).

These collaborations aimed to enhance the efficiency and effectiveness of clinical care by addressing the gap that was identified by researchers in the

evaluation and adoption stages of the innovation pathway and were a national model for collaborative research. They were funded by the NIHR to undertake research that was generalisable, focused on the needs of patients and supported the translation of research evidence into practice. One of the nine pilot CLAHRCs was the Birmingham and Black Country (BBC). CLAHRC-BBC had nine themes, one of which focused on health service redesign (also referred to as theme 1). The members of this research team were multidisciplinary with experience in applied health services research. The team members consisted of experienced qualitative and quantitative researchers with backgrounds in academia from areas such as sociology and economics as well as clinicians working within the trusts.

Theme 1 aimed to evaluate health service redesign in three acute trusts in the region over a five year period. The theme 1 research team completed a 'baseline' study that identified drivers and processes for change, central to service redesign (Shapiro et al. 2010). This was followed by a longitudinal phase that evaluated redesign in particular service areas. The overall study was informed by the principles of realist evaluation (Pawson & Tilley 1997) and involved the use of mixed methods to collect qualitative and quantitative data. These data were triangulated to build a comprehensive account of service redesign in three NHS acute trusts (CLAHRC theme 1 2013).

The redesign of services at two trusts involved the development of ambulatory care facilities, which was important for trusts to achieve nationally set targets as well as improve efficiency. The third trust was reconfiguring services across two acute hospital sites and working with primary care to develop integrated care pathways with the prospect of a brand new acute care facility being built in a few years. The analysis of data from the baseline phase revealed that reducing length of stay and financial stability were drivers for change at all the trusts. These changes and drivers for change indicated that day surgery was an important service that needed to develop in order to help maximize the organisations' effectiveness and efficiency.

This piece of research was developed and conducted to complement the evaluation of health service redesign that theme 1 CLAHRC-BBC were carrying out.

Day surgery

The definition used for the purposes of this study is that of the Department of Health (Darzi 2002, page 2): procedures requiring "full operating theatres facilities and / or general anaesthetic and day cases not included as outpatient or endoscopy". This is different to 23 hour stay, which could mean that patients stay overnight after a procedure but still go home within a 24 hour period.

The putative benefits of day surgery based on Hospital Episode Statistics (HES) and expert judgements, fall into four categories (summarized in table 1): patient experience, clinical outcomes, service delivery and benefits for staff. The specific advantages are described (NHS Modernisation Agency 2004) and given the current financial strictures in the NHS as well as the current focus on improving the patient experience these benefits remain applicable to the present day.

Table 1: Benefits of day surgery

Benefit	Specific advantage described
Patient experience	Provides patient choice Minimal disruption to life Reduced waiting times Focused patient pathway Better provision of information Lower risk of cancellation
Clinical outcomes	Quicker recovery Lower rates of infection
Service delivery	Shorter length of stay for patients reducing the pressure on in patient beds Better theatre utilization Reduced costs to the trust
Benefits for staff	Flexible working Enhanced nursing roles (pre-admission and discharge processes) Job satisfaction Clear work patterns (start and finish times for staff)

Trends in day surgery – a timeline

Audits of day surgery activity demonstrate that, although day case rates have improved over time, progress has been slow and that day case rates vary

widely. The findings of these audits are summarised to provide a setting for the study.

Over 12 years from 1974-1986, day cases increased from 9% of the acute workload to 17% (NHS 1987), despite the Royal College of Surgeons suggesting a third of general surgical admission in district hospitals might be suitable for a day surgery. In 2001, evidence from an Audit Commission report indicated that day case rates had increased nationally, especially in ophthalmology, but in general surgery the variability in day case rates ranged from 0% to 80% for inguinal hernia repairs at different hospitals (Audit Commission 2001). These figures demonstrated that it was possible to achieve high rates of day surgery in some hospitals, however the report failed to identify successful strategies hospitals were implementing to achieve the highest day case rates. A report by the Healthcare Commission, in 2005, identified that some progress had been made with many trusts taking on board operational recommendations from the previous audit commission report (Healthcare Commission 2005). However it conclude that expansion in this area remained slow, because the target, 75% of elective surgery being performed as day cases, set out in the NHS Plan had not been achieved. The authors thought it was possible to increase day surgery rates within hospitals' existing capacity. In order to do this the report recommended that trusts should:

- Maintain the momentum in improving patient care by continual monitoring of standards
- Work closely with clinicians to explore why day case rates were below average
- Use feedback to ensure adequate utilisation of resources.

Since then, there have been no further national reports detailing day surgery activity. Although the day case laparoscopic cholecystectomy rates have been reported by the National Institute for Innovation and Improvement (Solly et al. 2007). More recently there has been a focus on providing a 'seven day service' (NHS England 2014), which would address issues surrounding utilisation of resources and maximising efficiency.

In 2000, while the Conservatives were in government, the NHS Plan (Department of Health 2000) was published and outlined the reforms that were intended to deliver patient centred care. The reforms were aimed at redesigning the NHS to enable it to deliver care, that remained tax funded and free at the point of need, which is the basic principle claimed to underpin the NHS (NHS England 2013). This has been made more challenging given the increasing demands of an ageing population with higher incidence of chronic disease. Other principles that the NHS Plan was based on include the provision of "clinically appropriate, cost effective service", ongoing

improvement in efficiency, productivity and performance and the adoption of innovation.

Reforms, which included the expansion of day surgery, were announced (Department of Health 2000). This was supported by the Operational Guide (Darzi 2002) and the development of Diagnostic and Treatment Centres (DTCs) (Department of Health 2002a). DTCs provided an environment free from emergency pressures and were intended to drive productivity by stimulating new models of service delivery. The health minister, at the time, John Hutton said,

“This programme of investment will enable doctors to perform more operations every year. It will also bring reforms to the way health care is delivered. Patients will be treated in modern high quality facilities with the latest equipment and the best trained staff. Waiting times will be reduced” (Department of Health 2002b).

The NHS Plan reported that 75% of elective surgery would be carried out through day surgery by 2005. It was not clear in this document how this figure of 75% was arrived at, so it can only be assumed that this was based on expert opinion as there was no published evidence to support this.

In addition, day surgery was one of ten ‘High Impact Changes’ that was identified by the Modernisation Agency that would allow organisations to make significant improvements in the delivery of health care (NHS

Modernisation Agency 2004). It recommended that day surgery was the “*norm for elective surgery*”. The British Association of Day Surgery (BADS) basket of procedures was also introduced (Jackson & McWhinnie 2007).

Another paper examining national trends in colorectal day case surgery (Faiz et al. 2008) reported the slow expansion of day surgery. It provided a descriptive analysis of colorectal day case surgery over a seven year period. The day case rates for the procedures examined were significantly below the 75% Department of Health target. The authors offered three principal reasons for their findings.

1. Infrastructure, i.e. the lack of DTCs
2. Safety concerns for “intermediate risk” patients
3. Psychological barrier, i.e. the scepticism of both doctors and patients

This suggested that the government’s plans to increase day surgery capacity, with the creation of diagnostic treatment centres in 2002, had not increased day surgery rates.

Professional view of day surgery

The focus of reforms and policies to expand day surgery described above came from central government, however the need to increase day surgery rates has also been advocated by the Royal College of Surgeons of England for almost 35 years through the British Association of Day Surgery (BADS) (Verma et al. 2011).

BADS was set up by a group of enthusiastic surgeons and anaesthetists in 1988, who wanted to encourage the practice of day surgery. The message from BADS is clear: for a carefully selected group of patients there is a number of procedures that are clinically appropriate and effective if performed as day cases (Jackson & McWhinnie 2007). BADS was instrumental in creating evidence based guidelines and giving advice on the management of day surgery units (Healthcare Commission 2005; Royal College of Surgeons of England 1992; Audit Commission 1990). The guidelines addressed issues such as the design and function of day surgery units, implementation of integrated care pathways, appropriate pre-operative assessment and efficiency assessment tools.

Efforts to increase day case activity continued with an increasing number of procedures being listed as suitable to be performed as day cases, such as mastectomy (removal of breast tissue), thyroidectomy (removal of thyroid tissue) and laparoscopic cholecystectomy. The index procedures were listed in the Directory of Procedures along with target rates (Jackson & McWhinnie 2007). The target rates in the directory vary for each procedure. The table below gives examples of these from the directory.

Table 2: Examples of procedures in the BADS directory with expected length of stay

Procedure	% day case	% 23 hour stay	% <72 hour
Simple mastectomy (including cases with axillary node sampling)	15	75	10
Primary repair of inguinal hernia	95	5	0
Umbilical hernia	85	15	0
Laparoscopic cholecystectomy	60	30	10
Closure of Colostomy	5	15	40

Innovations in day case laparoscopic cholecystectomy

The procedure, laparoscopic cholecystectomy, was the focus for this piece of research, which had also been the subject of the NHS Institute of Innovation and Improvement initiative. Laparoscopic cholecystectomy was one of eight Healthcare Resource Groups (HRG), which required action to improve the quality and value of care. HRGs are a way in which organisations can understand their activity by grouping clinically similar treatments in order to compare performance between trusts. Information on healthcare resource groups can be found on the Health and Social Care Information Centre. This involved the development of an optimal pathway for cholecystectomy following qualitative research carried out to explore the processes at five NHS trusts (Solly et al. 2007). This reported a national average for day case

laparoscopic cholecystectomy of 6.4%. The highest performing organization managed a day case rate of more than 50% and it was believed by clinical experts that a rate of 70% was readily achievable. The document clearly outlined the financial benefits that could be achieved by high day case laparoscopic cholecystectomy rates.

Following this review of the pathway, the Institute selected a further nine trusts to participate in a project to increase day case rates by facilitating the change through process mapping and local project groups. There has been no published literature following this process, however the outcomes have been presented, at a conference (NHS Institute for Innovation and Improvement 2010). These demonstrated variable outcomes. Some sites had been very successful achieving day case laparoscopic cholecystectomy rates of 80%, but others showed much smaller improvements. It was evident that there was not a general prescription that each trust could adopt or follow and that the trusts with low day case rates were facing problems with the opinions of their staff. It was clear that some organisations found it difficult to engage staff and adopt a new pathway. It should be noted that one of the trusts participating in this study was one of the nine trusts involved in this project prior to this piece of research commencing.

Most recently, the need for efficiency savings in the current economic climate and the focus on improving quality alongside delivering productivity, were

the reasons for introducing a new concept – best practice tariffs (Health Briefing 2010). Their introduction by the Department of Health was presented as a way of facilitating quality and productivity improvements (Department of Health 2010). Best practice tariffs were developed by clinical experts, providers and commissioners. They were for service areas that demonstrated unexplained variation in current practice and where there was clear evidence for clinical best practice.

Four best practice tariffs were introduced in the financial year 2010-2011; cholecystectomy, cataract treatment, acute stroke and hip fractures. They rewarded trusts that performed high rates of day case laparoscopic cholecystectomy. Trusts received £1369 for elective laparoscopic cholecystectomy if it involved a patient staying for one or more nights and £1694 for those completed as day cases (Department of Health 2010). However in order for a trust to receive the higher payment for each day case laparoscopic cholecystectomy performed day case rates of 60% or more had to be achieved. This figure matched the suggested figure in the BADS Directory of Procedures for day case laparoscopic cholecystectomy (Jackson & McWhinnie 2007).

Laparoscopic cholecystectomy and why it was chosen

A cholecystectomy refers to the therapeutic removal of the gall bladder. This operation is the recommended treatment for symptomatic gallstone disease

because non operative management has been shown to be unsuccessful (Beckingham 2001). Removing the gallbladder in a patient who develops symptoms prevents the development of complications such as cholecystitis, cholangitis and pancreatitis, which often result in recurrent admissions to hospital.

The management of patients with symptomatic gallstones is important not only to trusts but the NHS as a whole because annual Hospital Episode Statistics (HES) data demonstrates the workload it creates for the NHS (Health and Social Care Information Centre 2010). This data reported that just under 250,000 admissions a year are related to the gallbladder and 60 000 cholecystectomies are performed each year. This made it one of the most common operations that trusts provided. Therefore efficient delivery of care for this group of patients was important for trusts trying to achieve waiting time targets, meet patients' needs, shorten length of stay and reduce costs.

The traditional technique of open cholecystectomy has been superseded by laparoscopic surgery in the majority of cases and is the preferred approach for surgeons because there is no significant difference in the morbidity or mortality of the 'key hole' approach when compared to the open and patients have a reduced length of stay and shorter recovery period (Keus & Jong 2006). In Europe, Natural Orifice Transluminal Endoscopic Surgery (NOTES) for cholecystectomy is under development (Chamberlain & Sakpal 2009) and

may lead to further miniaturization of the equipment required and has the potential to further reduce the length of stay.

The first laparoscopic cholecystectomy was performed, in 1985, by Eric Muhe (Reynolds 2001). The transition of surgical techniques from open to laparoscopic was rapid when compared to previous technological innovations, despite the lack of firm evidence for its safety at the outset. Laparoscopic cholecystectomy is identified as a high volume procedure, which was why it was included in the initiative by the NHS Institute of Innovation and Improvement (Solly et al. 2007). HRGs are collections of clinically similar activities that require a similar quantity of resources (Health and Social Care Information Centre 2014). Reports of surgeons performing day case laparoscopic cholecystectomy were published as early as 1991 (Arregui et al. 1991).

The operation was listed in the BADS directory of procedures as an acceptable day case operation and a Cochrane review had been published demonstrating that day case laparoscopic cholecystectomy was safe (Gurusamy & Junnarkar 2008). This evidence was scrutinized as part of the literature review for this study and is reported in a later chapter. To support day case laparoscopic cholecystectomy practice BADS has produced guidelines to help trusts move in this direction (McWhinnie et al. 2004).

This has led to day case laparoscopic cholecystectomy being the focus of efforts to improve day case rates from the government by the introduction of a best practice tariff and the Institute of Innovation and Improvement (Solly et al. 2007) by facilitating process mapping of the pathway. This is included for reference in the appendix (Appendix 2). The success of these initiatives remains to be documented.

As reported earlier in this chapter, there is wide variation in the practice of day case laparoscopic cholecystectomy with little explanation of why it exists. This made it an interesting area to explore further. Laparoscopic cholecystectomy was also performed at all three trusts collaborating with CLAHRC-BBC and as the baseline report showed (Shapiro et al. 2010), these trusts were working to reduce length of stay, increase day surgery rates and be more efficient. This made the research reported here important to the trusts as well.

The choice of exploring variable day surgery rates, in particular laparoscopic cholecystectomy, was also influenced by my concerns. As a surgical trainee, I am interested in surgical techniques and advances. Laparoscopic cholecystectomy was a procedure that I will need to be competent in by the end of my postgraduate training and day surgery is a service that I am likely to be involved in throughout the rest of my career. Also, previous undergraduate work and postgraduate professional development has

stimulated my interest in the organisation of health services. During my 5 years of clinical experience since graduating I have observed variable practice, some of which results from the different organisational structures and leadership at different hospitals. The information gathered in the initial stages of this project supported my observations of variable day case rates. Therefore, this project was something that was relevant to my professional development and my current and future clinical practice. The variation in the organisation and management of day case laparoscopic cholecystectomy prompted questions about what influences clinical practice and which approaches facilitated day surgery.

3. Literature Review

The Introduction chapter described the problem: professional bodies (BADs) and the government expected that at least 60% of elective laparoscopic cholecystectomies that were performed at each NHS trust could be day cases, however audit had shown that day case laparoscopic cholecystectomy rates were variable and on average much lower. The aim of this study was to explore the factors influencing day case laparoscopic cholecystectomy rates at three trusts within the same region.

In order to address the research problem, it was necessary to examine the literature that already exists on the topic and identify areas that are lacking or that require further investigation. This chapter provides a description of how the literature review was carried out before discussing the literature in more detail.

The specific questions that this literature review addresses are:

1. What is the level of evidence to support the safety of day case laparoscopic cholecystectomy?
2. What evidence is there to explain why day case laparoscopic cholecystectomy rates so variable?

Literature search

As described above, two clear questions needed to be addressed in the literature review. Therefore a systematic literature search was performed using the Medline databases, a recognised and widely used biomedical literature databases (demonstrated in figure 1) in 2009. By using this approach the aim was to collate, summarise and critique published papers on the safety of day case laparoscopic cholecystectomy, the variation in day case rates and factors affecting clinical practice. The process and findings of the literature search was also designed to identify any gaps in research. There was no intention to combine study results or perform meta-analyses as the foci of the literature search was expected to retrieve research papers that ranged from discussion pieces to randomised controlled trials. The inclusion of discussion pieces was important to identify potential facilitators and barriers for which there was little or no evidence.

The search terms entered were “laparoscopic cholecystectomy”, “ambulatory”, “day case”, “trends”. These search terms were combined to retrieve the literature that was most relevant to the questions posed. A filter was placed to retrieve English articles where the full text was available. Three separate searches were performed:

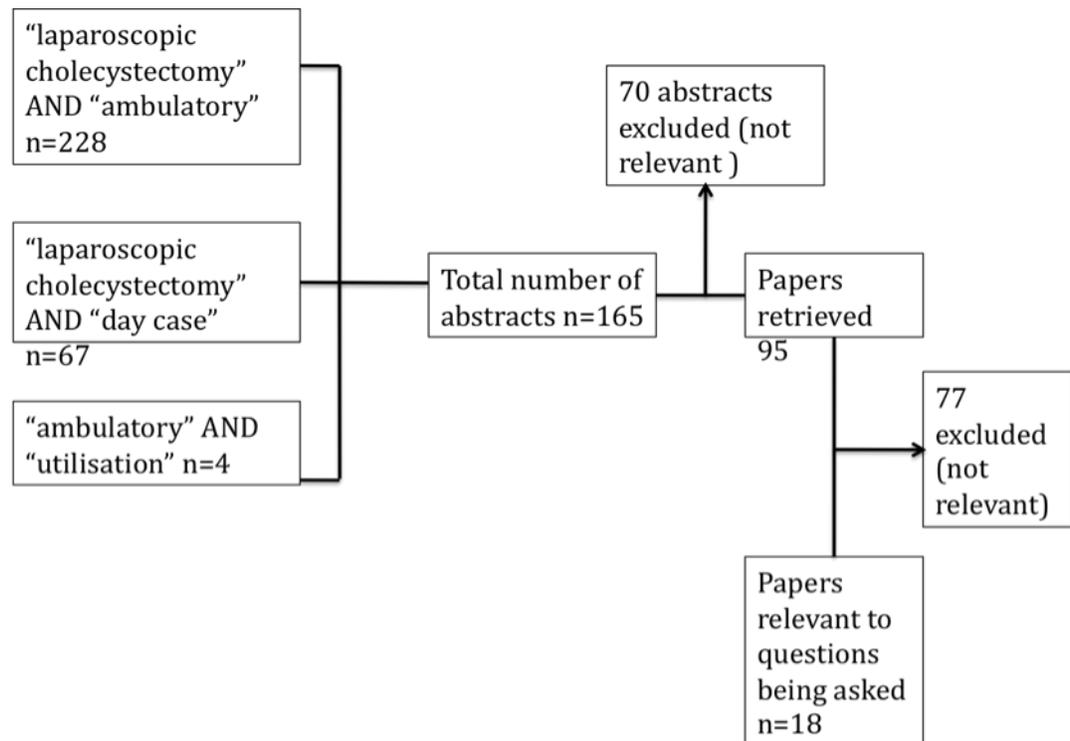
1. “Laparoscopic cholecystectomy” AND “day case”
2. “Laparoscopic cholecystectomy” AND “ambulatory”

3. “Ambulatory” AND “utilisation”

The individual searches were combined using ‘OR’ to identify papers that would be able to answer the questions stated at the beginning of the chapter.

95 papers were retrieved by the systematic literature search. The abstracts for the remaining papers were read and those that included data relevant to the specific questions stated at the start of this chapter were critiqued in full. 18 papers were critiqued and are discussed in this chapter. No date limit was set for the literature search.

Figure 1: Flowchart showing systematic literature search



What is the level of evidence to support the safety of day case laparoscopic cholecystectomy?

The literature search demonstrated that research studies have addressed this question by reporting outcomes for a cohort of patients having day case laparoscopic cholecystectomy or by comparing two groups of patients – those having day case procedures versus those staying overnight. They have been carried out in various international settings.

Among these research studies, there was a Cochrane Review article (Gurusamy & Junnarkar 2008), which was a meta-analysis of randomized clinical trials comparing day case laparoscopic cholecystectomy with overnight stay analyzing data from five randomized controlled trials. It concluded that day case laparoscopic cholecystectomy was safe and effective in a selected group of patients and because of the reduced length of stay in hospital it may reduce costs. This was level 1a evidence according to the Oxford Centre for Evidence Based Medicine (Appendix 3: Hierarchy of evidence), because it was a systematic review of randomized controlled trials. It was also published by an organization, the Cochrane Collaboration, which reputes itself on providing reviews on the best available evidence to make clinical decisions.

Guruswamy produced a meta-analysis according to PRISMA guidelines (Moher et al. 2009) to address the safety concerns from clinicians about day

case laparoscopic cholecystectomy. The PRISMA checklist has 27 points to help authors report systematic reviews and meta-analysis and ensures that the process is clear.

This meta-analysis provided clear information about the process of selecting the randomised controlled trials that were included in the review. Guruswamy et al not only used published data from the randomised controlled trials, but also approached the authors of the included RCTs to examine primary data collected for inclusion in the meta-analysis. They also addressed the risk of bias in individual studies as well as across studies and their methods for assessing this were clear.

The systematic review identified haemorrhage, bile duct injury, postoperative pain relief and postoperative nausea and vomiting to be the key concerns of clinicians regarding the safety of laparoscopic cholecystectomy. The former two are recognised serious complications of the procedure and logic concluded that poor pain relief and ongoing emesis would impact patients being able to go home the same day. The systematic review reported these outcomes and included mortality as a primary outcome measure with patient anxiety, quality of life and return to work measures as secondary outcomes. This was a very comprehensive list of outcomes, which were relevant to clinical practice.

The meta-analysis showed no significant statistical difference in overall morbidity, unplanned prolonged hospital stay, readmission rates, further review by a doctor during the hospital admission, post operative pain levels or post operative nausea and vomiting, between the day case and overnight stay patients. Nor did it demonstrate a statistically significant difference between the two groups of patients when comparing quality of life measures, patient satisfaction and timing of return to work. Although there were differences found in patient anxiety levels on day 1 post operatively, by day 7, no significant difference was found in patient anxiety levels.

There were some limitations in this meta-analysis that need to be recognised. The numbers randomised in the trials that were included and therefore the participants included in the meta-analysis were relatively small so it may fail to identify uncommon complications. This means that the study was not powered to provide accurate results on the incidence of bile duct or vascular injuries. However the consistency of the results between the trials does negate this. It was also not possible to perform analyses on all the outcome measures for all 429 participants because the five RCTs included did not all measure the same outcomes. For example, in reporting patient satisfaction, only one RCT collected this data and so the review analysed data on 86 out of 429 patients.

The five RCTs included in the meta-analysis all had slightly different inclusion criteria for their participants and this probably explained the heterogeneity reported in the study. Although this meant they were unable to perform the intended subgroup analyses, the results were relevant to the low risk anaesthetic patient with a support network and living in relative proximity to the hospital. It was important to note that only 50% patients were eligible for day case out of the total number of LC that were performed during the recruitment period of the study, which means the day case rate was 35.8%. This questioned whether it was possible to achieve 60% or 75% day case rates of total cholecystectomy procedures.

Despite the limitations of the paper, the evidence provided in this meta-analysis supported clinicians who practice day case laparoscopic cholecystectomy on a highly selected group of patients. There were no cases of mortality in either group with low rates of surgical morbidity. These findings were also largely supported by cohort studies, which provided level 2 evidence, that mortality and morbidity in these patients was low (Lillemoie et al. 1999; Vuilleumier & Halkic 2004; Jain et al. 2005; Victorzon et al. 2007). These evidence from these studies reported 0% mortality and less than 10% morbidity.

The table below demonstrates that five of the cohort studies retrieved by the systematic search have morbidity rates greater than 10% (Blatt & Chen 2003;

Skattum et al. 2004; Sherigar & Irwin 2006; Akoh et al. 2011; Brescia et al. 2013). Although the reported morbidity appeared high, these included patients who reported post-operative pain or emesis, which did not lead to unplanned admissions or readmissions. It also included patients who required a conversion from keyhole surgery to open surgery, which was not regarded as a complication, and patients who had drains left in due to a difficult procedure, which was also not a complication of the procedure. This explained the higher reported morbidity in these papers.

The table below illustrates the variation in unplanned admission rates from the cohort studies. This was explored further to see if there were any explanations for this because high unplanned admission rates may deter clinicians from practising day case laparoscopic cholecystectomy. Victorzon et al, 2007 recorded the highest rate of unplanned admission. The reasons reported for unplanned admission included social circumstance, surgeons' preference, patient preference and late start time when operating. These did not necessarily reflect a clinical reason for admission. Interestingly the largest number of unplanned admissions was a result of patient preference (n=88). If the unplanned admission were based on clinical reason alone (n=32), it would be 5.6%. This was far more acceptable and reassuring to clinicians that day case laparoscopic cholecystectomy was clinically safe.

Table 3: Outcomes reported in the cohort studies reviewed

Paper	No. of participants included in study	Unplanned admission rate	Readmission rate	Mortality	Morbidity
(Lillemoe et al. 1999)	130	6.2%	4.6%	0%	6.2%
(Blatt & Chen 2003)	101	19.5%	2.4%	0%	26.8%
(Skattum et al. 2004)	1060	9.9%	6.6%	0%	12.5%
(Vuilleumier & Halkic 2004)	136	2%	0%	0%	7%
(Jain et al. 2005)	269	16%	2%	0%	<3%
(Sherigar & Irwin 2006)	198	15%	3.5%	0%	12.1%
(Victorzon et al. 2007)	567	37%	2%	0%	6%
(Akoh et al. 2011)	258	31%	5%	0%	22%
(Brescia et al. 2013)	400	3.2%	0%	0%	12.8%

Similarly the main reason for unplanned admission in Akoh et al, 2011 was the placement of a drain and a late operation start time (n=46). Also included in the unplanned admissions was a cancelled operation. The use of drains, as explained in the paper, is clinician dependent. There are techniques that can help to avoid the use of drains.

As demonstrated in the meta-analysis (Gurusamy & Junnarkar 2008), the randomized controlled trials did not recruit all patients having elective laparoscopic cholecystectomy. Only 50% of the total number of patients that required laparoscopic cholecystectomy was included in the studies. Similarly, in these cohort studies only a proportion of patients that needed a laparoscopic cholecystectomy were recruited. This ranged from 26% (Jain et al. 2005) to 78% (Sherigar & Irwin 2006) of the patients having laparoscopic cholecystectomy. If less than half of the patients undergoing the procedure were booked as day cases, the feasibility of achieving 60% (to acquire the best practice tariff) or 75% (to meet government targets) was brought into question.

In conclusion this systematic search of the literature has shown that there was level 1 and level 2 evidence that day case laparoscopic cholecystectomy was as safe as an overnight stay and was acceptable to patients. The meta-analysis of randomised controlled trials showed no significant difference in morbidity between patients staying overnight or being discharged on the

same day and no mortality. The cohort studies also reported low mortality and morbidity rates. There was, however, a variation in unplanned admission and readmission rates, which may influence a clinician's practice.

What evidence is there to explain why are day case laparoscopic cholecystectomy rates so variable?

In the main the papers that were retrieved by the literature search report day case rates at individual centres, one reported day case laparoscopic cholecystectomy rates as part of an analysis of day surgery trends. Aylin (2005) examined day case laparoscopic cholecystectomy in his paper on trends in day surgery rates and revealed that 0.83% of laparoscopic cholecystectomies in 1996-7 were performed as day cases. In 2003-4 this percentage rose to 4.4%, which still fell short of the 75% recommended by the DoH and 60% recommended by BADS. In 2006, national audit findings on day case laparoscopic cholecystectomy rates reported the national average as 6.4% and the range 0-50% (Solly et al. 2007).

The literature search was adapted to provide papers that provided explanations for the variable rates of day case surgery in general. An assumption was made that research that had been conducted to explain the variability in day case surgery would also be applicable to specific day case procedures such as laparoscopic cholecystectomy. The literature search was

performed to retrieve papers based on the following key words; 'day case' OR 'ambulatory' AND 'trends'.

Six of the papers found examined the variability in day case rates, in the NHS setting specifically, and are discussed in some detail below. Papers that examine surgical day case rates outside the UK were subject to the impact of how their health service was funded, the organisation of health service provision and cultural differences. The papers were all relatively old, but raised important issues that were relevant to this piece of research and its findings. Two further papers are discussed as they examine surgical day case rates specifically.

A retrospective study in Oxford (Henderson et al. 1989) analysed data over a period of nine years for 12 surgical procedures within the region. The procedures were all ones that met the definition for 'day surgery'. It specifically examined readmission rates for day surgery and inpatient admissions as well as reporting day case rates. The authors reported a gradual increase in day case rates for some operations but for others there was a consistently low rate (inguinal hernia repairs) or a decline in rates (haemorrhoids and varicose veins). It highlighted the difference in rates between the five Oxford districts included in the study; for example, the range of day case myringotomy was 0.5% to 50.1%. The authors recognised that inaccurate hospital activity data may contribute to some of this reported

variation in day case rates for procedures, but it was possible that this was not the only explanation. Explanations offered by other papers (Morgan & Beech 1990; Aylin et al. 2005) were the “continued reluctance” in some districts secondary to clinical beliefs, the lack of infrastructure, in the form of facilities and administrative support, and the lack of leadership in day surgery. These were all feasible explanations.

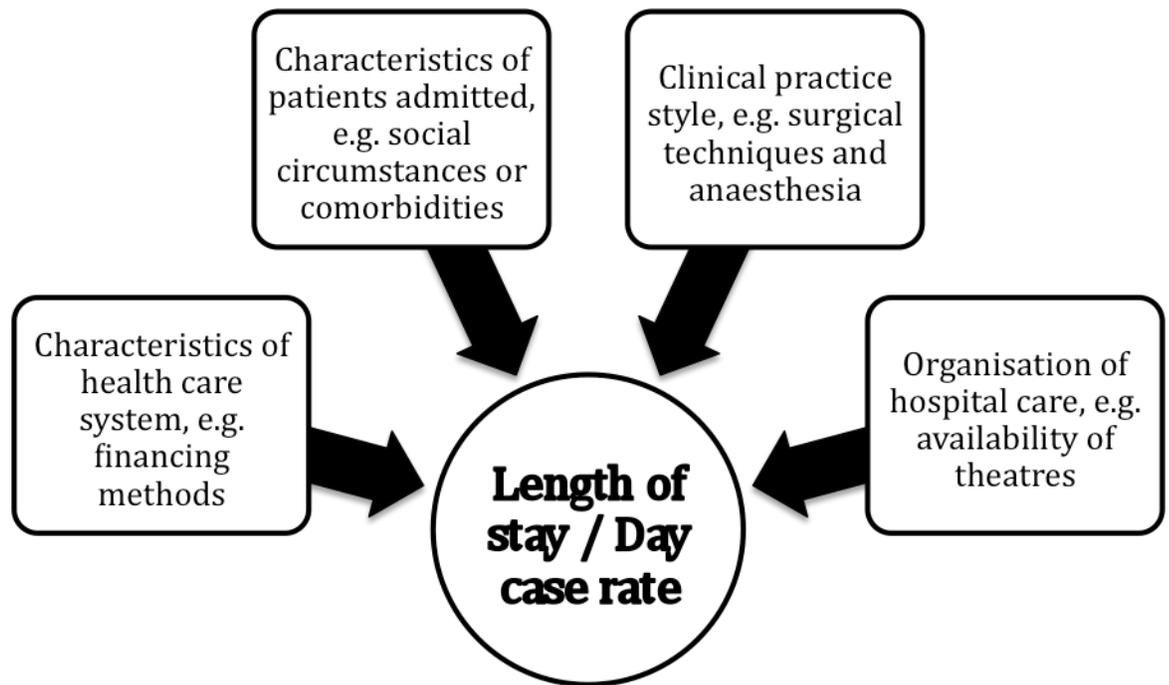
Similar explanations, for the variation in day case rates, were given by Morgan and Beech (1990). This paper, which was a discussion piece, reported that the variation in day case rates existed at many different levels; between nations, between hospital, between specialties and between individual surgeons. The different models of financing health services using the UK and the USA as examples explained the difference in the uptake of day surgery between countries. They argued the need for hospitals in the NHS to work within a fixed budget provided no financial incentive for day surgery due to potentially greater costs and overspend. In the US the predominant method of financing was based on a fee for service and this encouraged high rates of hospital admissions and procedures that are performed. Medicare also encouraged day case surgery by providing better rates for day cases. This was of particular interest because one of the current changes during the study period for ‘Day case laparoscopic cholecystectomy – what’s stopping us now?’ was the introduction of the best practice tariff, which was a financial incentive

given to trusts for performing day case laparoscopic cholecystectomy (Department of Health 2010).

Four explanations were offered for the variation in day case rates (Morgan & Beech 1990): the needs of patients, the differences in health service provision, the organisation of care at a hospital and the style of clinical practice. The relationship of these factors and length of stay are shown in the diagram below adapted from the paper. The paper concluded that the slow progress in day case surgery was due to a lack of appropriate financing and because performing day case surgery was not what most surgeons were interested in.

This paper provided a comprehensive explanation for variation in length of stay and day surgery rates and included key references that supported the reasoning. As a result it highlighted the issues that influence the practice of day surgery. This summary was used to guide this research project and identify appropriate data to be collected both quantitative and qualitative. Regional variation in day case rates may be related to the comorbidity of the regional population and whether patients were suitable for day case surgery. Individual clinical practice was reported as an independent contributor to the variation in length of stay because clinical practice was a reflection of their own preferences and how quickly they adopted new innovations or practices. Some of the issues raised, with regard to service provision and organisation of care, can be explored further through this project.

Figure 2: Explanations for variation in day case rate, adapted from (Morgan & Beech 1990)



The significant difference between day case rates at different hospital was also described by Aylin et al (2005), in his epidemiological report on the trends in day surgery rates, focussing on the procedures in the BADS list, in acute trusts. This reported day case rates to range from 40.2% to 82.7% and that only 12% of trusts were achieving 75% overall day case rates. The explanation provided in this report for the variation was incorrect coding and

differences in case-mix. Other reasons, such as the availability of day surgery facilities or surgeon preference were not addressed in this paper.

Smith et al. (2006) identified three main barriers to achieving high day case rates. They were the misuse of day surgery units, the mismanagement of units and surgeon preference. It described a “Thirteen Point Plan” for achieving an increase in day surgery rates but they all addressed issues surrounding the misuse of day surgery units and the mismanagement of units. However it did not tackle the issue of surgeon preference despite recognizing it as an influence on clinical practice.

A questionnaire of surgeons performing day case inguinal hernia repair revealed a generational difference in the attitudes of consultants but that improving the facilities of day surgery would have a positive impact on practicing day surgery (Morgan et al. 1992). Since then there has been significant investment for the development of diagnostic and treatment centres, as described in the Background chapter. The first of these were operational by the end of 2002 but were not being used to their true potential according to audit findings (Healthcare Commission 2005). Papers and reports published since these audit findings (Smith et al. 2006; Hopkins et al. 2007; Faiz et al. 2008) still showed variable day case rates for the Basket of Procedures (Jackson & McWhinnie 2007). Therefore, it would be safe to assume that there was more than infrastructure influencing practice and that

the attitudes of consultants may have a greater part to play. The literature search did not identify any papers that examined clinical attitudes specifically and how they influence individual practice. This made it important to address clinical attitudes and beliefs in this study.

A more recent multicentre study examining ENT procedures shows that those operating within dedicated units achieved significantly higher day case rates than those that did not, but also described a clear variation between different trusts and surgeons (Hopkins et al. 2007). The authors of this paper examined why they were unable to improve their day case rates. The results demonstrated only 15.5% of sinonasal procedures were performed as day cases – well below the government target of 75%. The study reported the continued short coming in meeting day case rate targets. The reasons provided for this were case-mix, the timing of lists, patient demographics and clinical preference.

The authors of this paper did raise an interesting point. Although the procedure that was being carried out may have evidence to demonstrate how safe it was to perform as a day case, it was the patient characteristics, or comorbidities, that may determine whether they can safely have a day case procedure. For example, the 40 year old with symptomatic gallstones and no other medical problems would be an ideal day case laparoscopic cholecystectomy candidate, but the 40 year old with symptomatic gallstones,

diabetes and chronic airways disease would not be the ideal day case laparoscopic cholecystectomy candidate. The recommendations from BADS on day case laparoscopic cholecystectomy, and on other day case procedures, were quite specifically for a “selected group of patients”, i.e. those who are low risk (McWhinnie et al. 2004). Hopkins et al (2007) described how day case rates would be 67.2% for their practice if they only included patients who were ASA grades 1 and 2. The American Society of Anaesthesiology (ASA) grading system (Appendix 4) was a commonly used tool that anaesthetists used to assess fitness for surgery, which took into account the comorbidities of the patient and how it affected their daily activities. However the authors also recognised that a *change* in practice and culture may be necessary.

It also highlighted the underuse of day surgery units as identified by the Healthcare Commission. The study demonstrated that only 69% of Trusts were making use of dedicated day surgery facilities despite them being available at many of the other Trusts. They also suggested that if in-patient facilities were used for patients to recover post-operatively that staff were tempted to keep patients overnight to protect beds for the next day’s patients.

In summary, the literature reported a wide variation in day case rates and the explanation for this was the way the NHS was financed, the lack of or misuse of day surgery facilities, various organizational elements such as scheduling

or discharge planning and clinical beliefs and attitudes. These were all areas that can potentially influence the provision of day case laparoscopic cholecystectomy and needed to be addressed in this study.

There were a few papers that attempted to explain the low day case laparoscopic cholecystectomy rates. These mainly focused on clinical elements of the pathway, and did not address the elements that were thought to influence day surgery activity in general.

One of the papers retrieved was a systematic review that provided level 1 evidence for pre-, intra- and post-operative interventions (Ahn et al. 2011). It recommended the use of dexamethasone and non steroidal anti-inflammatories pre-operatively, use of local anaesthetic and anti-emetics intra-operatively. This was a well reported review that used 68 randomised controlled trials and met most of the criteria set out by PRISMA (Moher et al. 2009). The paper did not address the risk of bias from individual studies. It reported on the primary outcomes of pain and post operative nausea and vomiting, which were assumed to be the main barriers to day case laparoscopic cholecystectomy. It did not take into account other factors that may influence the clinical service, in particular those that had been mentioned in the previous section of this literature review.

A second cohort study of 106 patients at a single institute on the introduction of day case laparoscopic cholecystectomy reported outcomes based on a well

defined surgical approach to performing the procedure by standardizing timing of the surgery, the surgical technique and anaesthetic technique (Briggs et al. 2009). It reported a 84% day case rate for this cohort. Once again the study focused on the easy to tackle tangible aspects of the pathway. In their discussion, the authors described how staff underwent significant training prior to the start of the study and how this aided the introduction of the pathway and they also reported that only two surgeons at the institute were willing to subject their patients to involvement in this study. This showed the difference in clinical opinion by doctors within a single institute, but also how the decision of the surgeon affected the type of care that patients received. Although this cannot be measured easily, the inclusion of staffing seminars prior to the study, may have been a factor in the successful delivery of the service. The reluctance of all the surgeons at the institute to be involved was an example of how individual surgeon preference influences practice. Interestingly one of the conclusions of the paper was not related to the measured outcomes but how the education of patients and staff was the most important influencing factor.

An American study examined the impact of introducing a specific clinical pathway (Calland et al. 2001). This examined day case rates for patients who underwent laparoscopic cholecystectomy before and after the pathway was introduced and so reported a rise in day case rates from 21% to 72%. This was a much more comprehensive pathway that not only addressed

techniques but also included an element of patient education. A strength of this study, despite it being conducted in a single centre, was that it reported some of the contextual factors about the centre and the involvement of clinicians that participated. Another strength was that it reported on all elective laparoscopic cholecystectomies that were performed during the study period rather than those pre selected for day case only.

The literature review was only able to identify these three papers that reported on factors influencing the practice of day case laparoscopic cholecystectomy specifically. They only examined the technical aspects of the service delivery focussing primarily on surgical or anaesthetic techniques, and although the importance of patient and health professional education was discussed it was not specifically measured. The issues of funding for the procedure or surgeon preference were not addressed at all by these studies, but were potentially as important as the factors that were by these studies. It can be concluded that although a specific pathway or guideline can aid the provision of day case laparoscopic cholecystectomy, it may not be the only element that needs to be addressed.

4. Methodology and methods

The research question posed at the outset of the study was to explore the reasons why hospitals were not doing more day case laparoscopic cholecystectomies. The national average day case rate for laparoscopic cholecystectomy was 6.4% in the financial year 2005-6 (Solly et al. 2007) and the government anticipated that a day case laparoscopic cholecystectomy rate of 60% should be easily achieved by all acute trusts (Department of Health 2010). In order to address this question, it was important to be able to identify facilitators and barriers to the delivery of this service. This required a description of infrastructural and process changes that may be occurring at the trusts, a description of the day case laparoscopic cholecystectomy trend at each trust and the views and opinions of clinicians at the trusts. This chapter presents the study design, the data collection methods and data analysis procedures that were used to answer the research question stated above. The chapter provides reasoning for the choice of methods.

The chapter begins by describing the research paradigm and the approaches used; case study design, realistic evaluation and mixed methods, explaining why these approaches were important. It then provides a description of data collection methods and information about data analysis, which includes both statistical tools used for quantitative data and content analysis used for

qualitative data. A timeline of the study period is included (figure 3, later in the chapter) to show when significant events occurred and how this related to data collection.

Research paradigm

The problem being studied here was the laparoscopic cholecystectomy day case rate and the information provided explains how several factors may influence the situation, some that were easily measurable and others that were tacit. The problem required approaches that combined the “formal classical methods with some pragmatic, immediate and more informative forms of learning and investigation” (Berwick 2005, page 317) and an acceptance of the real world setting.

This fitted with the assumptions that were described in the naturalistic paradigm, a way of looking at the world described by Lincoln and Guba (Lincoln & Guba 1985). It recognised that the researcher influenced the study phenomenon, required the research to acknowledge any researcher bias and accepted the use of inductive and deductive approaches (Johnstone 2004). Other features of the naturalistic paradigm were the preference for a natural setting and emergent theory (Erlandson et al. 1993).

These assumptions and directions that naturalistic inquiry exerted were wholly appropriate for the research problem being examined and therefore help to explain the research approaches that were used in the study. The case

study was the approach of choice for reporting naturalistic inquiry (Lincoln & Guba 1985) and the acceptance of inductive and deductive approaches allowed for the use of mixed methods.

Research approaches

Case study

Gillham's description of a case study was comprehensive and explained that it was an investigation designed to answer specific research questions using a range of different types of evidence (Gillham 2000), which was an expansion on Yin's definition of a case study (Yin 2013). It was the researcher that decided which data was required, how to extract the data and how to analyse it in order to find the answer to research questions. The case study approach was suited to this piece of research because it allowed the reporting of naturalistic inquiries and because it allowed the exploration of phenomena within each trust (Yin 2013) and each trust can easily be defined as a 'case'. By exploring and, potentially, explaining what was happening to day case laparoscopic cholecystectomy at each trust, the study could inform the service redesign processes taking place (Keen & Packwood 1995).

Stake (Stake 2003) explained how the case was a bounded system that has a purpose and that behaviour was patterned as found in an organisation. Research examining organisations has used the case study approach frequently in the management discipline. The bounded system of a hospital

trust was the real-life context within which the study was set and therefore this made the hospital trust the equivalent of a case. Treating each trust as a 'case' also allowed comparisons to be made within each trust and across trusts and consequently findings could be relevant not only to the trusts involved but also other trusts that could relate to the individual organisations.

The case study was also particularly useful when the investigator has little or no control over the changes occurring at the 'cases'. This made it almost impossible to use experimental designs. The 'cases' or trusts were all undergoing significant redesign processes that the researcher had no control over but would either directly or indirectly impact on the service being studied. The service, in this case laparoscopic cholecystectomy, formed the unit of analysis (Stake 2003) because this was the particular phenomenon being investigated and was delivered across all cases.

The case study design accommodated the use of qualitative methods, which Keen and Packwood (Keen & Packwood 1995) advocated for capturing differing views and therefore identify where there was collaboration or conflict. As stated in the introduction, one of the objectives of this study was to explore the views and opinions of clinicians who performed laparoscopic cholecystectomy and to report their accounts of facilitators or barriers to their practice. This was best done by using qualitative techniques. Although this data can be gathered using quantitative tools such as surveys, this was

not suitable for exploring clinical beliefs and attitudes. A survey would need to pre determine barriers and facilitators in order to be designed and could fail to recognise important issues. Participants would not be allowed to explain their clinical decisions or perceptions. Therefore it was important that any approach used allowed for the use of qualitative methods.

However, another objective of the study required the collection of quantitative data. This was the description of day case laparoscopic cholecystectomy trends. Data that related to the demographic of the patients having the operation and the length of hospital stay was numerical and categorical. This clearly needed quantitative data.

The use of multiple methods, both qualitative and quantitative, was a key characteristic of case study research (Gillham 2000) and helped to capture the important aspects of an intervention (Keen & Packwood 1995) and had the advantage of providing triangulation. Triangulation was the “comparison of results from two or more different methods of data collection” (Mays & Pope 2000, page 87) and added rigour and confidence to reported results.

Designing a case study usually involved case selection, but in this particular study case selection was pre-determined. The trusts had already agreed to participate in the CLAHRC BBC project. This opportunistic case selection was addressed in the discussion chapter, but it allowed for the examination of similarities or differences between the trusts.

As inquiry was concentrated on three trusts, a collective case study design was used, to enable each organization to be examined separately. The focus on laparoscopic cholecystectomy as the unit of analysis created “intrinsic” and “instrumental” interest in the study (Stake 2003) because this was a service that was provided by all trusts.

Intrinsic case studies (those that focus on reporting what was happening in a particular setting, but not outside that setting) were performed to develop a better understanding of the particular case. This was important for each trust to enable understanding of what was happening and how to refine any changes taking place in order to meet their objectives. At the same time the case study was instrumental because it provided insight into the issues surrounding day surgery and facilitated the understanding of why there was such a variation in practice. This gave the research a wider audience than just the trusts themselves, because specific issues may be transferable to other trusts.

Criticisms of the case study research strategy revolved around issues with lack of rigour and lack of generalisability. Some authors believed that case studies may be good at examining processes or documenting changes over time, but were weak at showing causal links between interventions and outcome (Ferlie & Shortell 2001). However it was argued that combining this

strategy with realistic evaluation increases the validity, which was incorporated into this study.

Lack of rigour was thought to stem from the investigator allowing bias to influence the findings of the study. Although this may not be overcome, it was important to identify and acknowledge bias. This is dealt with in the discussion chapter.

With regard to generalisability, Yin (2003) argued that case studies were “generalisable” to proposed theories even if not to populations (or organisations) and that level two inference or ‘analytical generalisation’ was possible in collective case studies. There were three trusts in the study and the individual case studies of each organisation allowed for this to be possible and therefore analyses to be more robust.

Mixed methods

As mentioned in the earlier sections of this chapter, both realistic evaluation and case study approaches, generally involve the use of mixed methods. The use of mixed methods was important to the study in order to capture both quantitative and qualitative data that was required to answer the study questions. Mixed methods, as an approach, is defined and discussed here.

Mixed methods research involved the collection, analysis and integration of quantitative and qualitative data to answer research questions (Cresswell & Plano Clark 2011). This was a design that has evolved over 20 years with its

roots in the fields of evaluation, sociology, education and management, with particular support in the field of evaluation (Tashakkori & Teddlie 2003). Many of the questions proposed in these studies required measurement of some kind but also a greater understanding of the nature of an issue.

It was used because qualitative and quantitative approaches offer a “powerful resource to inform and illuminate policy or practice” (Ritchie & Lewis 2003, page 40). The problem outlined at the start of this thesis was that although policy directives indicate that day case laparoscopic cholecystectomy rates should be higher, this had not happened. In order to discover the factors that have contributed to this problem it was necessary to examine the views and experiences of those involved in the process. Combining qualitative and quantitative approaches was one way of doing this.

The clinical values, beliefs and attitudes of the decision makers in the day case laparoscopic cholecystectomy could only be captured using qualitative research methods and tools. In particular they:

- Identified factors that contribute to delivery of a programme, service or intervention, both successful and unsuccessful
- Explored organizational aspects surrounding the delivery of a service
- Explored the contexts in which interventions are implemented and the impact they have on effectiveness.

Quantitative research methods provided the tools to measure and create numerical data that can subsequently be statistically analysed. To determine the impact of service redesign on day case rates the collection of numerical data was required. Specifically data recording how many laparoscopic cholecystectomies were being performed at the trusts and the length of stay related to these admissions. It was for this part of the study that quantitative methods were used. This was thought to be the best way to measure outcomes, which needed to be recorded in line with the realist approach. It would reflect the success or failure of service redesign in the trusts by demonstrating whether rates remained static, increased or even fell.

Mixed methods have increased in popularity, reflected in the increasing number of publications, in recent years as a result of health service researchers acknowledging the complexity of health care and understanding the impact of service delivery and organization. One fifth of health services research studies in a 10 year period used mixed methods (O’Cathain et al. 2007). There were several reasons for using mixed methods described by researchers in this paper, which included providing a deeper understanding, increasing confidence in the findings of a study and to aid the sampling, data collection or data analysis. For similar reasons this approach was chosen for this study. The mixed methods approach provided opportunities for triangulation of data and added breadth to the inquiry. This was where the strengths of this approach lie by reducing gaps in data collection and

minimising any pre-existing assumptions held by the researcher as well as appreciating that a single method will not provide all the data required to answer the questions posed.

The strengths in the mixed methods approach also lead to the potential weaknesses of the approach. The need to collect different types of data was labour intensive and the need to analyse both qualitative and quantitative data required expertise in both fields of data analysis.

For this study, a convergent design was used as described in Creswell and Plano Clark (2007). Quantitative and qualitative data were collected around the same time but analysed separately. This allowed for different analysis techniques to be used, which were appropriate to interpret meaning from particular sets of data. The analysed data can then be merged when reporting and interpreting results. The convergent design was useful for bringing together data from two different databases and show convergent or divergent results between the two.

Realistic Evaluation

The delivery of a particular service, in this case, day case laparoscopic cholecystectomy, in the health service setting was dependent on the context in which it was provided and the mechanisms with which it was delivered. These concepts relate to those described in realistic evaluation (Pawson & Tilley 1997) and therefore the evaluation of this service should address these

concepts and be included in the study design. The third concept in realistic evaluation was outcomes and here the outcome was day case laparoscopic cholecystectomy rates. The use of this approach was also consistent with the CLAHRC-BBC theme 1 protocol for evaluating service redesign. It provided a framework for exploring features of health service redesign particularly in this natural setting, which can be messy and as a result difficult to know how to start examining a phenomenon.

Realistic evaluation aims to provide explanations that go beyond answering the question 'what works?' but answer the question 'what works for whom under which circumstances?' (Pawson & Tilley 1997). Realistic evaluation can be used prospectively, concurrently and retrospectively. It had no preference for quantitative or qualitative methods and encourages the use of mixed methods, which was important in this study. McNulty and Ferlie (McNulty & Ferlie 2002) described realist evaluation as being appropriate in "messy and naturally occurring settings" and therefore suitable in large, complex and internally segmented health care organisations, which was an accurate description of the case sites in this study.

The approach has been used in health services research (Ham 2003; Greenhalgh et al. 2007; Greenhalgh et al. 2009; Pommier et al. 2010) to review the effect of programmes. These programmes align with the service redesign processes happening at the three trusts. These studies mentioned

above identify which aspects of the programme(s) were most effective in delivering the anticipated changes and therefore offered ways of refining the process. For example, Greenhalgh et al, 2007 made the following points in their evaluation of school feeding programmes: that interventions should be aimed at children with malnutrition (context) and that the design of interventions should involve the community (mechanism) in order to achieve the outcome intended by the programme.

Realistic evaluation of service redesign was used to explore the successes and failures of the national booked admissions programme (Ham 2003) and to examine the modernisation of health services (Greenhalgh et al. 2009). The identification of the separate concepts helped to identify the factors that facilitated the desired outcome and therefore the contexts or mechanisms that could be created or implemented in other areas of service redesign. In these studies the concept of context received a high level of scrutiny. This was not new because the “receptive context” was previously described by Pettigrew (Pettigrew et al. 1992). The research questions being asked by Ham et al, (2003) and Greenhalgh et al, (2009) were to identify the factors that facilitated quality improvements in health care settings and these relate closely to the questions that this investigation of day case gall bladder removal focussed on.

There were three concepts that are important:

1. Context, which describes the features of the conditions in which programmes are introduced
2. Mechanism, which describes what it is about interventions that bring about any effect
3. Outcome pattern, which comprises of the intended and unintended consequences of interventions in different contexts.

The studies, referred to above, that have used realistic evaluation illustrate the importance of the concepts described in being able to deliver the intended outcomes. The increase in day surgery capacity at the trusts and introduction of best practice tariffs, as described in the Background, were equivalent to the interventions or programmes in the studies. This meant that it was important to ensure that the concepts of context, mechanism and outcome were addressed as part of this study because this would help not only the individual cases to identify important aspects of the pathway but also other trusts to identify potential elements for adoption in their own organisations.

In the present project, the features relating to context were the economic pressures on trusts to create efficient services and infrastructural changes that were taking place that directly affected the provision of day case surgery. The mechanisms used were increasing capacity for day surgery work and clinicians leading others to promote day case laparoscopic cholecystectomy rates.

It was important to remember that although this was a useful approach and provided the structure for how to assess services, it did not give us a simple recipe for success (Greenhalgh et al. 2009). Realistic evaluation can help identify which contexts and mechanisms make an outcome more likely but not predict outcomes. This was in contrast to research that provided evidence for causal links.

Bringing these three concepts together developed a fourth, which is context-mechanism-outcome pattern configuration. It was this configuration of features that were needed to sustain a programme that realist evaluation strives to identify. The relationship between these concepts was not seen as fixed, but particular pre-conditions were seen as creating generative or conditional causality (Greenhalgh et al. 2009). For example, it would be useful for organisations to be able to determine whether a well equipped and functioning diagnostic and treatment centre (context) is able to increase day case laparoscopic cholecystectomy rates (outcome) following the introduction of the best practice tariff (mechanism). Therefore it may not be the presence of a DTC alone or the introduction of the best practice tariff alone that cause day case laparoscopic cholecystectomy rates to improve, but both conditions to be met for the desired outcome to be achieved.

Methods

Qualitative methods

One of the objectives of the study was to capture the views and opinions of clinicians performing laparoscopic cholecystectomy and examine how this affected their practice. This was best acquired using qualitative techniques, in particular by using interviews (Britten 1995). The semi-structured interview was chosen because it allowed an interview schedule to be created that defined the areas to be covered during the interview. The literature review helped to inform the predefined areas. At the same time, semi-structured interviews gave the researcher the freedom to pursue issues brought up by the interviewee. Therefore, this freedom allowed the researcher to explore topics that were not predetermined at the outset of the study.

An advantage of semi-structured interviews was that they allowed observation of face to face interviewing, which had a better response rate than postal questionnaires or surveys, and allowed the observation of non-verbal cues from the interview (Barriball & While 1994). The technique was also familiar to the researcher, having been used for previous work.

It was decided that two separate rounds of semi structured interviews should be conducted to gather qualitative data before and after the changes occurring at the trusts and whether clinical perception or opinion changed as a result of the changes taking place.

As well as semi-structured interviews, a period of observation at each trust was undertaken to see the day case laparoscopic cholecystectomy pathway and whether clinical behaviour was supported by interview collected data. Observation in qualitative research was used to gain understanding of the social setting and help explain behaviour. It was for this purpose the observation periods were carried out with the researcher taking a non participant role. The observations were recorded by note taking.

With these techniques it was important to acknowledge the bias that the researcher's personal characteristics, including race, gender, social class and occupation can have on the interview or observation processes and the participants' interaction and responses. These personal characteristics were reported earlier and any bias in the findings is described in greater detail in the discussion. Although it may not be possible to negate these researcher biases, qualitative methods ensure that these were acknowledged and accounted for in the reporting of inquiries. Using a mixed method design and collecting different types of data can help minimise the potential influence of the researcher's characteristics. It should also be noted that the personal character of the researcher can also have a positive influence on the findings of a study because subjects relate better to them and open up more rather than seeing them as an outsider. This was hoped to be the case for this study because the researcher was a clinician familiar with the laparoscopic cholecystectomy service.

Participant selection and recruitment

As the study focussed on the practise of day case laparoscopic cholecystectomy, the participants invited to interview were the clinicians involved in the delivery of this procedure. This meant the surgeons and anaesthetists and demonstrated purposive sampling. Purposive sampling was an accepted approach to participant selection in qualitative study as it identified the subjects likely to yield data that was most useful to the study (Gray 2009). It would be ineffective and inappropriate to interview a paediatrician on day case laparoscopic cholecystectomy.

Informal discussions with lead clinicians at the three Trusts helped to identify the consultant surgeons performing laparoscopic cholecystectomy. The numbers were small and all were invited to participate. Emails were sent to all with participant information sheet (Appendix 5) and consent forms (Appendix 6).

The number of anaesthetists at each Trust outnumbered the surgical consultants and given researcher capacity and time limitations not all anaesthetists were invited for interview. Anaesthetists were invited to participate in the study because they play a key role in the patient pathway for elective laparoscopic cholecystectomy. As described in the literature review, the management of post operative analgesia and emesis are recognised clinical issues after laparoscopic cholecystectomy. It was the anaesthetists who deal with this element of patient care. A sample of 4-6 from

each Trust who regularly anaesthetised cholecystectomy patients was invited to participate. Initial suggestions were from lead clinicians and then from other participants. This was purposive sampling combined with a snowball strategy. The snowball sampling (Gray 2009) strategy relied on participants providing others who were of interest to the study.

Although there were other health professionals such as nursing staff and administrators that were involved in the patient's pathway, which were important to the patient experience. The decision to book surgery was made by the surgeon and the suitability for surgery was assessed by the surgeon at the same time. It was the surgeon deciding whether to perform operations as a day case. This decision can sometimes be changed when an anaesthetist made their assessment of the patient. This was why the focus of this particular study was on the clinical attitudes of the surgeons and anaesthetists rather than other staff members involved.

Anonymising interviews

Interviews were anonymised by providing a code for the Trust, and the number of the interviewee at the Trust.

Interview schedules, interviews and observations

The initial interview schedule was developed using open-ended, neutral and clear questions (Patton 1987) and began with easily answered questions, progressing into questions about more sensitive issues. This allowed both

interviewer and interviewee to build a rapport through the process and hopefully provide the interviewee with the confidence to respond freely.

The schedule covered issues that had arisen from the literature and was piloted with three surgeons and an anaesthetist. It was revised based on the findings and feedback of this process. The final schedule (Appendix 7) was not revealed to participants at interview.

The second interview schedule was developed in a similar fashion, but not piloted. The questions that were developed for this schedule were created to build upon findings from the round 1 interviews and therefore this was not developed until after the round 1 interviews were completed and analysed.

Face-to-face interviews were conducted at the place of work for each interviewee. Appointments were arranged at a time and in a private area (such as office space) was requested. Consent was confirmed prior to the start of the interview ensuring that participants had read and understood the information sheet (Appendix 4), that the process was voluntary and that permission was granted for anonymous direct quotes to be used. An explanation of the study was given and any questions about the study were answered. Interviews were recorded so that they could be transcribed verbatim for coding purposes. Notes were also kept to aid following up of information and the recordings, which included a post interview initial summary by the researcher. The original notes taken at the interview were

scanned and kept for reference to be used during data analysis if necessary and as an audit trail.

A series of observations at all three trusts, in the clinical areas where patients having laparoscopic cholecystectomies were being admitted and discharged, was planned during both phases of the interviews to provide supplementary information. These provided an illustration of the patient pathway and of contextual factors that affected the process and therefore the outcomes. Notes were made during these and the findings reported in the Context chapter.

Qualitative data analysis

The interviews were analysed using the Framework method (Ritchie & Lewis 2003), which is a type of content analysis. It was used to identify commonalities and differences in qualitative data, then connections and relationships between different parts of the data and seeks to draw descriptive and/or explanatory conclusions.

When using this technique it was suggested that good quality transcriptions are made of the interviews. Familiarisation with the recordings of the interviews was achieved by listening to them and by repeated reading of transcripts. A list of themes or codes was made having listened to the interviews, which was then used to develop a framework. All interviews were coded and charted into the framework matrix, which was in the form of a spreadsheet (Appendix 8). This matrix allowed data to be analysed by

interviewee, trust or theme. Illustrative quotes were noted in the appropriate box in the matrix.

This was finally interpreted to identify similarities or differences between clinicians at each trust and clinicians across trusts and potentially provide explanations for variance in clinical practice.

This process started as soon as the first semi structured interview was conducted and continued throughout the periods of qualitative data collection. Therefore, data gathering and data analysis took place concurrently.

Audit trail

All interview recordings were stored in a secure location on the hard drive of the CLAHRC theme 1 at the University of Birmingham and then destroyed once no longer needed. The transcribed interviews were stored electronically and as hard copies. The hard copies show the written coding analysis. Notes that were taken during the study period were also filed securely. Observation notes that were hand written were transferred to electronic, password protected documents for storage.

Quantitative methods

Another objective of the study was to describe the historical and current trend in laparoscopic cholecystectomy activity at each trust. This required quantitative data to demonstrate whether there was a change in the trend

during the study period. The quantitative data was extracted from the Hospital Episode Statistics (HES) database. The data that was requested from the HES database was for all cholecystectomies performed at the Trusts from April 2005. This was extracted using the Office of Population Census and Surveys Classification of Interventions and Procedures (OPCS) code for cholecystectomy J183.

It was important to highlight the problems that researchers face when using HES data. These were widely reported in the literature and mainly relate to problems with the coding (ICD and OPCS codes), completeness and quality (Kenney & Macfarlane 1999) and the inaccuracy of local data that was supplied. It has been suggested this was due to lack of clinical involvement (Spencer & Davies 2012) from clinical staff, who do not understand or take interest in the coding of clinical activity. After discussion and a brief analysis of stored data with a research team member, that dealt with HES data on regular basis, it was determined that we could rely on the OPCS code to be accurate because there was only one code for laparoscopic cholecystectomy unlike with some other procedures that may be recorded under different codes and ICD codes were not an essential data item.

The Charlson Comorbidity Index was used to assess how fit patients undergoing the procedure were, i.e. how many chronic diseases they had. It takes into account 22 diseases. Each of these 22 diseases has a weighted

score, depending on the disease that is affecting the individual and the total provided an estimate of 1 year mortality of patients (Charlson et al. 1987).

Table 4: Charlson Index and 1 year mortality

Charlson Index	1 year mortality
0	12%
1-2	26%
3-4	52%
>4	85%

The quantitative data that were collected were numerical and categorical. This data included patient demographics, the number of laparoscopic cholecystectomies performed at each trust and the length of stay. This data were necessary because it was the only way of addressing the objective to report day case laparoscopic cholecystectomy rates, but also to demonstrate and explain any differences in population demographic that might exist between trusts. Also as discussed in the Background chapter, day case procedures were not acceptable or safe in every patient, but in a certain group of patients. Therefore measures such as the Charlson comorbidity index, described above, would help explain any differences in the outcome

(day case laparoscopic cholecystectomy rate). Statistical analysis was used to compare data within and across trusts. A null hypothesis was adopted for this: There was no statistically significant difference between the patient demographics for each trust. This was in keeping with the mixed methods approach that brings together different types of data to explain a situation clearly.

Another objective of the study was to report trends in day case activity within each trust and between each trust over a period of time and whether there was any statistically significant difference between activity at the trusts or whether an increase or decrease in day case activity could be demonstrated.

Quantitative data analysis

The data that was requested from the HES database was a record of all cholecystectomies performed at the Trusts from April 2005 to 2011. Several fields of data were provided for these records that are shown in Appendix 9, along with a brief description of each field. Since the records included emergency cholecystectomies and patients undergoing other procedures during the same episode, some records were excluded.

This was done using Microsoft Excel data sort function. All emergency cholecystectomies were excluded. All open cholecystectomies were excluded. All records where there was another procedure performed at the same

admission were excluded. This left all elective laparoscopic cholecystectomies that were not complicated by any other procedures.

This was then transferred into Stata10 and analysed using descriptive statistics to provide tables and graphs to present quantitative data. ANOVAs, chi-squared, Kruskal-Wallis were used to compare data between trusts and trends and demonstrate any statistically significant differences. Statistical significance was inferred at $p < 0.05$.

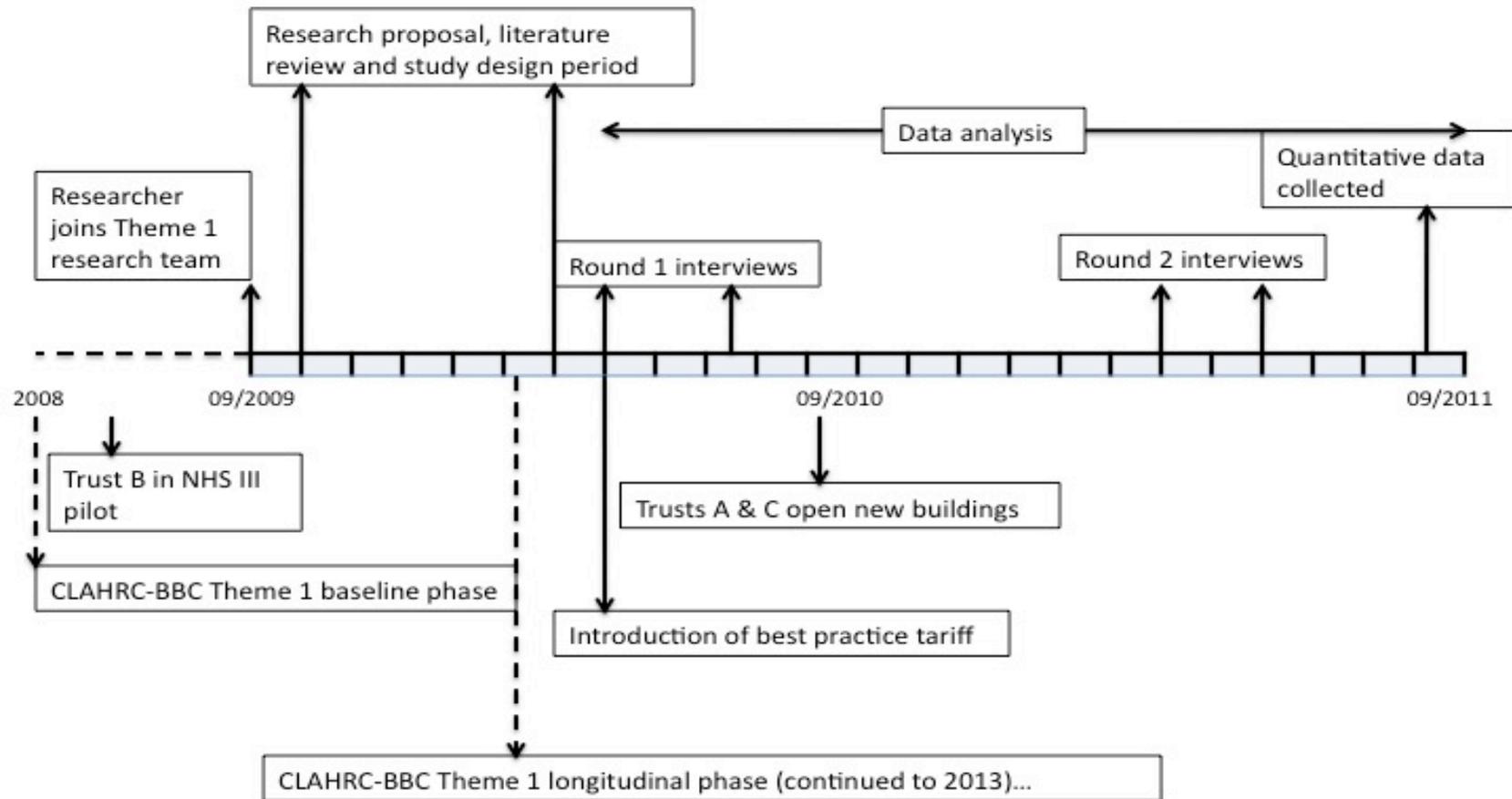
Time frame

The study comprised qualitative and quantitative elements, which covered slightly different time frames, but there was an overlap. The qualitative component captures the views and opinions of clinicians performing laparoscopic cholecystectomy as a day case procedure and the factors influencing their practice before and after service redesign efforts. As a result two rounds of interviews were conducted, the first set prior to changes and the second set, approximately 6 months later, after changes had occurred. Although this may not reflect long term changes and it captured any changes in attitudes or practice amongst the clinicians with regard to performing day case laparoscopic cholecystectomy.

The quantitative component aimed to describe historical and current trends in day case laparoscopic cholecystectomy activity in the trusts. It was insufficient to examine this data in the same time frame as the qualitative data

as this would be too short to demonstrate any trend. Therefore data was examined for the period April 2007 to March 2011.

Figure 3: Timeline of research study



Ethics

Ethical approval was sought from NRES. The study was classed as an evaluation by NRES and therefore did not require ethical approval. University of Birmingham ethical clearance was granted ERN_11-0786. However, approval was sought from the individual Trusts' research and development department.

5. Context

Naturalistic inquiry acknowledges and embraces the importance of context. The paradigm assumes that it is the relationships between subjects or components of an investigation that shape outcomes, events or occurrences (Erlandson et al. 1993). The context or setting of one trust was not the same as another and therefore the unique relationships between subjects differ. Although Erlandson accepted that no naturalistic inquiry could fully describe the setting, this type of research can provide evidence for managing further inquiry in similar settings. It was said “the best predictor of an organisation’s behaviour in the future is its behaviour today” (Erlandson et al. 1993).

This chapter explains the importance of context in this study and provides evidence for how contextual factors impact on quality improvement in healthcare. It provides information about the region and the trusts that may directly or indirectly influence day case laparoscopic cholecystectomy activity and clinicians’ perceptions depending on where they work. It draws on information from annual reports, trust personnel and the baseline phase findings of CLAHRC-BBC theme 1 (Shapiro et al. 2010). In addition, information gathered during observation periods is reported to further describe context. To provide anonymity to the local authorities, primary care trusts and acute hospital trusts, they have been numbered or lettered as necessary.

The Importance of Context

Decisions in medicine or surgery are dependent on context, taking into account the patient's clinical picture and the services the trust can provide. In cases of trauma, paramedics need to assess the circumstances of the accident to decide whether the victim needs to be taken to a trauma centre or any accident and emergency department. It is recognised that patients who have sustained injuries as a result of trauma, are managed better by a trauma centre. The decision should be made as a judgement of the circumstances of the trauma and the clinical picture of the patient (context). This is a simple illustration of how 'context' can change events and therefore why it is important.

However, a clear definition of context was difficult to determine. The definitions that are provided (Bate et al. 2014) do not stray too far from the Oxford English Dictionary definition, "the circumstances in which an event occurs", but it still did not provide clarity on what the 'circumstances' were. In other words, what were the variables that make up the 'circumstance' or the situation? In his essay, Bates (2014) presented a summary of studies that have identified variables relating to context that were important when it comes to quality improvement. Through his own ethnographic case studies of quality improvement programmes both in the US and Europe, an outer and inner context was described. The outer context included environmental factors such as social and cultural, political and regulatory, market and

resource, and technological. The inner context included organisational elements such as structure, size and performance. (Appendix 10). It was therefore important to ensure that these were addressed in order for this study to be understood fully. In addition it allowed for a deeper understanding of the study and predictions about future events to be made (Erlandson et al. 1993).

As discussed in the Methodology chapter, in the section on research approaches, the idea of the “receptive context” (Pettigrew et al. 1992) affected the success of the service being delivered. Pawson and Tilley (1997) explained the importance of context in realistic evaluation because here it was assumed that mechanisms will depend on the context in which they are implemented. Both of these were examples of how social scientists recognise the importance of providing a contextual background to the study. However, in her essay, Dixon-Wood (Bate et al. 2014) argued for a balance between realist principles (configurations of context-mechanism-outcome) and correlation logic and the need for “practical wisdom” a blend of clinical and social sciences. It promoted the understanding of the dynamic properties of quality improvement programmes and the need to create bespoke versions of initiatives to suit local contexts. This certainly fitted with the naturalistic approach that aspires to an understanding of the real world and was a combination of quantitative and qualitative elements.

The Introduction and Literature Review reported the variability of day case rates and specifically day case laparoscopic cholecystectomy rates. It was accepted that laparoscopic cholecystectomy was the treatment of choice for patients with symptomatic gallstone disease and was routinely offered by surgeons, but the variability in day case rates was a reflection of the effect that different contexts have on the organisational and clinical delivery of the service. This made a thorough description of the setting of the study important to help understand what influenced the day case laparoscopic cholecystectomy rates at each trust. An appreciation of the context of the study helped to explain and understand why some mechanisms were successful in one setting but not another.

The importance of context was that if it is adequately addressed the findings of the study may have some generalisability. If the reader is able to draw similarities between the research setting reported and their own context or environment, they may find the results applicable to their own context (Gray 2009).

Regional characteristics

The Trusts where the research was conducted were all within a geographical area covered by one Strategic Health Authority, which served the populations of three local authorities. This structure has now changed but was in place at the start of the study. It was important to provide a brief description of the

populations of these local authorities because it provided additional information about the context of the study and how this influenced service provision and clinical practice at the hospitals. For the purposes of this description the local authorities were named LA1, LA2 and LA3.

This population had a lower than average life expectancy for England with all three local authorities being 'spearhead' authorities. This means that they were amongst the authorities with the worst health and deprivation indicators in England (Shapiro et al. 2010). In particular, LA1 and LA2 local authorities had statistically lower life expectancy for men and women compared with the rest of the [REDACTED].

The ethnic mix of the populations in these local authorities demonstrated the majority were White and the second largest group Asian or British Asian. [REDACTED] has the largest percentage of Asian or British Asian with 21% of the population falling into this category. These figures were from 2006 (Shapiro et al. 2010).

There were four main Primary Care Trusts (PCTs) feeding activity into the three Trusts: PCT1, PCT2, PCT3 and PCT4. A proportion of activity came from other PCTs. One trust, Trust A, had a greater proportion of activity from other PCTs than Trust B and Trust C because it was a tertiary referral centre. The figures for inpatient and day case activity from the financial year 2008-9 are given in the table below.

Table 5: Activity in percent and in numbers from each PCT to each trust

PCT	Trust					
	A		B		C	
	%	Number	%	Number	%	Number
PCT1	54	43,814	6	6,362	0	42
PCT2	4	3,092	51	58,673	4	1,853
PCT3	10	8,006	28	31,550	0	172
PCT4	2	1,540	3	3,409	86	43,995
Other	30	23,949	13	14,477	10	4,964
Total	100	80,401	100	114,471	100	51,026

The age of the population from the PCTs showed some variation. The percentage of patients who were over 75 years of age in PCT1, PCT2 and PCT4 was approximately 8%, but in PCT3 this age group made up only 4.4% of the population. The burden of an older population comes from the higher rates of chronic disease and the requirements for more complex care. This was evidenced by the higher rates of heart disease and respiratory disease in PCT1, PCT2 and PCT4 than those in PCT3.

The challenges faced in this region relate to lower life expectancy of the population, social deprivation, ethnic mix and an aging population (Shapiro et al. 2010). These regional characteristics influenced patient behaviour and presentation not only in groups suffering with chronic diseases, but also those with acute disease processes, such as gall bladder disease. Therefore, it was important to take this into account when looking at day case rates because social factors or multiple comorbidities may influence the number of patients

who were actually suitable for consideration of day surgery (McWhinnie et al. 2004).

Trust A

This was a secondary, tertiary and quaternary service provider treating more than 600,000 patients a year from PCT1 and the rest of the region. It provided specialist care in trauma, burns, plastics, neurosciences, cancer and solid organ transplantation. [REDACTED]

This Trust was divided over two sites, which will be referred to as sites Q and S. It had had a capital development scheme that united the acute facilities onto one site (site Q) [REDACTED]

Prior to the development of the new hospital, there was no specific day surgery unit at site Q. All cases went through the main theatre suites, which were on different floors and 'belonged' to individual units, Laparoscopic cholecystectomies were performed in theatre 3 and 4 which were on level 3 and 4 respectively. These operating rooms were part of an operating suite that included a reception area, office, recovery area, anaesthetic room,

changing rooms and coffee room (Appendix 11). Theatre 3 was used for all HPB cases and theatre 4 was used by all other surgical specialties depending on which day of the week it was. Both theatres had a mixture of old and new equipment. Sterile operating equipment for laparoscopic cholecystectomy was kept by general theatres and was therefore not the responsibility of the staff working in theatres 3 and 4. Conversations that were overheard between theatre staff suggested there were many incomplete and damaged sets. Theatre lists were handwritten and posted on the wall of the theatre, which was interesting as many other processes in the hospital such as patient records and prescriptions were electronic.

Like most theatres, there were three clinical teams that came together to work in this environment; the anaesthetic, the nursing and surgical teams. During the observation periods, there was an anaesthetic consultant, with a junior trainee, an ODP, a surgical consultant with two trainees, four members of the nursing staff and a medical student. Each member of staff in theatre had their own role and function but also worked together as a team. Several interactions were observed between staff, which included other consultant surgeons popping in to talk about patients on the ward. Conversations were punctuated with more informal talk.

Patients for major, complex surgery, such as the liver resections who were observed, were admitted on a ward close to the theatre but those admitted on

the day, which were most of the laparoscopic cholecystectomy patients, were on the short stay ward. The short stay ward was at the other end of the hospital on the 1st floor. This was a rather small, busy area with several members of staff at any given time preparing patients for theatre. The patients remained here until being taken to the operating theatre.

Patients arrived in the reception area of theatre and were checked in before being anaesthetised in the anaesthetic room. They were moved to the theatre where the operation was carried out. Prior to starting the operation, the World Health Organisation (WHO) checklist (Haynes et al. 2009) was used led specifically by the anaesthetist. Other staff had to be encouraged to participate. After the operation the patients were woken up and recovered in the theatre area before being taken back to the ward by the porter. During this recovery time, the theatre was cleaned and prepared for the next operation and the next patient was being put to sleep in the anaesthetic room. The patient who had a laparoscopic cholecystectomy during the observation period went back to the short stay ward and was discharged the following day.

On a subsequent observation period, one laparoscopic cholecystectomy was cancelled because the patient was unfit for surgery and another was converted to an open procedure due to technical difficulties. Therefore none of the observed cholecystectomies were performed as day case.

The new hospital had thirty theatres, including the physical development of a brand new ambulatory care centre that incorporated day surgery. This increased the capacity of the day surgery unit from a two-theatre suite to a seven-theatre suite. This was planned to be fully functional during the proposed period of study allowing for the impact of this change to be recorded and reported on.

Trust B

Trust B operated from two sites; that will be referred to as sites D and W. Each hospital provided emergency and elective care fitting the description for a large district general hospital. The Trust also hosted some tertiary services such as ophthalmology, gynaecological oncology, dermatology, haematology and the regional base for [REDACTED]. This made it a secondary and tertiary care provider. It also provided community services to the local population in the form of a community Hospital, an intermediate Care Centre and a centre for Health and Social Care.

[REDACTED]

[REDACTED]

[REDACTED]

Despite being part of the same trust for eight years, the two acute sites operated very differently, for example, using different clinical protocols and HR procedures.

The trust was involved in a programme collaborating with local authorities, local primary care trusts and general practices. The aim of this programme was to provide secondary care services through new models of care in community locations. They had incorporated a tool that allowed frontline staff to lead this redesign process, which had been nationally recognised to aid staff engagement. As part of this, a new hospital had been approved by the Department of Health that was due to open in [REDACTED]. This would combine services from site W and site D onto one site. In the lead up to this, the Trust was focussing its efforts by reconfiguring services and improving quality and productivity.

An example of reconfiguration was the division of elective and emergency surgical services between site D and site W. An example of improving quality and productivity was the participation in the National Institute of Improvement and Innovation pilot scheme “Focus on: Laparoscopic cholecystectomy” (Solly et al. 2007) to help improve day case rates.

Both main sites had their own day surgery facilities. Site D housed a diagnostic and treatment centre, which provided modern facilities for one-stop diagnosis and treatment including an adult surgical unit with six theatres, each with its own anaesthetic room. The facility could remain open overnight if necessary. There was a reception area outside the day surgery unit on the third floor of the building where relatives waited. The day surgery

unit was made up of three 'pods', two of which were for adults and one for children. Adjoining this area were the theatres, changing rooms, a coffee room and some offices (Appendix 12).

During the periods of observation, staff nurses would bring the patients in from the reception area into the pods to prepare them for surgery. There was a healthcare assistant and nursing student to help with this. Surgeons and anaesthetists also reviewed their patients prior to theatre in this area. Shifts for nursing staff were staggered with some arriving at 7am, 8am, 9am and 11.30am.

Patients were told to arrive at 0730. Each pod would have a copy of the theatre lists but there was also a white board outside every theatre that would have the operations listed. Theatre lists were electronic. Patients for morning lists were ready by 9am. They were collected for theatre by the anaesthetic nurse, who went through a checklist before taking them to the anaesthetic room. Patients were asked to walk to theatre and their trolley was wheeled behind them. The trolleys were also used as operating tables. After the operation they were brought into the recovery area on the trolley where they would spend a variable length of time. The first patient arrived in this area at 9.40am during one observation period and by 10am there were three patients. The patients then returned to their pod area to be prepared for discharge, which was nurse led. Patients walked out to the reception area, by

the nurse, to meet their relative, who was picking them up. Patients on afternoon lists started arriving at 11.30am.

There was a real sense of pressure felt during the late morning and afternoon observation periods; this was related to discharging morning patients and admitting afternoon patients. Nursing staff were encouraging patients to eat and drink post operatively and then contacting relatives to come and pick up the patients. Discharge and admission processes occurred simultaneously to ensure a smooth running of the service. During one of the observation periods, the children's pod was opened for adults to increase capacity temporarily. This was only possible because there were no paediatric cases.

There was a clear pathway that was well defined; similar to a production line. It was routine to have laparoscopic cholecystectomies here. Five were witnessed during the observation periods. There was some concern expressed by nursing staff about discharging patients late in the day after this particular procedure.

Site W has a smaller day surgery unit located in the outpatients department with three theatres that closed at night. There were only five bays for patients. Only one of the three theatres had its own anaesthetic room (Appendix 13). This was only partially operational at the time of observation because the facility was about to undergo refurbishment. There were four staff nurses and a healthcare assistant working on the shift preparing patients

for theatre. The list scheduled on the day of observation was delayed because there was no surgeon available. In a conversation between two consultant surgeons, one of who was the clinical lead, concern was expressed that day case rates were static and not increasing. Site W used electronic theatre lists that were posted at the nursing station, in the ward area and theatres. Nurses brought patients in to the unit individually and checked them in before preparing them for surgery. This process started at 0800 and operating time was scheduled to commence at 0900. Patients walked to the theatre area but returned on trolleys.

Trust C

[REDACTED] [REDACTED] [REDACTED]
[REDACTED] The hospital was a district general hospital that offered secondary care to the local population and hosted the [REDACTED] For other specialist services, the Trusts either hosted visiting consultants or referred patients to other trusts in the region. [REDACTED]
[REDACTED]

Trust C had also undergone capital redevelopment, but this was on a smaller scale in comparison to Trust A. The new hospital was [REDACTED] and opened in Summer [REDACTED] This housed [REDACTED] inpatient beds and a new

diagnostic and treatment centre that hosted family health, outpatients and a day case centre.

During the course of this project, the trust had also integrated with a local community health group to create a new healthcare NHS Trust.

The observation period here was carried out while an interim day surgery unit had been set up. This area was small and did not fit the purpose because it was for the physiotherapy department. These two rooms were used by nursing and medical staff to assess patients. Staff complained about the lack of space and patients were often left standing or waiting for a seat to become available in the waiting area. There was an adjoining room that had 17 chairs and no trolleys with a small curtained area for patients to change in (Appendix 14). There were some patients in here waiting for their operations. Staff also informed me that this was an area used as a discharge lounge for patients, from anywhere in the hospital, waiting to be collected by relatives. Five nurses were working in the arrivals lounge area, with a receptionist and two healthcare assistants.

There was no short stay ward in this block of the hospital so patients were sent to the main ward after their operation. Operations were held in the main theatre block, which was down the corridor and consisted of four theatres each with their own anaesthetic room. In theatres there was a consultant surgeon, a surgical registrar, an anaesthetic consultant, an anaesthetic

registrar, a scrub nurse and two runners. During the laparoscopic cholecystectomy that was observed, there were equipment problems. Some equipment did not work and required equipment was not ready to hand and this was a source of frustration for both surgical and nursing staff. The surgeon was heard to complain about the old equipment.

Although I was informed that patients that underwent laparoscopic cholecystectomy were discharged on the same day, the case that was observed was not discharged on the same day.

6. Results

The next two chapters present the quantitative and qualitative data findings. They are reported separately as the analysis of both data sets was done separately. The quantitative and qualitative results are brought together in the discussion chapter to explain findings and demonstrate similarities or differences within and between trusts.

Quantitative results

Using the search term J183 as main operation code, 5,947 HES patient records were retrieved over a 5 year period. These records included cholecystectomies that were not coded as laparoscopic, those that were admitted as emergencies and those that had other procedures carried out as part of the same admission. The focus of this research was elective laparoscopic cholecystectomies and so the emergency cholecystectomies were excluded from analyses.

3,905 records were included for analysis and the findings are presented here.

Table 6: Number of laparoscopic cholecystectomies performed at each trust between 2007 and 2012.

Trust	Total number of LC performed in between 2007 and 2012
A	1298
B	1597
C	1010

Total	3905
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Trust B performed the most elective laparoscopic cholecystectomies, followed by Trust A. Trust C performed the fewest.

Table 7: Number of laparoscopic cholecystectomies performed each financial year from 2007-2012.

Financial year	Number of LC performed each year	%
2007-2008	774	19.8
2008-2009	801	20.5
2009-2010	747	19.1
2010-2011	796	20.4
2011-2012	787	20.2
Total	3905	

The percentages given in the table above show that each year a similar number of laparoscopic cholecystectomies were performed. There was no significant increase in the overall number of operations carried out year on year in the given period.

Analysis of data by trust

The following section presents the analysis of the demographics of patients that underwent elective laparoscopic cholecystectomy.

The proportion of male to female patients undergoing laparoscopic cholecystectomy at each trust is presented in the table below and a chi-squared test was performed to see if there was any statistically significant

difference between the trusts' operation rates. The results were in keeping with reported epidemiology, which described a higher incidence of gall bladder disease in women. This was necessary to ensure that there were no significant differences between the trusts in the proportion of male and female patients undergoing laparoscopic cholecystectomy or that there was a significant difference when compared to reported incidence of the disease.

Table 8: Number of male and female patients having elective laparoscopic cholecystectomy at each trust

Trust	Number of male patients	% of male patients	Number of female patients	% of female patients
A	258	19.9	1040	80.1
B	287	18.0	1310	82.0
C	204	20.2	806	79.8

The male to female ratio of patients having elective laparoscopic cholecystectomy was similar between trusts. The chi-squared test showed no statistical difference (p-value 0.27), where significance was assumed when the p value was less than 0.05

The age of patients when they had their operation was examined and followed a normal distribution pattern. This was demonstrated in Graph 1. Therefore, the average used to compare the age of the patients when they have their operation at each trust was the mean and the figures presented in

table 9. ANOVA was used to test for statistically significant difference between the mean ages.

Graph 1

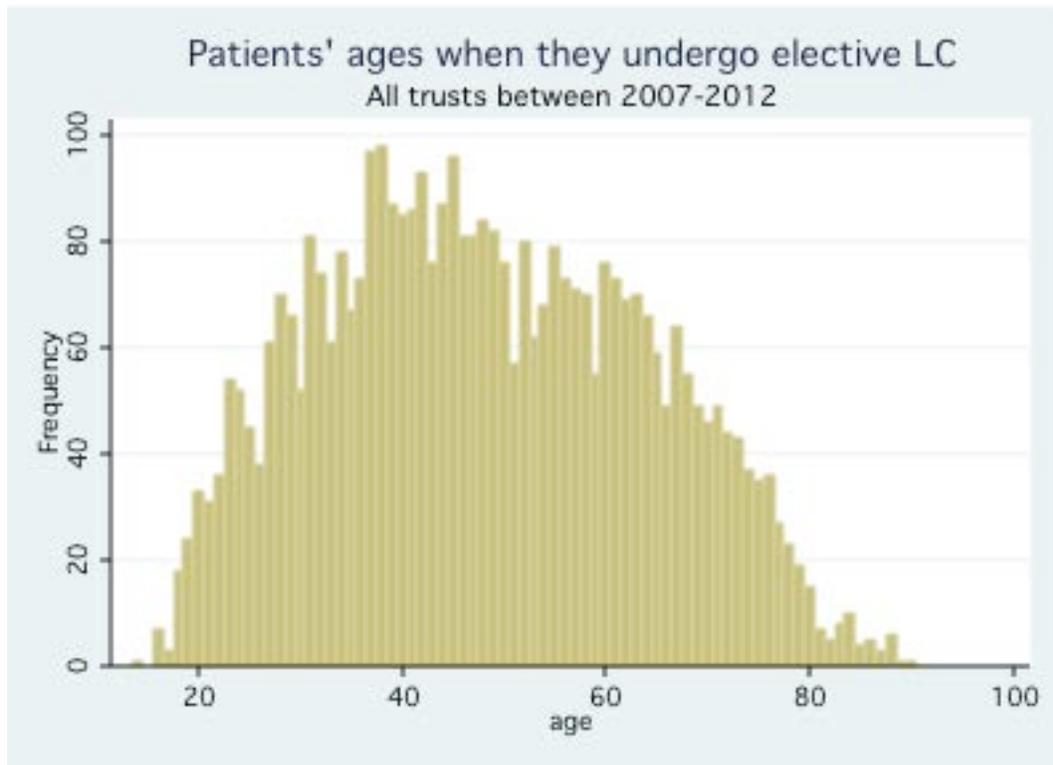


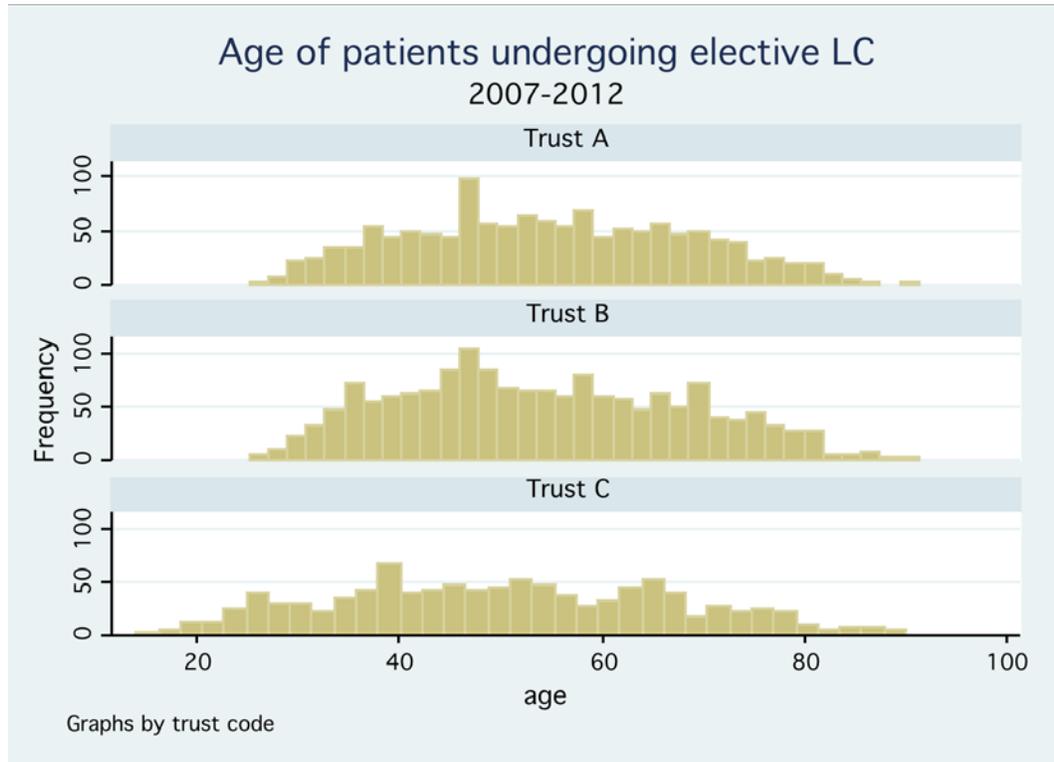
Table 9: showing the age range, the mean age and the standard deviation for patients having their laparoscopic cholecystectomy at each trust.

Trust	Age range	Mean age	Standard deviation
A	16-89	47.78	15.41
B	14-88	47.14	15.92
C	16-90	50	16.35

The ANOVA test results show there was a significant difference between the mean age of patients at the three trusts, F value 10.41 with a p value of 0.00. A further Bonferroni test was applied, which identified where this significant difference arose. It was used because the mean age of patients being treated with laparoscopic cholecystectomy at trust A and B were very similar and the Bonferroni test counteracted multiple comparisons. This demonstrated the statistically significant difference between the mean age of patients treated at trust A and trust C and trust B and trust C.

A graphical presentation of the ages of the patients having the procedure at each trust is provided below (Graph 2). The graphs for trust A and trust B show a peak in frequency between 40 and 50 years of age. The graph for trust C was much flatter with the age of patients more evenly distributed between 40 and 60 years, although the peak was at 40 years. This reflects the higher average age of patients undergoing elective laparoscopic cholecystectomy at trust C.

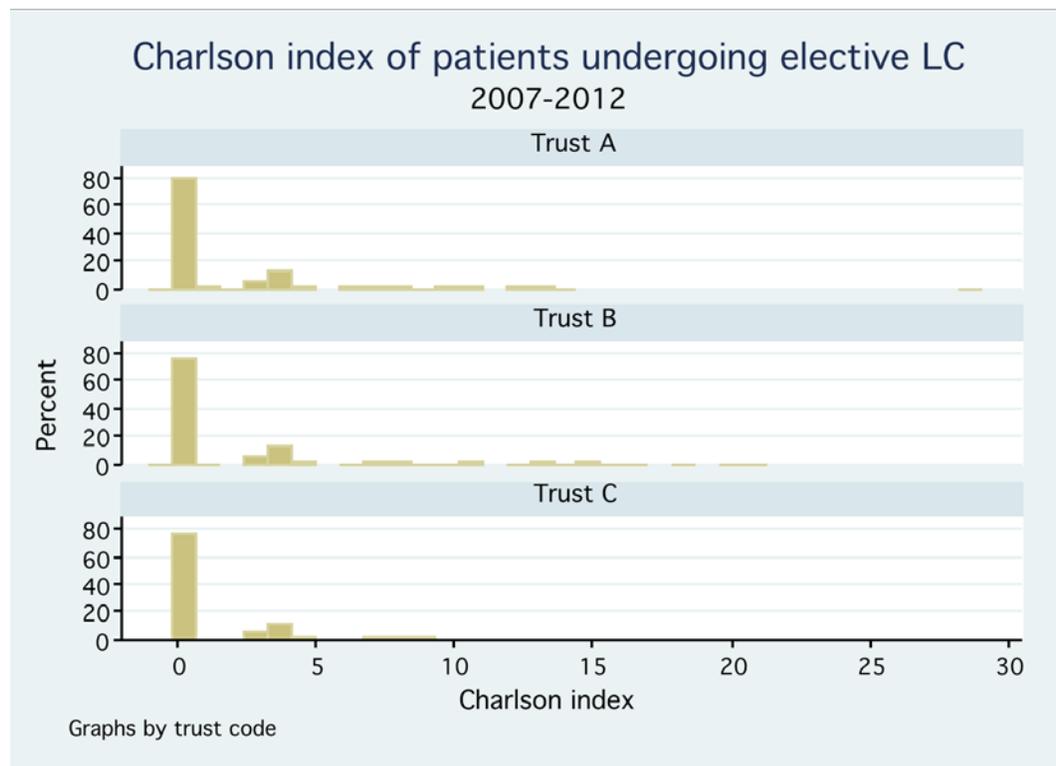
Graph 2



The next graph (Graph 3) presents the data on Charlson comorbidity index for the patients included in the quantitative analysis. The majority of patients having elective laparoscopic cholecystectomy at each trust had Charlson comorbidity indices of 0 (explained in the quantitative methods section of chapter 4). This represents a relatively well group of patients as they have no chronic diseases and a 1 year mortality of 12%. The Charlson Index for patients at each trust was compared for significant difference using Kruskal-

Wallis non parametric test. This showed a chi-squared figure of 4.501 with two degrees of freedom and a p-value of 0.10. Therefore there was no significant difference.

Graph 3



The income rank score is a weighted score that was provided in the HES database. It takes into account socio-economic factors such as income, employment, barriers to housing services and the environment. The lower the score the more deprived the individual (less skilled and lower income). The higher the score the less deprived the individual (more skilled and higher income). It was important to record this to see if it reflected the regional

characteristics of the population as described in the Context chapter or whether there was a difference in the population that underwent laparoscopic cholecystectomy to the general population treated by the hospital. This is presented in graph 4.

The Kruskal-Wallis test was applied to income rank. This showed a chi-squared figure of 165.744 with two degrees of freedom and p-value of 0.0001. This showed there was a statistically significant difference between the income rank of patients at the different trusts. This was also demonstrated in the graphical presentation of data. This showed that patients who had treatment at trust B had higher income rank scores. Lower income was reported to be related to poorer health outcomes and higher comorbidity (Michie et al. 2009) and this can affect the suitability of patients for day case surgery.

Graph 4

Income rank of patients undergoing elective LC 2007-2012

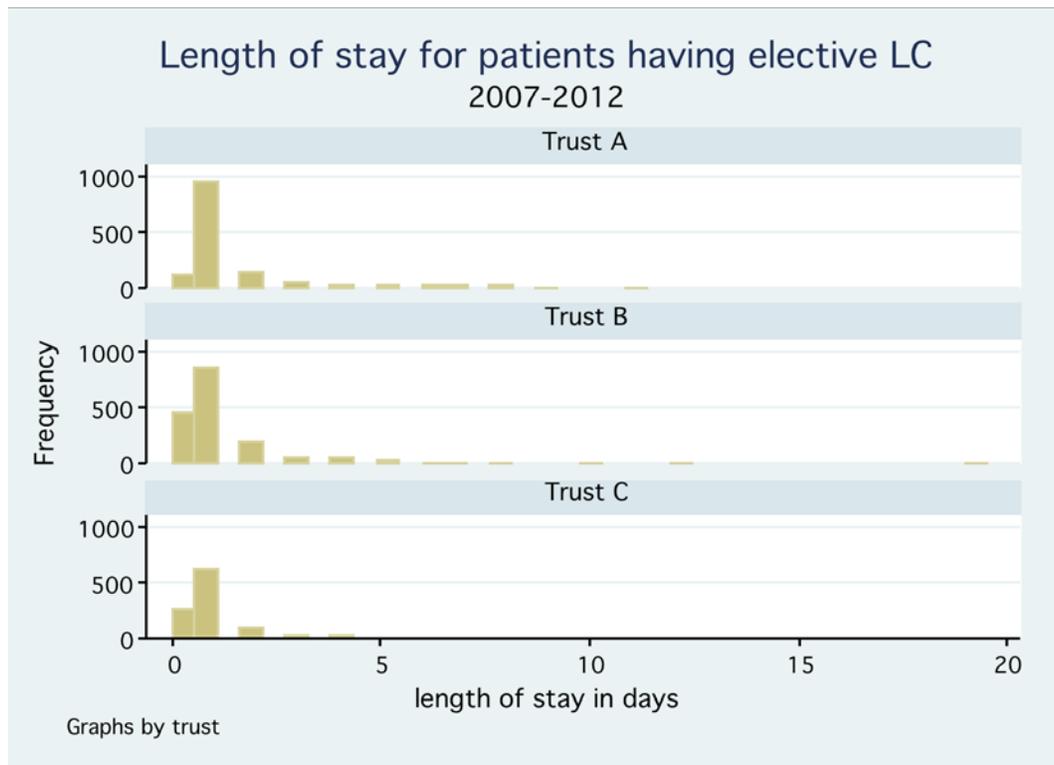


Graphs by trust code

Length of stay data

This section presents the analysis for length of stay data at each trust.

Graph 5



The graph above illustrated the length of stay for patients having elective laparoscopic cholecystectomy for the whole 5 year period by trust. The majority of patients had a length of stay of 1 day. A small number of patients had a length of stay greater than 1 day. It also showed that the 0 length of stay was different at all three trusts, with trust B (n= 451) having the largest number of day cases followed by trust C (n= 271) and then trust A (n=119).

This was also analysed per trust to examine for any trends year on year.

Graph 6

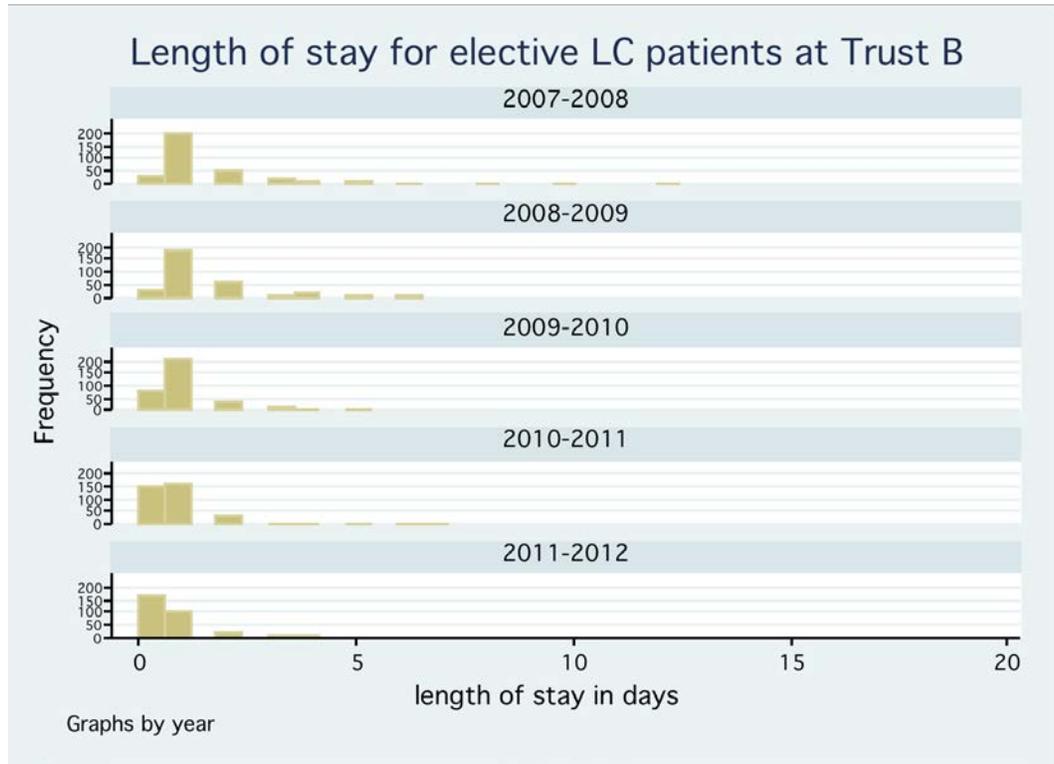


This shows that the length of stay for patients at trust A shows a similar pattern for each financial year. There was no clear trend that patients' length of stay was reduced in each financial year. The majority of cases stayed in for 1 night. It was not possible to say from the data collected whether these were intended to be day cases or not, but what it did show was that the majority of cases were not being performed as day case laparoscopic cholecystectomies.

Table 10: Number and percentage of patients shows these figures with percentages for comparison at trust A

Year	Length of stay = 0		Length of stay = 1		Length of stay >1	
	number	%	number	%	number	%
2007-2008	10	3.8	197	74.6	57	21.6
2008-2009	25	8.4	212	71.6	59	19.9
2009-2010	13	5.2	180	72.6	55	22.2
2010-2011	25	10.3	184	76.0	33	13.6
2011-2012	46	18.5	181	73.0	21	8.5

Graph 7



This was an interesting graph because it illustrated a change in the length of stay for patients who were treated at trust B. The number of 0 length of stay cases, or day cases, increases year on year. In the financial year 2010-2011, the number of day cases almost matches the number of patients who stayed overnight. In the financial year 2011-2012, more patients were treated as a day case than were kept in hospital over night. The figures and percentages were also presented here in table format.

Table 11: Number and percentage of patients shows these figures with percentages for comparison at trust B.

Year	Length of stay = 0		Length of stay = 1		Length of stay >1	
	number	%	number	%	number	%
2007-2008	27	8.7	205	65.7	80	25.6
2008-2009	30	10.2	183	62.2	81	27.6
2009-2010	81	24.3	206	61.9	46	13.8
2010-2011	145	41.7	161	46.3	42	12.1
2011-2012	168	54.2	107	34.5	35	11.3

The graph and table below showed how the length of stay pattern changed at trust C. Patients staying for 0 days increased from 2007 to 2012. Those who stayed 1 day decreased. By 2011-2012, the number of patients not staying overnight was greater than the number staying overnight.

Graph 8

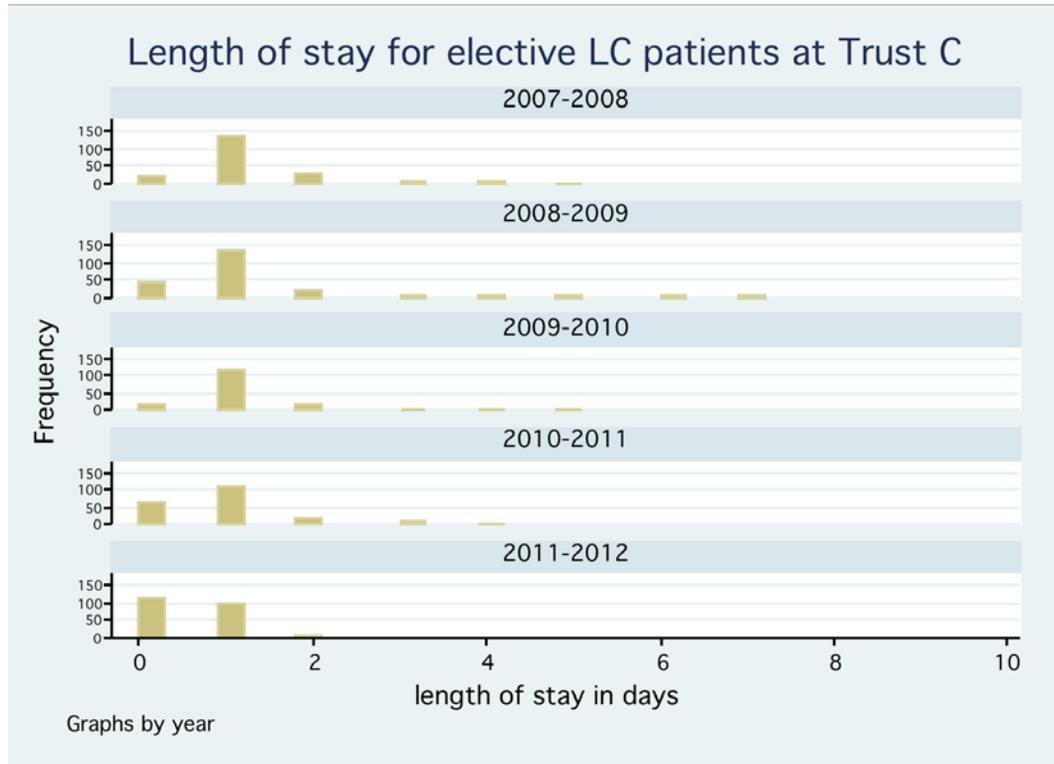


Table 12: Number and percentage of patients shows these figures with percentages for comparison at trust C

Year	Length of stay 0		Length of stay 1		Length of stay >1	
	number	%	number	%	number	%
2007-2008	25	12.6	138	69.4	36	12.8
2008-2009	45	21.4	138	65.7	27	12.9
2009-2010	21	12.7	122	73.5	23	13.9
2010-2011	66	32.0	112	54.4	28	13.6
2011-2012	114	49.8	103	45.0	12	5.2

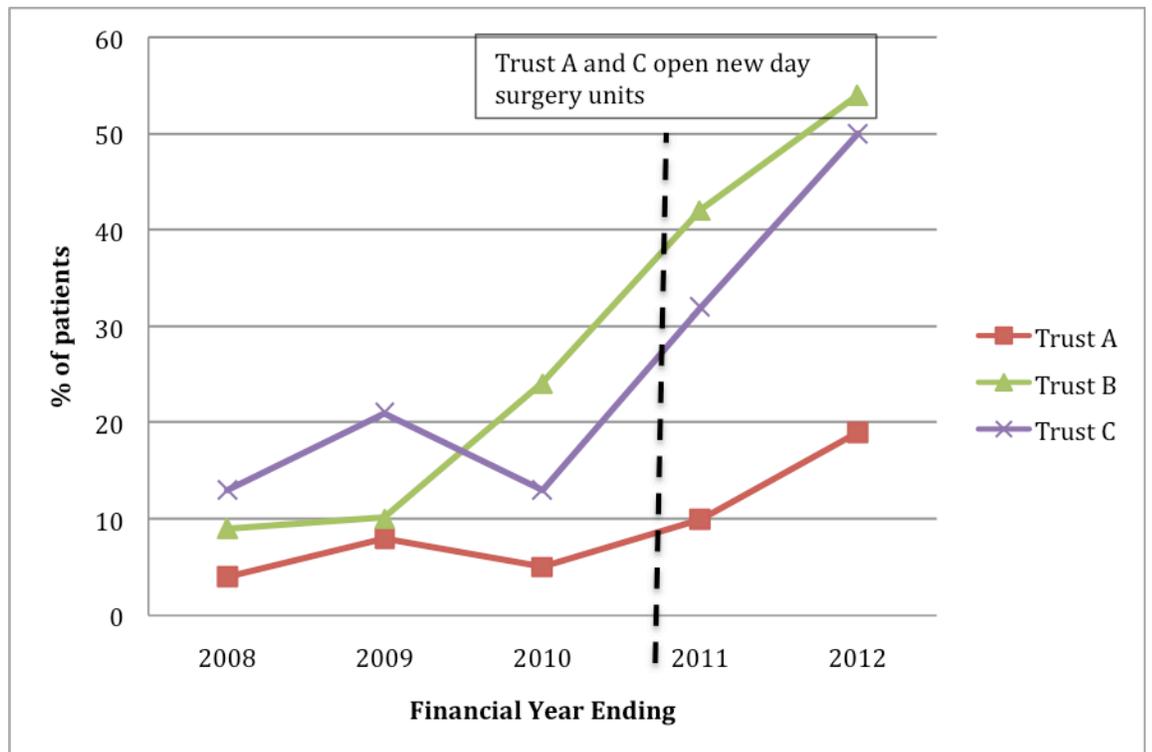
The figures and statistics presented above all related to the total number of elective laparoscopic cholecystectomies carried out over the five year period at each trust. The following section focuses on those that were performed as day case laparoscopic cholecystectomy.

Day case data

This section presents the analysis for day case rates.

The line graph illustrated the day case rates for each trust for each financial year. Trust A consistently had the lowest day case rates, but did show a gradual increase from April 2009 onwards. Trust C had the highest day case rates in the financial year 2007-2008, which then fell before increasing from April 2009. The trust that performed best was Trust B with the highest day case rates. There was a clear difference in practice at all three case sites and none of them had achieved the 60% day case target (best practice tariff target and BADS directory of procedures recommendation).

Graph 9 Temporal trends in day case laparoscopic cholecystectomy rates at each trust



In summary, the quantitative data has shown that the number of elective laparoscopic cholecystectomies performed between 2007 and 2011 at the three trusts was not significantly different between the trusts and is in line with the incidence reported in medical texts (Beckingham 2001). The mean age at which elective laparoscopic cholecystectomy was performed was similar in all three trusts, although statistical analysis shows that trust C performed this operation on a slightly older population. The data demonstrated that there was no statistically significant difference between the Charlson comorbidity index reported for the patients, who underwent

elective laparoscopic cholecystectomy, between the trusts. This meant that patients having the operation at each trust were not sicker at one trust than another. The differences in income rank score that were demonstrated reflect the regional characteristics that were described in the Context chapter.

For the 5 years that data has been collected, trust B had the highest day case laparoscopic cholecystectomy rate, followed by trust C and then trust A. However the length of stay for the majority of elective laparoscopic cholecystectomies performed at all the trusts was 1 day. Trusts B and C showed a trend where day case laparoscopic cholecystectomy rates improved over the five year period with day case laparoscopic cholecystectomy forming the majority of cases in the financial year 2011-12. Trust A did show a trend to improve the elective day case laparoscopic cholecystectomy rate in the five year period, but not to the same extent as the other two trusts.

Graph 9 showed that neither of the trusts had reached the 60% target that would mean they receive the financial reward of the best practice tariff. The data also demonstrated that laparoscopic cholecystectomy day case rates varied between the trusts despite the demographics of the patients being treated at each trust not showing any significant difference. The significant difference shown in the data with regard to income rank did not appear to impact on laparoscopic cholecystectomy day case rates as Trust B performed

the most day case laparoscopic cholecystectomy despite the patients having a significantly lower income rank score.

The next section presents the findings of the semi-structured interviews that were performed.

Qualitative Results

Semi-structured interviews – round 1

A total of 20 interviews were conducted in the first round. All interviewees were consultants. Eight of these had qualified abroad (India, Nigeria and Ireland). They included 16 surgeons, two of whom were female and four anaesthetists, all of whom were male. The age range of the consultants was 37 years to 62 years. The table below shows how many consultants were interviewed from each trust and their backgrounds. A more comprehensive table of interviewee characteristics can be provided on request.

HPB indicates specialist in hepatobiliary surgery and Upper GI indicates specialist in upper gastrointestinal tract.

The anaesthetists all described themselves as having interests in day surgery anaesthesia.

Table 13: Summary of interviewee characteristics

Trust	Number of interviews conducted	Age range of interviewees	Gender	Specialties	Years as a consultant (range)
A	7	38-60	1 female 6 male	HPB Upper GI Anaesthetics	0.5-24
B	8	39-57	8 male	Colorectal General & breast Upper GI Anaesthetics	3-15
C	5	37-62	1 female 4 male	Colorectal General & breast Anaesthetics	0.5-23

Thirteen topics emerged from the coding of the interviews, which are shown in the table (Table 14) below. These categories were grouped into two themes, the first being *context* and the second being *mechanisms* in keeping with realist evaluation concepts and to construct the framework. The third concept described in realist evaluation was outcome, which for this study was covered by the quantitative data. In this study, the outcome was day case laparoscopic cholecystectomy rates.

A description of the topics has been provided in table 14 to demonstrate how comments were coded. Examples of the framework and coded data entry are provided in appendix 15.

The summary findings with illustrative quotes from the interviews follow taking each topic in turn.

Table 14: Topics emergent from interviews

Theme: Context	
Infrastructure	Comments about physical space, equipment and staff and how they affected working practices
Money	References to how money may or may not influence practice or incentivise particular activities
National targets	References to stated national targets and comments as to how this may affect practice
Theme: Mechanisms	
Clinicians' practice	Comments about what factors influence practice – comments that reflect attitudes towards day case LC
Scheduling	Description of current practice and how this affects service; comments on case-mix, ordering or allocation of operating lists
Patient selection	References to medical and social criteria for the selection of patients for day case LC
Protocols	Comments about the presence and use of protocols for day case surgery generally and LC specifically, and how these do/could affect the process
Patient education	Reference to this element in the pathway and the effect it has
Anaesthetic	Comments on whether technique affects the process for a day case LC; comments on the relationship between surgeons and anaesthetists
Pre-admission	Reference to pre-admission processes
Discharge	Comments about current discharge process, whether nurse led discharge is practised and whether this is important
Back-up facility	References to having back up facilities, what they are and how they affect practice
Project groups	References to any project groups that are specifically looking at day case LC and whether they are effective

Infrastructure: physical space, equipment and staff

Of the 20 clinicians interviewed, nine did not have regular theatre lists in the day surgery facilities, despite undertaking procedures that were appropriate

for day case surgery. However these nine participants were still able to describe and comment on the day surgery facilities because they occasionally used these facilities or had done so in the past. The comments relating to infrastructure varied according to the Trusts in which the clinicians worked. These have, therefore, been separated for each trust.

Trust A

This Trust had two separate hospital sites. The only day surgery facility described by interviewees was on the site S and had two theatres, which were predominantly used for hand surgery. However, the adjoining ward area was occasionally used by the upper GI surgeons for 'day case lists', which were performed in the main theatre suite (at site S). This was possible because the main theatre suite was physically attached to the day surgery unit. The clinicians were unable to perform laparoscopic cholecystectomy in this unit because the appropriate theatre equipment was not available and theatre staff was not trained in setting up laparoscopic equipment.

The clinicians would book laparoscopic cholecystectomy in the main theatres at the other site (site Q), where they had their 'own' theatre, staff and equipment. They described their infrastructure here using words such as "*excellent*" and "*brilliant*". It was clear from their comments that they enjoyed the freedom of running their lists as they would like to and strong professional relationships were built between the health professionals. The

importance of this working relationship between the surgeons and theatre staff and anaesthetist was made explicit by one interviewee,

“I prefer to work with a regular surgeon because the working relationship provides better outcomes for the patient” (Anaesthetist 1, Trust A)

This was not a dedicated day surgery unit. They were using main theatres and a surgical short stay ward through which patients were admitted and discharged. There were problems reported by the surgeons who had patients admitted to the short stay surgical ward and this affected scheduling. Three of the surgeons had experienced delays in getting patients ready for theatre. This resulted in lists having to be re-ordered so that theatre did not remain idle. This led to frustration amongst clinicians and often meant they could not rely on starting the list with a patient from the short stay ward or even cancellations. Part of this was attributed to the physical distance between the short stay ward and the theatre block, which were in different wings of the hospital.

Trust B

This Trust was split across two sites, one of which had a diagnostic and treatment centre with six theatres (site D) and the other a day surgery unit comprising of three theatres (site W). The clinicians at each site did not work across both sites and performed theatre lists only at one site. This meant that those at site W were not familiar with facilities at the other site, reflecting also the separate functional nature of the two sites described in the Context chapter.

Site D functioned as an isolated day surgery unit. The surgeons had a lot of praise for the building and space. Comments that were made include *“well designed... has a fantastic atmosphere for people who work there and the patients”* (Surgeon 6, Trust B). The elements described when referring to how well the unit works were the proximity of the ward area and theatres and the use of trolleys that can be used as operating tables and the staff room.

One criticism that was raised by two interviewees was the bottlenecks in the system that affected throughput. The examples given were the recovery area and the number of trolleys, *“the disadvantages are that the total area that has been given for that theatre complex is cramped so there is no place for people to wait...the through put is too quick then patients get stacked up that’s why everything comes to a standstill.”* (Surgeon 6, Trust B)

Clinicians scheduled and performed laparoscopic cholecystectomy here, but most of the surgeons were critical of the theatre equipment at Site D referring

to the poor quality of laparoscopic stacks and instrument sets. One commented the following, “*day surgery lap chole equipment at [site D] are crap*” (Surgeon 1, Trust B) and went on to say this was so dangerous that he would not want to be operated on himself in the setting for this reason alone.

They reported the equipment in the theatres at site W was newer and better. However, the surgeons who were familiar with site W day surgery facilities reported that the equipment for laparoscopic cholecystectomy in this setting was not always complete and needed to be borrowed from main theatres. This was one of the reasons why laparoscopic cholecystectomy was not scheduled on lists at the day unit. Some consultants were not allocated lists in the W day surgery unit and therefore could not take advantage of the benefits a day case facility would offer to their patients.

The interviewees’ comments indicated there was a culture within the day surgery units (sites D and W) that enhanced the efficiency. Anaesthetist 1, Trust B described this by saying, “*the [redacted] is a purpose built day surgical unit, which means they’ve got theatres for day surgery, they’ve got beds close to theatres, recovery is also purpose built and there is this streamlined approach, where the patient gets on to a bed and stays on that particular bed, bed or trolley that is, until they are ready to go. So there aren’t any delays in getting the patient, there aren’t any delays in taking them off to the ward again. And it’s not just the facility, the people working there are tuned into doing things*

quickly and efficiently". Surgeon 3, Trust B also commented on the, "well developed culture of day surgery" at site D. Staff were more focused on streamlining process. Having members of staff dedicated to these units enhanced this mind set and was a key part of the process as they were the health professionals motivating patients post operatively.

The limits on the site W day surgery unit activity were thought to be because of shorter opening hours, lack of laparoscopic theatre equipment and hijacking of the ward area by emergency admissions as reported by surgeons 1, 2, 4 and 5 at trust B. Responses that reflected this, "*at the day case unit at [site W], we haven't done any laparoscopic work...[no] kit, it needs to be transferred...traditionally the unit would close at 5 or 6 o'clock*" (Surgeon 4, Trust B) and "*the ward space is occasionally hijacked by main theatres when we have no beds.*" (Surgeon 5, Trust B).

The advantages of 'stand alone' facilities were raised by interviewees at both trust A and trust B. It was felt they were more efficient, "*well designed and fantastic atmosphere*" (Surgeon 1, Trust B) patients moved through the units better and there was a culture amongst staff that supported the process, "*things are done quickly and efficiently...there is a culture that enhances the process*" (Anaesthetist 1, Trust B). These were features that were also directly observed.

Trust C

At the time of interviews, there was a temporary day surgery facility set up because the trust was in a transition phase. The existing day surgery theatres were being used, but there were temporary ward facilities. There was frustration here among clinicians that the ward area was not suitable and constantly changing through this transition phase illustrated by this comment, *"I have no problems doing lap choles as day cases, it's the facilities"* (Surgeon 1, trust C). There were problems with bed availability and the preparation of patients for theatre and these were resulting in delays and cancellations. One surgeon was using the gynaecology ward and theatre facilities and did not report any problems with the flow of patients in this particular setting.

There were few positive comments about the facility at trust C. The unit was described as *"old and not very nice to work in."* Although this was an area that ideally should work in isolation and close at night, the beds were being occupied by emergency medical admissions and elective surgical patients were arriving on the day of surgery without a bed ready for them. The misuse of the 'day surgery unit' was identified by all the surgeons interviewed at trust C.

A few consultants commented that having the theatres one floor above the admissions area was not ideal and that the small recovery area created bottlenecks.

The consultant using the gynaecology day surgery facilities described experiencing repeated problems with the equipment in theatre and issues with staff – *“substandard equipment and untrained staff”* (Surgeon 1, Trust C). As a result he had actually ceased to perform laparoscopic cholecystectomies here for the last three months because he felt it was unsafe.

He was not alone in his opinions that members of the theatre staff in the day surgery theatres were not familiar enough with laparoscopic cholecystectomy as a procedure or with the equipment that was required for it because they were not as exposed to it as much as those who worked in main theatres, *“Staff in my theatre are very competent with breast problems and even though they are gynae trained and should be used to laparoscopic work, they struggle a bit with the lap chole. I don’t think they fully embrace the procedure. Erm, and I’m concerned that they don’t know how the stacking system works.”* His surgical colleagues at the Trust shared this opinion.

Money

There were variable opinions on how money influenced practice. It was interesting to find that some clinicians were not aware of the best practice tariff that had been introduced for day case laparoscopic cholecystectomy (explained in the Background chapter).

Those who were aware of the change in tariff felt it had focussed the attention of management on the process. Some felt that if management had a reason to

improve day case laparoscopic cholecystectomy rates, they would help clinicians deliver a day case service.

However, even the clinicians who were aware of the best practice tariff felt it would have no impact on their clinical decisions or practise – it was clinical need that determined what they did according to Surgeon 2 at trust B, *“if it’s not in the patients’ interests, clinicians do not respond to the [financial] pressure”*. Surgeon 4 at trust A, summarises the response best in his comment *“I don’t think most clinicians will walk around with the knowledge of how much tariff is...but it shouldn’t really be influencing us that much. We should be doing things on clinical need.”* These data provided evidence that it was a shared opinion across the three trusts rather than unique to one. One clinician’s response to being asked how money influenced their practice was that the clinical benefit for patients who were able to have day surgery outweighed any monetary benefit for the organisation (Surgeon 4, trust B).

Despite the differing financial positions of the trusts, opinions were too variable to demonstrate a consistent impact of money on the process. However, surgeons at trust C referred to money as having a stronger influence on driving the organisation in general and this was reflected in comments such as, *“money drives everything unfortunately”* (Surgeon 2, trust C). This was in keeping with the findings from the baseline report from theme 1 (Shapiro et al. 2010), which discussed how financial constraints were felt by

Trust C more than the other two, although they were all subject to the financial constraints.

National targets

Some interviewees spoke about national targets and drivers in their interviews, but not all. This reflected how important these issues were to the individual clinician or how aware they were of national policies. Even the clinicians that did comment on this topic made brief responses and these varied with little consistency to summarise findings. Four clinicians recognised national targets and drivers as an explicit way of driving day case rates. These clinicians were based at trust B and trust C, both of which were feeling the impact of fiscal scrutiny, which was a finding of CLAHRC-BBC theme 1 baseline phase (Shapiro et al. 2010).

Responses from clinicians based at trust A, showed that although they may be aware of the national context, they were not driven by them illustrated by this quote, *"I don't feel affected by national target"* (Surgeon 4). Interestingly this fits in with the baseline phase findings of theme 1 CLAHRC-BBC (Shapiro et al. 2010).

Clinicians' practice

The majority of the interviewees said they were happy to perform day case LC, but not all were equally enthusiastic about it; two respondents reported that they would not like to have had the procedure themselves as a day case

and referred to the private sector where they “*usually keep cases in overnight*” (surgeon 5, trust B). Interestingly, there was no surgeon who said that they did not agree with the process of performing day case laparoscopic cholecystectomy. The responses revealed that the clinicians felt that a proportion could be day case. The reasons for not booking day case laparoscopic cholecystectomy were shared amongst clinicians and are described further detail below.

Issues that related to infrastructure that hindered practice have been described earlier such as access to dedicated units and problems with equipment and staffing – “*I have no problems doing lap choles as day cases, it’s the facilities*” (Surgeon 1, trust C). The interviews also highlighted how clinicians found it difficult to pre determine the technical difficulty of the procedure based on the patient’s history and therefore it was difficult to plan for a day case operation. This meant that patient selection for day case was difficult.

Almost all the clinicians felt that being able to schedule laparoscopic cholecystectomy first on the list or on morning lists would help the process, “*They should be done first on the list*” (surgeon 7, trust B). Scheduling is discussed in more detail later in the chapter as it emerged as a topic of its own.

It was evident from the responses that there was still some clinical concern about laparoscopic cholecystectomy, *“not straight forward operations... potentially serious harm can be done”* (Surgeon 1, trust C). This resulted in caution amongst some of the clinicians interviewed and why they were less enthusiastic about booking day cases. Some also said they did not want to *“push”* patients out, which was illustrated by the following quote, *“I always have a problem sending people home 10 or 11 o’clock at night, just doesn’t seem right”* (Surgeon 2, trust B).

Another concern that was raised by some interviewees was with back-up processes, which is again described in greater detail below. Worry was expressed about the lack of beds for *“just in case”* (surgeon 1, trust B) admissions or patients who had no access to telephones at home. This was not a concern that was shared by all. One interviewee, who was one of the most experienced surgeons, said, *“I cannot recall a case that was fine at 6pm that has had problems overnight”* (Surgeon 4, trust C) when asked about his thoughts on day case laparoscopic cholecystectomy.

Some surgeons from trust B and trust C felt that the social deprivation and poor general health of their local population had a negative impact on their day case rates. They reported a *“significant number of complex cases”* (Surgeon 1, trust B) because their patients presented late, had a significant number of co-morbidities and were socially deprived. However, there were

other clinicians (surgeon 7, trust B) at the same trust who felt that the patients who suffered with gall bladder disease were generally young and fit (and by implication therefore less likely to need extra facilities). Interestingly, the clinicians at trust A (surgeons 4 and 5 and anaesthetist 2) reported that although they dealt with complex cases and “*regional complications*” (for example common bile duct injuries), the majority of patients they treated with gallstone disease were “*young and fit, straight forward cases*” (surgeon 1, trust A).

Eleven of the interviewees were enthusiastic about day case laparoscopic cholecystectomies. The comments that support this refer to a recognised change in personal practice to perform day case laparoscopic cholecystectomy as described by Anaesthetist 1 at trust B and Surgeon 2 at trust B. Surgeons at all the trusts (Surgeons 3 and 4 at Trust B, Surgeon 2 at trust A and Surgeon 2 at Trust C) estimated that they could perform more than 50% of their elective laparoscopic cholecystectomy as day cases. The following response summarises the enthusiasm of this group of clinicians, “*Every lap chole is potentially a day case*” (surgeon 6 at trust B)

Scheduling

All the interviewees agreed that being able to schedule elective laparoscopic cholecystectomies in the morning or first on mixed lists would make same day discharge more likely.

The allocation of lists in the day surgery units was variable. Of those interviewed nine surgeons did not have a regular day case lists allocated to them. Of those who did, only one reported regularly putting laparoscopic cholecystectomies on their day case list. Those that did not have day case lists allocated to them put day case procedures on their main lists.

Clinicians at trust A described advantages to scheduling mixed lists in a main theatre, as this allowed them to carry out their major procedures such as liver resections and transplantations. The HPB surgeons did not have any lists allocated to them in the day surgery unit. The upper GI surgeons did have lists in the day surgery unit at site S, but were not able to schedule laparoscopic cholecystectomies here because the equipment was not available.

All the surgeons at trust A explained that the mixed lists were more efficient for them because the nature of their other emergency and elective work required scheduling flexibility. The major cases they perform often require high dependency or intensive care beds post operatively. When this happens it is useful for them to start with a 'smaller case' such as a laparoscopic cholecystectomy. In HPB, the nature of their emergency work can often interfere with elective scheduling and when this happens cancer work gets prioritised over the smaller elective procedures such as laparoscopic cholecystectomy. Laparoscopic cholecystectomies therefore tended to occur at the end of the list and patients would not recover in time to be discharged.

The clinicians were content with this set up but consultants, at trust A and the other trusts, could see the advantages of having lists with the same procedure on, e.g. a whole day of laparoscopic cholecystectomy, because theatres function better. They felt that this was efficient and the clinical team worked better together, "*because everyone is in the zone*" as a result of the repetition.

Even in the other trusts, trust B and trust C, that had day surgery units, not all the consultants were allocated lists in this setting. This meant that clinicians would book their day cases on main theatre suite lists. Some would have preferred to have separate day case lists in order to make use of the facilities. They all felt that there were a large proportion of their cases that could be day cases. The limiting factor that was identified here was the lack of capacity for any more lists to be purely within the day surgery setting. Another problem that clinicians raised was being given afternoon day case lists which also meant they could not discharge patients home the same day.

Patient selection

There was very little variation in the medical and social criteria that is used by the clinicians to identify patients who were suitable for day case procedures. The clinicians all referred to ASA grades, obesity and other comorbidities. Age was a factor that was regarded with some variation with some consultants reporting that chronological age does not always reflect the health of the patient. Some of the consultants highlighted that the population

that suffered with gallstone disease were largely middle-aged and therefore fitter.

Although there was little variation in the medical and social criteria, it was recognised amongst the clinicians that determining how difficult the operation was going to be was always difficult. Even patients who described a short, uncomplicated history of gallstone disease could have technically difficult operations. This would mean that even when a laparoscopic cholecystectomy was intended as a day case the patient required overnight observation.

It was interesting that the consultants at trust A felt the majority of their elective laparoscopic cholecystectomies were uncomplicated despite being the tertiary referral centre for complex gall bladder disease and where trust B and trust C would refer to.

Three surgeons from trust B and trust C made comments about the social deprivation and poor general health of their population that they thought had an impact on their day case rates. They felt that as a result of the poor general health of the population, the patients were not suitable for day case laparoscopic cholecystectomy because of pre-existing comorbidities. Three other surgeons felt that the population of patients with symptomatic gall bladder disease are generally young and fit and therefore are suitable for day case procedures.

Protocols

Given the NHS Institute of Innovation and Improvement focus for tackling day case laparoscopic cholecystectomy was using process mapping (Solly et al. 2007) and the literature review discusses papers (Briggs et al. 2009; Calland et al. 2001) that report outcomes after implementation of a standardised protocol, it was felt important to ask the clinicians about this specifically. When asked about protocols or guidelines, the interviewees revealed that some of the processes within the laparoscopic cholecystectomy pathway have guidelines, but this was not consistent between the Trusts and not used uniformly within each Trust. This was demonstrated by comments that showed uncertainty about the presence of established protocols. It was difficult to draw any strong conclusions about this issue.

Specific mechanisms in the patient pathway: Patient education, Anaesthetic,

Pre-admission and Discharge

Nine of the interviewees made comments that illustrated an opinion of patients generally accepting day case surgery, providing they were given plenty of information and prepared. It was important to nurture the 'mind set' of the patients and they found that often patients were happier to go home, *"Patients in the area seem more than happy to accept day case procedures. If you counsel them to expect day cases, they will accept what they are told - it is this education that is important. Many patients prefer to go home to avoid hospital acquired infections"* (Surgeon 1 Trust C). Four clinicians feel that their

patients were less likely to accept being discharged on the same day because they were not prepared and needed time to recover from their operation demonstrated by this quote, *"If patients don't wake up well from the anaesthetic, then they feel like they are being "chucked out" of hospital"* (Surgeon 6, Trust B)

All but one of the interviewees felt that the anaesthetic was an important part of the process that had an impact on the day case rates. The subtle adjustments made by some anaesthetists to the general anaesthetic and post operative pain management seem to make a difference to how a patient feels when they wake up after their operation, *"anaesthetists are not uniform in their approach – some are definitely better than others"* (Surgeon 2, Trust B).

Another important aspect that was brought up through the interviews was the relationship between the surgeon and the anaesthetist. It was felt that by working together on a regular basis the consultants learned to read each other's actions. One example that was given was from an anaesthetist, who said that when the surgeon had clipped the cystic duct and artery, he knew that it was approximately 20 minutes from the end of the operation, so he adjusted his anaesthesia accordingly (Surgeon 1, Trust C) and another describes how he *"prefers to work with a regular surgeon because the working relationship provides better outcomes for the patients"* (Anaesthetist 1, Trust A).

Not everyone commented on this part of the process, but those that did recognised a need for this to be good in order to create a successful pathway. They also referred to it as a relatively successful part of the process.

Discharge

The interviews revealed that the three Trusts differ in their discharge process.

The day surgery units at trust B both had nurse led discharge protocols that were used quite successfully (Surgeons 1 and 2, Trust B). The surgeons described a discrepancy between discharges on the day surgery units and the main wards. Busy surgical ward nurses were less able to focus their attention on discharging postoperative day case patients. This may be because they were not used to motivating and discharging patients post-operatively, "*they [nurses] don't facilitate or promote discharge*" (Surgeon 4, Trust B) or because other more urgent clinical tasks or need divert attention away from the discharge process (Surgeon 4, Trust B). It was also felt by some that the pressure of having to close a unit at night was more focussed on getting patients out.

At trust C, the discharge of day surgery procedures was described differently by interviewees, "*nurse led discharge is just starting*" (Surgeon 1, Trust C) and they are "*just drawing up a nurse led discharge protocol*" (Surgeon 3, Trust C). The belief was that nurse led discharge was not well established here.

Back up facility

During the interviews and the analysis, one of the processes that many participants identified as a potential facilitator or barrier was the type of follow up or 'back up' that was or was not present. Comments or responses that were made relating to this issue were coded as back up facility. Interviewees interpreted back-up facilities differently. Some believed that there should be direct access to the on call surgical team or the acute surgical ward. Others referred to this as a day surgery facility that can remain open overnight allowing patients to be admitted if necessary. What was clear from the comments was that the presence of a back up facility provided surgeons with more confidence to plan a greater number of day cases.

Project groups

This was only relevant in trust B as they were involved in the NHS Institute for Innovation and Improvement pilot for day case laparoscopic cholecystectomy. The Trust had a laparoscopic cholecystectomy project group that met once a month that was actively trying to improve day case rates. However, the clinicians at trust B did not feel that the NHS III pilot had an impact on day case rates. Some surgeons may have been aware of the project group but others had no idea that the trust had been involved with this pilot scheme. The quantitative results demonstrated that trust B performed more day case laparoscopic cholecystectomies than the other two trusts.

Semi-structured interviews – round 2

A second round of interviews was carried out after the ambulatory care centre in trust A had opened and the diagnostic and treatment centre in trust C had opened. These interviews were conducted to explore whether participants had changed their practice at all since the changes to the trusts had been made. A total of 14 interviews were conducted in the second round. Of the initial 20 participants, one retired from work, one declined further interview and five did not respond to follow up interview invitations. One new participant was interviewed in the second round of interviews because they had not been identified during the first round of interviews, but during the project was highlighted as someone who performed a significant number of laparoscopic cholecystectomies. 13 consultant surgeons and 1 consultant anaesthetist made up the 14 second round interviews. The age range was 38 years to 62 years and there was only one female consultant surgeon interviewed (table 15).

Table 15: Summary of interviewee characteristics

Trust	Number of interviews conducted	Age range of interviewees	Gender	Specialties	Years as a consultant (range)
A	3	36-46	3 male	HPB	5-7
				Upper GI	
				Anaesthetics	
B	7	42-55	7 male	Colorectal	4-16
				General & breast	
				Upper GI	

C	4	38-63	1 female	Colorectal	1-24
			3 male	General & breast	

Only three participants reported a change in their role or job plan. Two were no longer doing any emergency work and one had gone from being a locum consultant to a substantive consultant with regular sessions.

These interviews were transcribed and coded in the same way as round 1 interviews. Responses that reflected codes that had emerged in round 1 were kept. The topics that emerged were slightly different from the first round of interviews, but have been grouped into context and mechanisms to maintain the realistic evaluation concepts. There were a total of 10 codes that emerged from the interview coding and analysis. The Framework method was used as before to sort and analyse data.

The new codes have been described below (table 16), but the overall themes of context and mechanism were kept. Two new topics emerged in the second round of interviews and these related to responses about emergency cholecystectomy and the decommissioning of elective cholecystectomy. Several interviewees made comments about these and therefore they were included as new topics in the results. They were both issues, which clinicians identified as influencing the service providing laparoscopic cholecystectomy.

Table 16: Topics emergent from round 2 interviews

Theme: Context	
Changes to infrastructure	Comments about how physical space, equipment and staff have changed or not with any impact on clinical practice
Money	Influence of best practice tariff and financial stability of organisation
Decommissioning of LC by PCTs	Comments about how decommissioning of elective LC may or may not affect clinical practice
Emergency cholecystectomy	Comments on how emergency LC may affect the elective LC pathway
Theme: Mechanisms	
Clinician's practice	Comments about any change in practice (more or less day case activity) and comments that reflect attitudes
Scheduling	Changes to scheduling practices or sessions
Patient factors/education	References to how this is or is not being addressed
Discharge processes	Introduction of nurse led discharge or protocols to aid process
LC project	Comments about any project work aimed at elective LC pathway
Anaesthetic issues	Comments about ongoing anaesthetic issues, or improvements and introduction of protocols.

Changes in infrastructure

As before, this is reported by trust because the physical changes that occurred were specific to each trust. Trust A had opened a new hospital on one site that incorporated an ambulatory care centre. Trust B did not have any new buildings but planned to increase activity through site W day surgery unit. Trust C had a new diagnostic and treatment centre opened.

Trust A

The most obvious change here was the new hospital that was being utilised. It was described as the *"big, shiny, new, bright hospital"* (surgeon 3, trust A).

There was a main theatre suite consisting of 23 operating rooms with a large adjoining recovery area that was more efficient to staff than the old hospital's isolated theatre complexes (Anaesthetist 2, trust A). The clinicians all identified the new ambulatory care unit that had seven theatres of its own with 84 patient 'spaces', which were made up of a few overnight beds, trolleys and chairs. This was seen as an improvement on the old set up at site S as it was clearly defined and increased ambulatory care capacity. It was being used to admit patients who were being operated on in the main theatres as well. However, the ambulatory care theatres were only being used by one of the surgical consultants interviewed. He had not performed any laparoscopic cholecystectomies there yet. It was interesting that despite the increase in day case capacity, that the clinicians that were interviewed did not all have access to using it.

Although the advantages of the large recovery area were identified, two participants identified problems with the size of the new main theatre complex. Due to the size, they found that the flow through theatre was slower than previously. Working practices had to be adjusted to account for the length of time to get a patient to theatre. This also affected the length of time it took for equipment to be fetched.

One of the surgeons described "*huge benefits*" (surgeon 3, trust A) because the new hospital meant that he had access to more theatres and this meant more

operating time. It was not clear whether the increased number of theatres did specifically provide more operating time for individual consultants. No examples of this were given during the interview. The new theatres allowed him to meet colleagues that he would not otherwise meet in the old hospital because all specialties used the same complex rather than the operating in isolated units.

When questioned about any changes in equipment, the interviewees did not identify any changes or problems. The first round of interviews demonstrated they were content with their equipment and this had not been changed so there was no reason for them to have any new comments to make in the second round.

Each of the interviewees had slightly different comments about staff, but this reflected the physical space they worked in and their interactions. For example, the surgeons mentioned how theatre staff had not changed, but that some had rotated (Surgeon 3, trust A). This did not have an impact on clinical practice. An anaesthetist reported the better use of recovery staff because of the new set up (Anaesthetist 2, trust A), but also recognised the short staffing of the admissions area at the start of each day. Interestingly, one surgeon felt that there was no different between the mind set of day care staff and other ward staff (Surgeon 5, trust A), which was different to the other clinicians.

Trust B

This trust was not subject to the large scale physical change that was occurring at the other two. Service redesign, as described in the Context chapter, centred around the reconfiguration of services rather than new buildings. The only changes to infrastructure that were reported here were by two interviewees: the refurbishment of the ward area of Sandwell day care unit (Anaesthetist 1, trust B) and new equipment at the site D (surgeon 3, trust B). Neither of these had made any difference to current practices at the trust when the clinicians were interviewed. The quality of the new equipment was questioned because the surgeon said he was told there was new equipment but did not believe this to be the case.

It was clear from the comments of interviewees working at trust B that nursing staff was enthusiastic about day case laparoscopic cholecystectomy, *“Staff on the short stay ward are keen and geared towards discharging pts. The nursing enthusiasm for day case laparoscopic cholecystectomy and enhanced recovery is helping the process”* (Surgeon 4, trust B). Their involvement was thought to be key to success. Although the cultural difference between the short stay ward nurses and the day care nurses was still reported, *“there is nothing obstructing discharge on the same day, but there may be a cultural issue”* (Surgeon 5, trust B). This reinforced the findings from the round 1 interviews about the working culture in ambulatory care units.

Trust C

A new diagnostics and treatment centre opened with a day surgery unit. This was described as “*okay*” (surgeon 1, trust C), “*looks very nice, lovely theatres, lovely wards*” (surgeon 3, trust C) and “*most of it is wasted space*” (surgeon 2, trust C). There was not the same enthusiasm about the new building here as at trust A and the interviewees did not report any change in practice as a result of the new physical space. No direct change to their operating lists or scheduling had taken place after the opening of the new building (Surgeon 3, trust C). One of the positive comments about the new building was bigger theatres, but this did not seem to make a difference to clinicians and their decision to perform day case laparoscopic cholecystectomy, “*it [the new building] has not had much impact on the clinical side – a outpatient clinic is still an outpatient clinic wherever it is*” (Surgeon 2, trust C). There was no change to equipment reported by interviewees in the second round and the observation period here had revealed that there were issues with this. Therefore, no significant change was described by clinicians that led to any change in their practice.

There were several criticisms about the ward area. The design was described as poor and this made it difficult to nurse. The flow of patients through here was not as smooth as expected. The capacity for patients being assessed in the admissions area was insufficient.

“The new ward has not created new capacity because another ward will close...the layout means that the pathway is slower...there are not enough rooms for assessing patients in the morning.” [Surgeon 3, trust C]

The same interviewee also highlighted how the original designs for the new diagnostics and treatment centre had to be changed because there wasn't enough money. The criticisms about the new physical space meant that clinicians felt that it would not function as well as dedicated day surgery units should and therefore impact on their clinical practice, which included performing day case laparoscopic cholecystectomy. However, the interviews were carried out shortly after the opening of the new diagnostic and treatment centre and processes may not have been completely embedded. It was still felt that day case staff was more proactive than in patient ward staff, who were more sympathetic towards patients (Surgeon 3, trust C). This strengthened the impression that staff working in the day case unit had a different working culture to staff outside this environment.

The same problems that were reported previously about the skill set of nursing staff were reiterated and it was recognised that theatre staff were often apprehensive about laparoscopic cholecystectomy because of the risk of conversion to open. Clinicians felt strongly about this and it did make a

difference to their clinical practice when it came to laparoscopic cholecystectomy.

Money

Although the first round of interviews revealed that clinicians did not feel any direct impact on their practice from best practice tariff, money remained a topic that emerged in the second round of interviews.

“It’s interesting you push something through as a good idea or good practice nobody is interested, the government decides that you get remuneration and it suddenly becomes number one priority.” (Surgeon 3, trust C)

This quote showed how a financial reward drove the change process rather than just good practice. In the first round of interviews, clinicians may have been aware of the current financial climate and constraints but it was not necessarily influencing the practice of individual consultants. The financial driver was something that the trust, as an organisation, reacted to, *“trust view [day case laparoscopic cholecystectomy] should be done because of financial implications”* (Surgeon 5, trust B). Another response that illustrated this was, *“the drive for day case surgery will continue for financial reasons”* (Surgeon 2, trust A).

It was pointed out that the trust received financial rewards in the form of best practice tariff and saving beds, which acted as an impetus for trust

management (Surgeon 4, Trust B) and this would help achieve change. Surgeon 3, trust B recognised that doing day case laparoscopic cholecystectomy would *“help improve the financial situation and anything that would do this is important”*. However, it was not a motivational factor for clinicians because there was no direct gain for them.

The best practice tariff was viewed with mixed feelings, which was probably a reflection of clinical attitudes.

“...ongoing pressure from the enhanced tariff...I think that’s the sad thing about it because the driver for change should be doing things better...but actually economic pressures take precedent” [Surgeon 1, trust A]

“The tariff has had a big push for doing day case laparoscopic cholecystectomy...it’s been a wake-up call although this hasn’t filtered down to nurses...it has made management acutely aware that things need to be done differently” [Surgeon 3, trust A]

Some welcomed the driver for change and others recognised it as a short lived innovation.

Decommissioning of elective cholecystectomy and emergency cholecystectomy

During the second round of interviews, some clinicians identified the decommissioning of elective cholecystectomy and this was followed up in the second round interviews. It was something that had not emerged in the first

round of interviews, but during the months between the two interview rounds, the decommissioning of elective cholecystectomy by Primary Care Trusts or the new Commissioning Care Groups had become an issue for surgeons. It was an issue being negotiated at commissioning boards and was at the forefront of many consultants' minds as surgeon 3 at trust B explained.

If this was put into practice, the impact on performing day case laparoscopic cholecystectomy was seen very differently. Some felt that no day case laparoscopic cholecystectomies would be performed, because the most suitable patients for this pathway would be the ones that were denied the operation by the PCT (Surgeon 1, trust B). Others felt that there would be no change at all and one clinician commented that "*patients will challenge PCTs*" (Surgeon 2, trust C). This did not have an impact on clinical practice during the study period since negotiations were still taking place, but was something that may have an impact on the future.

A further topic that emerged during the second round of interviews was the practice of performing emergency cholecystectomy on patients, who are admitted with symptomatic gallbladder disease. This was generally thought by most consultants as having an impact on the elective workload. It was felt at trust A and trust B and experienced at trust C that the elective cholecystectomies had reduced in number (Surgeon 1 trust C, Surgeon 6 trust B, Surgeon 3 trust C, Surgeon 4 trust C). However, this was viewed by Surgeon

2, 3 and 4 at trust B to have a positive impact on day case rates because the more 'difficult' laparoscopic cholecystectomies would be taken out of the elective pool of cases. Clinicians were also of the opinion that by performing emergency laparoscopic cholecystectomies that their operative skills improved and therefore the elective cases became 'easier' to perform (Anaesthetist 2, trust A). It was also interesting that one clinician at trust C thought that "*emergency cholecystectomy will probably increase in number, but the trust get more money for doing these so this would have greater financial benefit than elective laparoscopic cholecystectomy*" (Surgeon 2, trust C).

Clinical practice

A variety of responses were received when clinicians were questioned about their practice and their opinions in the second round of interviews. Some surgeons said that they were performing fewer laparoscopic cholecystectomies than the previous year because the focus of their clinical work had changed (Surgeon 1 trust C, Surgeon 6 trust B). Only four consultants recognised doing more day case laparoscopic cholecystectomies and three of these were based at trust B. The fourth was from trust A. One of the trust B surgeons reported 80% day case rates when performing laparoscopic cholecystectomy, "*I got better at it...my personal day case rate is 80%*" (Surgeon 3, trust B). It was clear that some surgeons from all trusts were doing day case laparoscopic cholecystectomy and this was also reflected in the quantitative data analysed. At trust C, it was felt that the new diagnostic

and treatment centre had not made it any easier to perform day case laparoscopic cholecystectomy.

Despite one of the trust A consultants claiming to “*throw them (patients) out regardless, but my registrars don’t*” (surgeon 3, trust A) when referring to his laparoscopic cholecystectomy patients, the other trust A consultant interviewed in the second round said, “*we’re now in a better position to start thinking about doing day case laparoscopic cholecystectomies*” (surgeon 5, trust A). It should be noted that these two consultants from the same trust were from different departments; HPB and upper GI respectively, demonstrating that one department was performing day case laparoscopic cholecystectomy but the other had not started yet.

Clinicians’ opinions about day case laparoscopic cholecystectomy had not changed or their enthusiasm to promote it. Surgeons from all trusts believed that it needed leadership to take it forward, although who should do this was not agreed upon. Some felt that the willingness needed to come from surgeons and others thought it should be nursing staff. The “*osmotic culture*” (surgeon 2, trust A) of the NHS was blamed for the slow change, which referred to the slow diffusion of practice change in the NHS. Interestingly one consultant said that he thought colleagues still thought of day cases laparoscopic cholecystectomy as unsafe, but during the interview process, no other clinicians explicitly stated this. Four consultants, two of whom

performed day case laparoscopic cholecystectomy regularly and two who did not, were still not sure whether patients liked it, illustrated by this comment, *“I’m not sure patient’s like it – it’s a major op...It’s being pushed as best practice and is accepted but I’m not sure whether it’s what they want”* (Surgeon 3, trust C). This also demonstrated that admitting and discharging patients the same day was in the hands of the surgeon rather than the patients’ choice.

The extreme opinions of the consultant can be illustrated using the following quotes:

“Those who are not doing day case laparoscopic cholecystectomy should not be doing it at all” (surgeon 3, trust B)

“I don’t think there is any clinical evidence that a day case laparoscopic cholecystectomy is any more superior than an overnight stay laparoscopic cholecystectomy” (surgeon 4, trust B)

These were both comments from consultants at the same trust, which demonstrated that clinical opinion was not shared within the same trust.

At trust B, regular updates were provided for the surgeons about their day case laparoscopic cholecystectomy rates, which was introduced during the study period, broken down by consultant, and it was assumed that this would create healthy competition between the clinicians. Although this was the case for two of the surgeons, the others felt it just made them aware but did not

encourage a change in clinical practice. It did reflect that there was more awareness about delivering laparoscopic cholecystectomy as a day case procedure.

It was clear that the awareness about day case laparoscopic cholecystectomy had increased through responses such as,

“I keep hearing that day case laparoscopic cholecystectomy rates are not as high as they should be” (surgeon 1, trust B).

“I think there’s an awareness and a desire to do more of it” (surgeon 2, trust B)

“Now it seems unreasonable to keep patients in” (surgeon 8, trust B)

Despite this increased awareness being reported amongst the interviewees, they did not report that clinical practice had changed as a result. The quantitative data did show that day case laparoscopic cholecystectomy rates did increase, but it was not clear from the interviews whether something specific had led to this.

Specific mechanisms in the patient pathway: Scheduling, Patient

factors/Education, Anaesthetic, Discharge Process

Only one consultant at trust C reported a permanent change to their scheduled lists. Therefore the majority felt most of the problems they were experiencing before were no different and so their day case laparoscopic

cholecystectomy practice had not changed. Those that did not have day case lists, were still not allocated day case lists (Surgeon 3, Trust A) because of lack of capacity in the new units. Those that had afternoon operating time were still finding it difficult to implement the day surgery pathway for their gall bladder excisions, *“the problem with laparoscopic cholecystectomy still that they are done late in the day and so they end up staying overnight...I’m still pushing for a list in ambulatory care, but there is no capacity”* (Surgeon 3, trust A). This made it difficult to change their practice even when the planned changes had taken place.

However, four of the clinicians from all three trusts said they were trying to place laparoscopic cholecystectomy first on the theatre list in order to encourage discharge the same day (Surgeon 4 at Trust A, Surgeon 5 at Trust B, Surgeons 3 and 4 at Trust C).

The changes described with regard to patient factors and patient education centred on the patient education process and the management of their expectations. The clinicians had previously highlighted how important this process was. In this round of interviews it appeared that there was more reinforcement of the same day discharge message by all staff members. It was clear that the consultants were informing patients that they would be day cases, *“the primed patient will be ready to go home”* (Surgeon 3, trust B). Although, the problem identified was that not all members of the medical

team reiterated this message, *“I tend to throw them [patients] out regardless, but my registrars don’t”* (Surgeon 3, trust A).

Anaesthetic issues were highlighted in the first round of interviews as an influential part of the process by almost all participants. In the second round of interviews the issues raised were reiterated, but there was a sense of improvement in this area. However, there were no protocols or guidelines implemented during the interim period.

Clinicians reported that there was still variability in the way anaesthetists dealt with patients, but those with regular anaesthetists found patients had fewer post operative recovery problems. The reduced use of opiates was a key part of the process, something that even the anaesthetist agreed was good practice.

At trust A one of the consultants described *“a set of skilled anaesthetists”* (surgeon 5, trust A) and at trust B it was felt that *“there’s a lot of good registrars and they have better day surgery mentality”* (surgeon 3, trust B).

At trust B, there had been some effort to introduce an anaesthetic guideline, but as with many guidelines, the uptake was poor and the surgeons sympathised with their colleagues recognising how, *“people don’t like being told what to do”* (surgeon 2, trust B).

Responses from participants about the discharge process were more consistent than in the previous round of interviews. Some form of nurse led discharge was now in practice at all the trusts, but to various extents. It was already well established at trust B and this continued to be successfully implemented using protocols. Nurse led discharge had been introduced at both trust A and trust C to varying extents. Clinicians could opt in to nurse led discharge at trust C and though not all did, they supported the nurses in this process. It was also introduced at trust A in the ambulatory care unit but it was not clear from the interviewees how successful it was.

Laparoscopic cholecystectomy project work

This only applied to trust B, as it had participated in the NHS Institute of Innovation and Improvement process mapping innovation. After the end of this process, regular meetings within the trust continued to tackle the day case laparoscopic cholecystectomy pathway. However, its impact was not recognised amongst the interviewees. One the consultants said that he attended the meetings but had no commitment to it beyond that (Surgeon 2, trust B).

7. Discussion

The findings of both qualitative and quantitative inquiry have been brought together in this chapter to provide an explanation for the trend in day case laparoscopic cholecystectomy rates at the case study sites.

The presentation of the discussion has been organised into four categories, which were initially described in the literature review. These were the characteristics of the health care system, the characteristics of the patients admitted, clinical practice style and organisation of hospital care (Morgan & Beech 1990).

As demonstrated in the literature review the reasons for the variability in day case rates fit neatly into these four categories and as found in this study the themes also fit neatly into these four categories as well as relate to the concepts that were described in realistic evaluation in the Methodology chapter. The characteristics of the health care system and the patients admitted described the context within which the trusts operated and the clinical practice style and organization of hospital care were the mechanisms through which service was provided.

Characteristics of the health care system

The topics that emerged and fit into this category were money, national targets that organisations were expected to reach and the decommissioning of elective laparoscopic cholecystectomy.

At the outset of the study, a best practice tariff was introduced by the Department of Health (Department of Health 2010). It was introduced for day case laparoscopic cholecystectomy, specifically to incentivise activity by paying more to trusts, which achieved a 60% laparoscopic cholecystectomy day case rate. Comments from the clinicians interviewed in the first round highlighted money as a driver for change for the trusts as organisations, but that this had little impact on individual clinical practice according to the responses received. In the second round of interviews, this opinion had not changed. Most consultants knew about the best practice tariff, but at best it was seen as an innovation that focused trust management on the issue and not a direct driver for individual surgeons to perform day case laparoscopic cholecystectomy. However, the day case rates for laparoscopic cholecystectomy did increase, as demonstrated in the quantitative data presented, and this may have been a reflection of the organization pushing things and indirectly influencing clinicians or other elements having a greater or more direct influence.

If the views of clinicians participating in this study reflect those from other Trusts, it raised questions about whether the financial incentive that was introduced facilitated any change. The incentive may appeal to trusts' corporate agenda, but did not provide a direct reward for clinicians. This was different to the 'aligned incentives' that are used in the Kaiser Permanente system in the United States, where surgeons personally benefit from a change in practice (Light & Dixon 2004). It suggested that other factors have a greater influence on day case rates than simple financial ones.

Despite the increase in day case rates that was demonstrated in the quantitative data, the trusts in the study did not illustrate a day case rate of >60%. It was not clear whether any of the trusts actually received the best practice tariff. This target figure was the same as the one suggested by the British Association of Day Surgery (Jackson & McWhinnie 2007), although the Literature Review did question whether this was achievable given the data presented in the papers reviewed. What has not been reported in this study was the overall day case rate for day case procedures, so it was unknown whether the 75% day case rate suggested in the NHS Plan (Department of Health 2000) was achieved by these trusts. Day case laparoscopic cholecystectomy was seen as part of the bigger national picture to reduce length of stay and create efficiency by all trusts. However, it was outside the realm of this study to report these specifically.

In the second round of interviews, it was evident that another issue emerged: the decommissioning of elective laparoscopic cholecystectomy by the commissioners. This had not come into practice, but it was thought by clinicians to influence their future work, although there was some discrepancy about how this might impact on day case laparoscopic cholecystectomy rates.

The analysis of the quantitative data that was important to the context and a reflection of the health system was the numbers of elective laparoscopic cholecystectomy that were performed in the trusts between 2006-2011. This demonstrated a relatively static operation rate over the five years with similar numbers of operations at each trust. This meant that surgeons were performing a similar number of laparoscopic cholecystectomies year on year for the period examined as part of the study.

Characteristics of the patients admitted

Analysing comments from participants about the characteristics of the patients they admitted for elective laparoscopic cholecystectomy, clinicians agreed on many of the criteria used to assess patients' suitability for day surgery, such as the American Society of Anaesthesiologists (ASA) grading (Appendix 4), body mass index and the number of comorbidities. Essentially patients, who were appropriate for day surgery, scored 1 or 2 on the ASA classification, were not too overweight and had no, or few, comorbidities. This

was in keeping with guidance from the British Association of Day Surgery (McWhinnie et al. 2004).

However responses about how clinicians perceived their case mix and patient demographic varied depending on their primary site of working. Data from the regional Public Health Observatory (provided in the chapter on Context) about the demographics of the population in the local authorities demonstrated that the population had some of the worst health and deprivation indicators in England.

Clinicians at trust A, despite dealing with complex cases because of their tertiary referral status, still felt the majority of their patients they performed laparoscopic cholecystectomy on were young, fit and straight forward. This correlates with the quantitative data analysed, which showed that patients that had laparoscopic cholecystectomies at trust A were 47 years old and had a Charlson comorbidity Index of 0. However, clinicians at the other trusts also discussed complex cases and it was important to clarify the definition of 'complex cases' by clinicians at trust A was different to those from trust B or C. When participants from trust A talk about 'complex' cases, they were referring to patients that suffer with problems such as liver cirrhosis.

Opinions of clinicians at trust B depended on their main site of work. Some of the consultants identified patient factors as a barrier to performing day case laparoscopic cholecystectomy. Other consultants recognised symptomatic

gallstone disease to be in the younger, fitter population. The quantitative data presented in the Context chapter supported the perception that the population as a whole was not suitable for high day case rates. However, as mentioned above, the demographics presented in the Results chapter on the cohort of patients that underwent elective laparoscopic cholecystectomy were young (average age of 47 years old) and healthy (Charlson comorbidity index of 0). This supported the perception of those clinicians who recognised they were performing elective laparoscopic cholecystectomies in younger, fitter people.

Trust C clinicians recognised that the patients who were having elective laparoscopic cholecystectomies were healthier and younger, despite the demographic of the population in the local authority. Therefore, the perceptions of the clinicians at trust C were reflected in the quantitative data as reported.

The important finding here was that some clinicians thought that they could not, or should not, perform day case laparoscopic cholecystectomies on their patients because they were not suitable day case surgery candidates.

Examining the quantitative results specifically, the patients, who were operated on at the three trusts, did not have any significant differences in their demographics (age or comorbidity index), but there was clearly a difference between the day case rates at each trust. There was, however, a

difference in income rank score between the trusts. Trust B patients had a lower income rank score but trust B also had the highest day case rates over the 5 years. This meant that other factors influence day case rates beyond patient characteristics.

Clinical practice style

The interviews captured the opinions and practices of a wide range of surgical consultants who were trained both in the UK and abroad. They were from a variety of specialties. Some were very new consultants (in post for 6 months) and others very experienced (in post for 24 years). This meant that some consultants had experienced the laparoscopic revolution and for some it was the norm. However, whether they had learned to use laparoscopic equipment as a consultant or had been trained to use it, did not appear to influence the opinions or practices of consultants with regard to day case laparoscopic cholecystectomy.

The analysis of the first round of semi-structured interviews suggested that clinicians vary in their attitude to performing day case laparoscopic cholecystectomy. The reasons for not using this pathway (irrespective of hospital) raised a number of issues, for example the scheduling of laparoscopic cholecystectomy only on morning lists. The study did not examine admission and discharge times for the elective laparoscopic cholecystectomy patients so no comment or conclusion can be made about

whether it was only possible to discharge patients if they were operated on in the morning. However, the study did demonstrate that scheduling was quite clearly a factor impacting on the clinicians' practice. There were clinicians who were willing to book and perform day case laparoscopic cholecystectomy for their patients but did not have access to a morning list or the nature of their other operative work meant that less priority was given to this group of patients. This had not changed by the time the second round of interviews was conducted. The study does suggest that this would be an issue to address further by organisations in order to facilitate their clinicians in their practice and achieve better day case rates.

There were clinicians whose opinions suggested that they were unlikely to change their practices whatever the external evidence was and those clinicians were not unique to a particular trust. This meant that the clinical attitudes amongst clinicians were similar across the trusts and that those at one trust were not bias towards or against the service. Therefore, it did not explain the difference in day case laparoscopic cholecystectomy rates between the trusts. The mixed levels of enthusiasm for day case laparoscopic cholecystectomy were demonstrated in the first round of interviews by the summary and quotes provided in the results section. The second round of interviews still demonstrated a varied level of enthusiasm for day case laparoscopic cholecystectomy, despite awareness of the pathway being more acute. Although individual opinions about day case laparoscopic

cholecystectomy affected individual clinicians and the decisions they made about their patients, it did not necessarily influence the opinions and decisions of those around them or indeed the organization, as a whole.

Variation in individual clinical practice was not analysed quantitatively but was indicated in the interviews. It has been recognised since the late 1980s and so was not something unique to the three trusts studied. It continued to be an issue, demonstrating the complexities of the 'human element' (Broughton & Baskerville 2004) in the day case laparoscopic cholecystectomy pathway. The question this leads to is how do you encourage less enthusiastic individuals to change their practice? In this study, the interviews demonstrated how individual clinicians react differently. For example only three clinicians were motivated to do more laparoscopic cholecystectomy because individual day case rates were being circulated at the trust, but others at the same trust were not motivated at all by this.

The study highlighted the importance that clinicians gave to anaesthetic techniques in the day case laparoscopic cholecystectomy pathway. The importance of this part of the process was clear from comments in both rounds of interview. There was a strong feeling that anaesthetic techniques adapted for day surgery could enhance the patient recovery and experience and the lack of such techniques may reduce the numbers of day cases. These comments came from doctors at all trusts and so they were likely to be

relevant in the wider clinical community as well. It is also supported by a number of publications (McWhinnie et al. 2004), which describe a 'cocktail' that ensures a better post operative recovery minimizing pain, nausea and vomiting. Professional bodies, such as the Royal College of Surgeons, recommend that both surgeon and anaesthetist are experienced in day surgery for the best outcomes. This was supported by a paper that surveyed unplanned admission rates after day case procedures and symptoms after discharge and related this to the grade of the anaesthetic provider (Hanousek et al. 2009). This demonstrated lower unplanned admission rates and post operative symptoms in patients who were anaesthetized by consultant anaesthetists when compared with those who were anaesthetized by staff grades or trainees. Given the available evidence in the literature and the opinions of participants in the study, it emerged as a real issue that needs to be addressed to better day case laparoscopic cholecystectomy rates.

What was clear from both first and second round interviews was that the culture of a diagnostic treatment centre or day surgery unit was different from the rest of the hospital and this affected nursing and theatre staff as well as doctors. However, even when they do exist, such units were not necessarily set up for performing laparoscopic cholecystectomy nor were they available to all clinicians, because their limited capacity was under pressure. This was evident in the first round of interviews and still evident in the second round despite the new ambulatory care facility at trust A and the diagnostic

treatment centre opened at trust C. Both of these trusts had surgeons who were willing and enthusiastic about day case laparoscopic cholecystectomy but they could not take advantage of the facility or the culture that dedicated day surgery units provided. The quantitative data demonstrated that there was an increase in day case rates in all three trusts, all be it different rates of increase in day case laparoscopic cholecystectomy. The increase in day case rates becomes steeper in the financial year 2009-10, as shown in the temporal trend graph 9, and this was prior to the new ambulatory care and diagnostic treatment centres being established. Therefore, the rise in the day case laparoscopic cholecystectomy rate that was demonstrated in the quantitative data cannot be all attributed to the change in infrastructure or service redesign processes because the increase began before the changes. The rise in day case rates may be just a reflection of the changing culture through osmosis in the organisations.

Clinicians rationalized reasons (often linked to the organization of hospital care) for not being able to do day case laparoscopic cholecystectomy, such as 'operative scheduling' or 'poor back up facilities'. It was difficult to ascertain whether these were genuine issues and whether changing these elements would indeed enable any change in practice because these were not processes that changed during the study period.

Organisation of hospital care

Before the new hospital was opened at trust A, the clinician's enjoyed having control of their own environment and the freedom to organize their wards and theatres. They were content. The very limited access to day case units was not seen to be an issue. However, the busy and slightly chaotic short stay ward area was a challenge for nursing staff and the clinicians also reported their frustrations with the way it functioned in the interviews.

There was a pathway that patients who were electively admitted for laparoscopic cholecystectomy but this was generic for all day surgery patients and, as witnessed, cancellations occurred. It was not seen as a clearly defined pathway as interviewees were not able to describe the pathway or its use in any great detail despite being specifically asked about it. The interviewees did not feel that the existence of the pathway addressed the problems with cancellations or delays that they experienced.

The qualitative findings from the study about day surgery units concur with the reports mentioned at the outset of the study (Audit Commission 2001; Darzi 2002; NHS Modernisation Agency 2004), which described the benefits of day surgery units when they are separate from the main spine of the hospital. The findings here also supported the idea that day surgery units nurture a culture and a patient passing through this unit was more likely to be

treated as a day case. The qualitative data presented in this study also showed an appreciation from clinicians for the modern environment.

However, despite the diagnostic and treatment centres being built or day surgery units being physically present, they cannot always be utilized by clinicians for specific purposes. The interviews here clearly demonstrated how day surgery units at trust A and B were not being able to perform laparoscopic cholecystectomy because the equipment was not available or the opening hours of the unit did not allow it. In the second round of interviews, by which time all trusts had their own ambulatory care centres up and running, the responses showed that some clinicians could not take advantage of the facilities and the advantages it would offer for day case patients because they were not scheduled to work within them. This meant that capacity was an issue and perhaps holding some clinicians back.

The analysis of quantitative data demonstrated an increasing rate of day case laparoscopic cholecystectomy at trust A even though the surgeons were not able to use dedicated day surgery units for this work. Although this was a reflection of HPB departmental activity because the upper GI clinicians reported that they had started thinking about day case laparoscopic cholecystectomy only in the second round of interviews.

This variation in practice between departments within the same trust was highlighted in the interviews, but the quantitative data to support this was

not available. This is an interesting area to explore further and if quantitative data complemented this finding, it would demonstrate the interdepartmental variation that has been reported in the literature (Morgan & Beech 1990).

At trust B, access to day care units was slightly better, although many surgeons reported not having a dedicated list in the day surgery units at site D or site W. Between the first and second round of interviews there was no change to physical space, utilization of day care units or scheduling of theatre lists. Plans to introduce laparoscopic cholecystectomy in site W day care had not materialized, yet the quantitative data shows trust B to have the highest day case rates of the three trusts. This meant that it was possible to increase day case laparoscopic cholecystectomy activity without increasing surgeons' access to dedicated day case units.

Similar to trust B, participants at trust C had newer day care facilities, but it was reported from the second round interviewees that they had not contributed to a change in clinical practice. Access remained an issue, as reported in trust A. This was a considerable problem because the clinicians here were quite enthusiastic about the pathway. They recognised it provided better patient experience and financial rewards. Therefore the evidence the study provided did not draw a conclusion unique to all trusts on the issue of having a day case facility because not all clinicians had access to it and the trust that achieved the highest day case laparoscopic cholecystectomy rates

had no change to the physical infrastructure or clinicians' access to existing day case facilities.

Issues about the use of elective facilities and the perceived lack of capacity have previously been reported by the Audit Commission (Audit Commission 2001). However, other authors have also reported day surgery units not being used to capacity (Healthcare Commission 2005). The responses from clinicians at the three study sites may not precisely mirror how infrastructure influenced practice at other trusts, but it suggested that it was important for other trusts to reflect on their own service pathway. Having the day case facility appeared not to be enough to increase day case rates but it was the way it was utilized that also mattered. It was particularly interesting that trust A clinicians interviewed were not given access to the new ambulatory care unit.

The issues that were described at each trust were not unique to each because capacity was a problem at all of them. This, and other factors, was likely to affect most acute trusts, not just the three case sites. Despite the implementation of the changes at the three trusts, impact was inconsistent according to the findings in the interviews. This leads to the conclusion that the opinions and perceptions of the clinicians had changed little during the course of the study or after the changes had been implemented. However, the quantitative data shows that there was a change in practice occurring, but it

was not clear whether this was an outcome based on changes to context or mechanism. Whether it was the involvement in change that was the facilitator or the changes themselves cannot be determined.

This inquiry has demonstrated a change in the day case laparoscopic cholecystectomy activity at the trusts. It showed a significant increase in day cases at each trust. Some have improved day case rates more than others; trust B fared better than trust C and trust A.

It was possible there was a link between the changes and the trend in activity at each of the trusts, because of the apparent rise in day case rates after 2009, but this cannot be proved. It may be a normal trend, but only by analyzing further years of data would it be possible to determine whether this was an isolated leap in day case activity levels or just chance. It was also possible that the trend in activity demonstrated was a result of the inquiry itself – Hawthorne effect (Harvard Business School 2012). As described in the original Hawthorne studies, clinicians may consciously or subconsciously change their practice when they are aware of their practice being observed or monitored. It was quite possible that the interview process may have made clinicians more aware of issues such as the best practice tariff that they were not aware of previously.

Interestingly the trust that made the most progress in day case laparoscopic cholecystectomy was the one that did not undergo major structural change.

The clinicians working at trust B did not perceive that the NHS Institute of Innovation had much of an impact on the day case laparoscopic cholecystectomy rate, but it was quite possible it had more of an impact than thought. The qualitative data shows that enthusiasm for day case laparoscopic cholecystectomy was not exclusive to trust B so the clinical attitude was no different to those at other trusts. What the study has not measured, but may influence practice was the culture at each trust. This was something that could be explored further.

Limitations of study

A good piece of research questions the process and appreciates the limitations of the process and consequently the findings. This section outlines the limitations of the study and provides a critique of the methods and findings.

Although this research had qualitative and quantitative findings, the most substantial part of the study was the qualitative element. It was appropriate to use appraisal tools that were specifically generated for qualitative research. I have used the guidance provided by Kuper (Kuper et al. 2008) in the form of the following six questions:

1. Was the sample used in the study appropriate to its research question?
2. Were the data collected appropriately?
3. Were the data analysed appropriately?

4. Can I transfer the results of this study to my own setting?
5. Does the study adequately address potential ethical issues, including reflexivity?
6. In conclusion, was what the researcher(s) did clear?

Sampling

There were two sampling issues that need to be addressed; the case study sites and the participants.

The trusts that participated in the study were not selected by the researcher. They had already agreed to be part of CLAHRC BBC prior to the study being conceived or designed. This makes the case selection “convenient” and “opportunistic” (Miles & Huberman 1994), although it did provide ‘buy-in’ from trusts to the work being carried out (including this study) by CLAHRC-BBC. This meant access to the cases was convenient and readily available and that there was a conscious effort from the organisations to redesign health services that had already been identified. The flaw here was that the cases were not purposefully selected for any reason other than their participation in CLAHRC BBC.

However, it could be argued that the ‘convenient’ case selection provided a description of what happened at three very different trusts, which can be used by other trusts to refine process depending on which organization they relate to. For example, a tertiary hospital in London may relate to the findings

of trust A, rather than trust B or trust C. Also, any consistent responses that were recorded for each topic across organisations allowed the inference of generalisations that were relevant to all trusts. For example, the finding that all clinicians felt being able to schedule laparoscopic cholecystectomies on morning lists would improve same day discharge.

Case selection was an important part of study design (Keen & Packwood 1995) and should be purposeful, although this was not possible given the setting within which the researcher was working. Purposive sampling of cases would mean picking a representative sample. For this study, this could be:

- A selection of similar sized district general hospital trusts
- Trusts selected according to the demographics of the population they serve
- Trusts selected depending on their day case laparoscopic cholecystectomy activity.

The strengths of using a collective case study method of inquiry allowed a better understanding of each trust enabling refinement of contexts and mechanisms to achieve objectives in each trust. It also allowed a better understanding of the issues affecting clinical practice.

Participant sampling was purposive and included the clinicians who were directly involved in the decision making process for patients undergoing

cholecystectomies. This was necessary rather than random sampling of clinicians because those who did not perform cholecystectomies (for example, care of the elderly physicians) were not selected. Some may argue that random sampling of the chosen clinical population could have been performed, however for surgeons, the numbers were small and it was felt that all could be invited to participate in order to achieve data saturation. Anaesthetists were sampled in the purposive way but also identified using snowball techniques to ensure that those who regularly anaesthetized cholecystectomy patients were included. It was reported in texts that snowball sampling was criticized for not being representative (Gray 2009).

Reasons for invited participants not to be interviewed cannot be identified because those who did not respond to invitations after a second time were not contacted again. This was the case for a few surgeons from each trust. The sample size of anaesthetists was small and this was because many did not respond to invitations to participate in the study. One explanation for this may be that they felt uncomfortable talking to a surgeon about their opinions. This small sample size makes it difficult to argue that the data presented was representative of their views and opinions.

Data collection

The methods used for data collection were described in the methodology chapter and the justification for these were also stated. Literature to support this justification has been provided.

The semi-structured interview was a recognised qualitative research method that allowed exploration of attitudes, beliefs and perceptions that then influence decisions, actions or non-actions. In keeping with other qualitative research methods it was particularly good at identifying factors that contribute to delivery of a service, exploring organizational aspects and the contexts in which service was being delivered. Therefore the greatest strength of this study was in its qualitative nature.

However note must be made of the 'Hawthorne effect' in this study, as described in the discussion. The act of conducting the research could have impacted on the findings and influenced participant behaviour. Awareness of government targets and the introduction of best practice tariffs may have been increased by the researcher. This in itself could have increased day case activity despite the success or failure of any other redesign processes.

The use of multiple methods in the study was to provide triangulation. This was the "comparison of results from either two or more different methods of data collection or from two or more data sources" (Mays & Pope 2000, page 87) to look for convergence of findings. In this piece of research triangulation

was attempted by using both observation and interview techniques. The descriptive quantitative data was also used to examine whether clinical opinions on demographics were statistically true. This was a strength of the study making it richer and more comprehensive.

Data analysis that begun and continued with the collection process meant that it could inform the data collection. As a result the emerging topics should reflect those most important to interested parties and ensure that researcher preconceptions did not guide data collection. The use of Framework method to organize and analyse data allowed intra and inter organizational comparisons to be made about responses to questions. This was useful in drawing out emerging themes, consistent and differing opinions and therefore generating hypotheses for future studies.

Concurrent analysis of data during the research process showed that there were no new topics emerging towards the end of data collection periods, which would indicate data saturation was reached. This was the goal with qualitative data collection to ensure that there were no gaps or missing data. However it was always difficult to be sure of this if there were issues with data collection and interpretation. Due to the small number of anaesthetic consultants, it was quite possible that data saturation for this group of individuals was not reached, although many of the topics that were discussed were similar for both surgeons and anaesthetists.

Response errors (Patton 1990) refers to information provided by interviewees that is inaccurate because they may have misunderstood the question or given what they feel to be the appropriate response rather than what they actually feel. The pilot interviews were performed to reduce any misunderstanding of questions, but although there was a guide for the interviewer, the questions were purposefully not fixed in order to provide the flexibility of semi-structured interviews. This left questions open to misinterpretation by the participant. It was the skill of the researcher that minimized misinterpretation by clarifying questions and guiding the participant to provide useful information during the interview process. In doing so, it was also important in qualitative research that information that was offered during data collection was not disregarded as it could potentially be pertinent to the study. This made it challenging for less experienced researchers as the inductive approach means that there was no predetermined theory or assumptions of what was important information and issues may have been missed.

Researcher bias also impacted on response errors. The researcher bias arose not only from the researcher's background and status but also how the subjects responded to this. There was little that can be done to minimise this, but when reporting qualitative research it had to be acknowledged and described. In order to address this issue further, the next section has been written in the first person because it explains who the researcher was. As a

clinician, I belonged to the same professional group as those being interviewed so this should have allowed for a good rapport to be built between interviewer and interviewee.

Other errors may have arisen from processing the data. This would have been as a result of my “processing skills” (Black 1993) due to my experience in qualitative research. Specifically this related to the way data was interpreted and coded into the framework. I may have failed to follow up on potentially important information relating to the day case laparoscopic cholecystectomy and therefore topics may have been missed.

It was also important to critique the method of data collection in terms of timing, technique and researcher bias. The time frame of the study was relatively short to capture changes to process and attitudes. Observation and semi-structured interviews were used because it was felt this would provide data required to answer the question the study hoped to answer. The reliability of the qualitative data could be questioned because of my inexperience with observation and interviewing.

Limitations of the time frame were recognised. If the study could be conducted over a longer period of time, it would be possible to make comment on the sustainability of changes, or whether changes occurred over the study period regardless of service redesign processes. The collection of outcome data for a further four years allowed a more accurate description of

trends in day case rates. However, the purpose of the CLAHRC was to collaborate with the Trusts and the ongoing evaluation of service redesign was intended to provide feedback of data in a timely manner to inform further service redesign. This was important to reduce the research to practice gap that the CLAHRC was seeking to address through its work and so there was a compromise in the amount and timing of data collected.

The quantitative data was extracted from central databases, mainly Hospital Episode Statistics. This limited the data that could be collected easily and as mentioned in the methodology chapter carries its own limitations. Other forms of quantitative data could have been collected and would have been useful, but time and resource limited the ability of the researcher to collect this.

When carrying out research in natural settings, such as NHS trusts, the researcher has no control over the environment of interventions that occur. This had its advantages and its disadvantages. It provided a realistic picture of what happens in the real world rather than in a controlled environment and therefore provided a better picture of how things may play out. However it also meant that it became difficult to define exactly what was happening. As the researcher, I had no control over interventions and it was not the intention of the study to introduce and measure change outside those already taking place.

Data analysis

A recognised system of data analysis, the Framework method, was used. It allowed a thematic analysis of interview findings and the comparison of data across the trusts and within trusts. This was important to the study in order to recognise whether clinicians' views on day case laparoscopic cholecystectomy were consistent within a trust, for example not being able to plan day case laparoscopic surgery in one trust because the equipment was not available within the day case setting. At the same time, the Framework Method was able to highlight differences in opinions within the same trust, for example the perception of population suitability for day case surgery. It was also able to identify topics where the view of clinicians was shared across trusts, such as the scheduling of laparoscopic cholecystectomy at the beginning of a theatre list to help enhance day case rates.

The Framework Method is commonly used for the analysis of semi-structured interviews, which was the main data collection method used in this study. This method of analysis can help explain what is happening in a certain context and contribute to planned improvement of health services (Gale et al. 2013).

The process of coding transcribed interviews generated the topics within the themes of context and mechanism. This was important as it reduced any researcher bias that may have predetermined topic headings. It means that

the topics that have emerged were those topics, which were most pertinent to the participants.

Throughout the study period an audit trail was maintained. The interview guide was piloted with clinicians outside the cases. All interviews were taped and anonymously stored on secure hard drives using unique identifiers. If necessary, the original data can be accessed, coded and interpreted for verification of the findings. This was important for providing rigour to the study.

Greater rigour could have been achieved by having more than one researcher to interview, code and observe. This would have provided more validity and reliability to the study and also challenge any researcher bias. If the same findings, interpretation and conclusions were still reached by multiple researchers, this would add to the strength of the study.

Transferability

Qualitative research findings were dependent on the context in which the research was carried out. A simple illustration of this in this study was the opinions clinicians gave about their work setting (infrastructure). Therefore in order for any findings to be generalisable, the reader needs to decide if their work setting was similar enough to the case studied and whether it has any meaning for the reader (Kuper et al. 2008). This study recognized the variable contexts of each case but the findings identified some common

topics, for example, the importance of anaesthesia on the process, it helped to enhance the understanding of the influences on delivering day case laparoscopic cholecystectomy for all organisations. This qualitative work has provided a clearer insight into the issues that are important to doctors, who are key stakeholders in this process, and their practice of day case laparoscopic cholecystectomy. It helped to explain why hospitals have varying day case rates and why the national average was only 6.4% (Solly et al. 2007).

It was important for this research to have some transference in order for progress to be made in the delivery of quality health services. This dilemma, research that provided significant findings and some level of transference, was recognised by evaluative researchers (Clarke & Dawson 2005) and this study was no exception to this.

Without evaluating what was happening at other similar trusts using the same methods, it was difficult to know whether any of these trusts were displaying atypical behaviour. This was a widely reported problem with case study research (Bryman 1988).

Reflexivity

Qualitative research acknowledges the presence of researcher bias, which was a consequence of my gender, background, prior training and credentials (Britten 1995). These were provided in the Background chapter. This was

important as it affected how participants related with me, as the researcher, but also how I interpreted the findings of the study.

My clinical background, experience of working within two of the trusts, and membership to the CLAHRC BBC team provided access to the organisations that other researchers would have found difficult. My clinical background, as a surgical trainee, allowed me to introduce myself as a practising clinician and therefore create a good rapport with participants from the moment of inviting them to participate. It also allowed a level of trust to be established between the interviewee and interviewer that other researchers would not be able to recreate. It may also explain why response rates were better from the surgical community than the anaesthetic community.

As a researcher my research skills were not extensive. I have used both qualitative and quantitative techniques for different projects. Black (Black 1993) lists thirteen “process skills of social science research” which researchers possess. I have used this to help critique my process skills.

Qualitative interviewing is a learned skill. The interviewing technique can be monitored by listening to interviews and critically appraising them and asking other experienced qualitative interviewers for their comments. This would provide feedback on the researcher technique and whether the data collected was flawed. Awareness of the problems of qualitative interviewing, which range from interruptions, being careful not to influence the

interviewee by the interviewer's opinions and not gathering the necessary information, help to carry out a successful interview. I was familiar with this from my previous experience and from qualitative reference texts.

It was almost certain that the periods of observation are flawed. As an untrained observer, it was likely that I unconsciously selected what I was seeing. I may have failed to record occurrences or situations that were important to the research. A researcher carrying out ethnographic research concurrently shared notes from her observations that highlighted this issue. It also demonstrated that our background also influenced what we saw, for example, our opinions on the physical space of the same hospital were different. This also demonstrates another potential for error, which is inference. This means a "subjective explanation of an observation" (Black 1993, page 19).

The second 'process skill' to mention is the identification and control of variables. In this study the number of variables were many and it was only possible to concentrate on those that were measurable and thought to be important. There were several other variables that should be taken into account, for example,

- The patient's perspective
- The manager's perspective
- The nursing perspective

- ASA grades for patients undergoing cholecystectomy
- Length of operation
- Number of previous admissions relating gallstone disease

This list is not exhaustive. These were all additional variables that were not collected or measured in this study, but could potentially impact on day case laparoscopic cholecystectomy rates. Data collected from these sources or on these particular occurrences may allow a different interpretation of the results or inference of the cases.

My employment at one trust made access there very easy. I was already known to many of the medical and nursing staff. During my observation periods, I blended in as another member of staff. This provided advantages and disadvantages. As described above, my familiarity with the setting and staff here may mean that I failed to notice important observations or that I may have been distracted by the environment. It could also mean that staff behaviour was unchanged from the norm because I was perceived as an insider and therefore not a threat and this was an advantage in capturing accurate data.

At the other trusts, I was an unfamiliar face and therefore staff may have reacted very differently. This could question the accuracy of findings at these trusts. It was quite possible that they were more acutely aware of being

observed and behaved differently because I was perceived here as an outsider. This would change behaviour and therefore not capture real data.

Suggestions for further studies

Given the findings of this study that were related to the characteristic of the health care system, careful consideration should be given to the place of incentives to encourage a change in practice. In particular, it would be worth exploring the role of incentives offered directly to the clinical teams or clinicians driving change for their trusts, rather than the organisational incentives that were available at the time of the study. This suggested that areas to explore further include the better engagement of clinicians, the issue of clinical leadership and the identification and application of appropriate incentives.

Some of the perceptions voiced in this study raised questions that could be answered through further audit and research. For example, do laparoscopic cholecystectomies have to be scheduled on morning lists only to go home the same day? Careful audit of elective laparoscopic cholecystectomy cases that record the pathway followed, the outcomes and the clinical teams involved to identify common factors between patients that promote or hinder same day discharge should be carried out.

One of the observations in this study was the poor awareness and/or dissemination of guidelines, which related to the issue of knowledge transfer

and how this can be improved to actually impact on clinical decisions and practice.

Prospective collection of quantitative data and analysis of data over a longer period of time would demonstrate trends and allow the use of statistical process control to examine whether day case rates were incrementally rising or whether there are significant changes year on year.

The qualitative findings of this study can be used to develop further structured questionnaires for surgeons that can assess clinical practice and attitudes towards day case laparoscopic cholecystectomy. This approach would be able to capture a larger number of clinicians from a greater number of trusts as would a survey approach. It would also be interesting to explore the nursing side of the pathway in more depth. As key members of the medical team, their involvement in the pathway is crucial.

As raised by the interviewees, it was not clear whether patients were satisfied with day case laparoscopic cholecystectomy. If the patients do not like it, should we be doing it?

It would be worth examining whether the 60% target (BADs) or 75% target (DoH) for day case rates is the more acceptable. A comparison of the actual population having elective laparoscopic cholecystectomy with the acceptable day case population described in the BADs booklet for day cases laparoscopic cholecystectomy could be done.

8. Conclusion

The aim of this study was to explore and explain the factors that influence the uptake of day case laparoscopic cholecystectomy, at three NHS trusts, and the impact of changes at three trusts on day case rates. The study concluded that there was an increase in laparoscopic cholecystectomy over a 5 year period: trust A increased their day rate from 3.8% to 18.5%, trust B increased their day case rate from 8.7% to 54.2% and trust C increased their day case rate from 12.6% to 49.8%. However, as these figures show, the trusts involved in the study did not achieve the 60% day case rates recommended by the Department of Health and the British Association of Day Surgery despite the introduction of new ambulatory care facilities or projects directly aimed at improving day case laparoscopic cholecystectomy rates. This brings into question the target figure, for which there was no evidence found in the literature. The failure to achieve the target rate also meant that the trusts did not receive the financial rewards available to them as part of the best practice tariff scheme.

Although the study showed an improvement in day case laparoscopic cholecystectomy rates, it was not possible to conclude whether this was a direct result of the infrastructural changes or the introduction of the best practice tariff because the qualitative data gathered did not support this. Participants did not feel that the best practice tariff influenced their decision

to perform day case laparoscopic cholecystectomy, nor did a change in their scheduling occur as a result of new infrastructure that would enable them to perform day case laparoscopic cholecystectomy and those at trust B felt no change following the NHS Institute of Improvement and Innovation pilot scheme focussing on laparoscopic cholecystectomy specifically. Therefore the increase that has occurred cannot be fully explained. The increase in day case laparoscopic cholecystectomy rates may have been the result of less tangible elements such as contexts and mechanisms, for example increased awareness, which was highlighted by the study, or simply the diffusion of practice within and among trusts. This means clinicians adopting and changing practice, passively, as a result of what others were doing rather than actively choosing to change their behaviour. It was clear from the data that the trust that performed best (trust B) and showed the largest increase in day case laparoscopic cholecystectomy rates was the trust that did not have a new facility built.

The literature review concluded that there is level 1 evidence to support the practice of day case laparoscopic cholecystectomy because it is safe and cost effective, but there was no consistent evidence to support the recommended target of 60%. It also provided evidence that clinicians who perform laparoscopic cholecystectomy expressed a range of views, which influenced their decision about whether to treat patients as day cases or not. This was a reflection of individual professional behaviour within a professional group,

where individuals had different attitudes towards providing the same service. The data presented here demonstrated that individuals were relatively immune to national attempts to modify their behaviour (in this case the best practice tariff). The participants were less immune to organisational attempts to change practice as evidenced by responses from clinicians in trust C that felt their organisation's financial constraints directly.

The study found that participants identified organisational elements as a limiting step in the provision of day case laparoscopic cholecystectomy. These organisational elements were the result of clinicians' perceptions and beliefs about the environment they work in, particularly not being able to utilise existing or new day case facilities to facilitate their practice. This was across all trusts and was reflected in comments that described the different culture in day surgery units compared to acute wards. However, although the qualitative data did not manage to capture any significant change to these organisational elements during the study period, the quantitative data clearly showed an increase in day case rates.

In conclusion, day case laparoscopic cholecystectomy rates were improving at the trusts in the study, but the large scale efforts of building new ambulatory care facilities did not appear to result in the highest day case rates. This was demonstrated by trust B: 54.2% day case laparoscopic cholecystectomy rate in 2011-12, which did not have a new ambulatory care facility, but a project

group directed at improving this service. It may not have been perceived by clinicians to be successful and the lack of comment during qualitative data collection on this project group is telling, but the figures were clear. Trust A, which had the biggest ambulatory care facility built during the study period, only managed to perform 18.5% of their laparoscopic cholecystectomies as day cases by the end of the study. However, it was clear from the qualitative data that although there were willing clinicians to provide the service, they were not provided with access to the new facility. Therefore, organisations needed to identify the organisational elements, such as scheduling, day unit capacity and guidelines, needed to help their proactive clinicians perform better. This study demonstrated that clinical perception and opinion varied within the trusts and therefore given the findings of the investigation, this factor may not influence the quantity of day laparoscopic cholecystectomies performed. For the reasons explained above, it would be important to explore the day case targets that have been set in the first instance, consider incentives to change individual clinical practice need to reward individuals or departments specifically and address the organisational elements described above.

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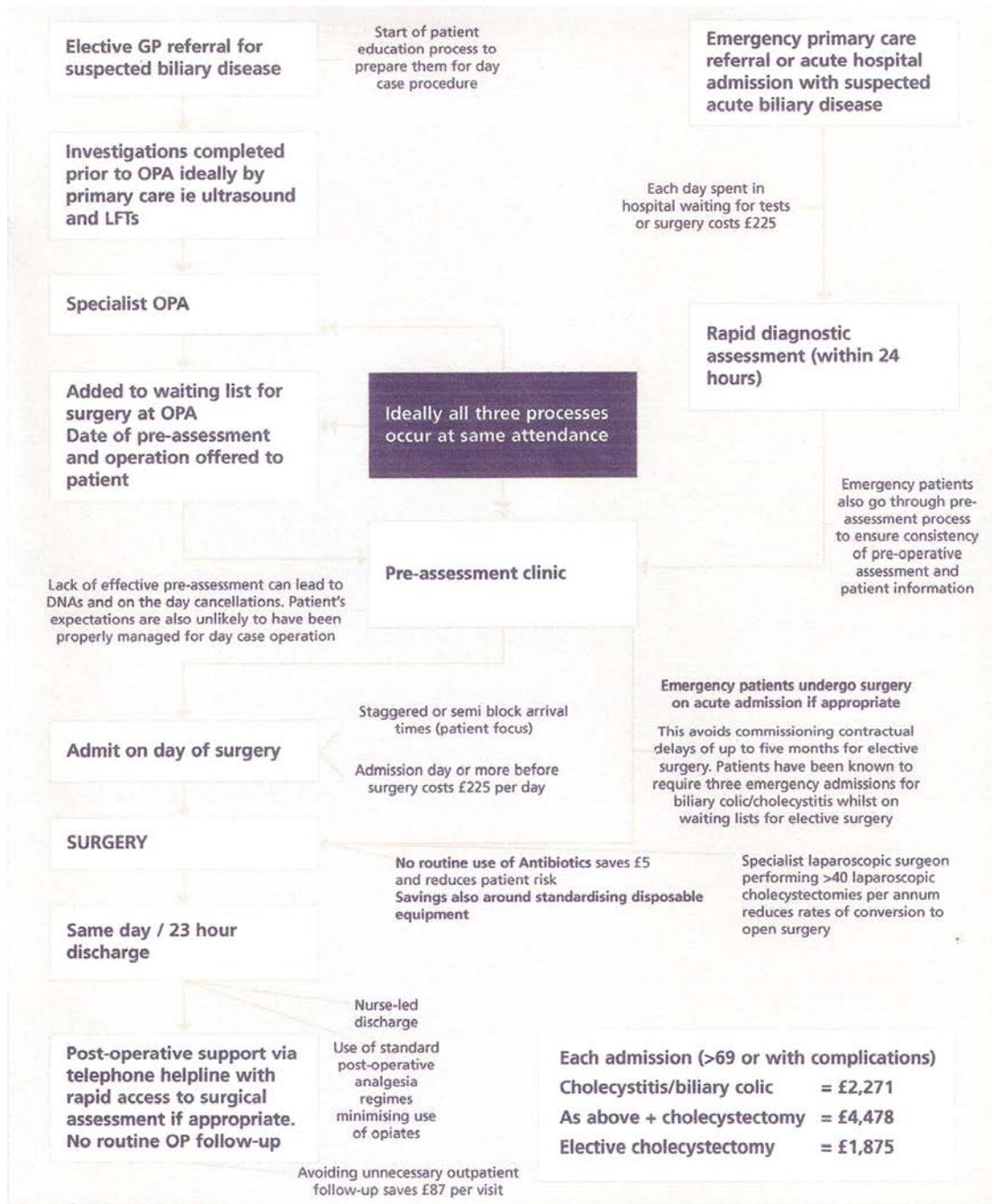
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10. Appendices

Appendix 1: The nine pilot CLAHRC regions

1. Greater Manchester
2. North West London
3. Cambridgeshire and Peterborough
4. Leeds, York and Bradford
5. Leicestershire, Northamptonshire and Rutland
6. Nottinghamshire, Derbyshire, Lincolnshire
7. South Yorkshire
8. Birmingham and Black Country
9. Peninsula

Appendix 2: Recommended patient pathway for cholecystectomy



(Solly et al. 2007)

Appendix 3: Hierarchy of evidence



(Phillips et al. 2009)

Appendix 4: American Society of Anaesthesiology grading



(American Society of Anaesthesiologists n.d.)

Appendix 5: Participants invitation letter and information sheet

Dear Dr

I am a surgical registrar currently doing an MD at the University of Birmingham. For this I am researching day surgery, and in particular day case laparoscopic cholecystectomy. The study is being carried out under the umbrella of the NIHR funded CLAHRC programme.

There is an element of the work that concerns opinions about surgeons who perform day case laparoscopic cholecystectomy, and I am hoping that I might be able to talk to you about this. I would like to interview you on a completely confidential basis about your views on day surgery and the manner in which such services are currently evolving. Your opinions and perspectives as a consultant surgeon would be highly relevant and would help me to explore various aspects of day case surgery. The interview would take approximately 30 minutes and I would be more than happy to travel to your hospital to speak with you.

All the information would be treated in strictest confidentiality, and none of the participants are going to be individually identifiable in the results.

I hope you will be able to spare me the time to be interviewed. If you would like any more information or have any questions then please contact me either by email [REDACTED] or by telephone [REDACTED]. I will try to contact you or your secretary within the next week to confirm a time for meeting.

Please accept in advance my thanks for your assistance.

Yours sincerely

Miss Sabina Rashid, MBBS BSc MRCS
Research Fellow, University of Birmingham

Appendix 6: Consent form for participants

CLAHRC Theme 1: From Structure to Function

University of Birmingham

CONSENT FORM

Title of study: Factors influencing day surgery

Name of researcher: Sabina Rashid

1. I confirm that I have read and understand the participant information sheet dated 14/03/2010 for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

3. I agree to take part in the above study.

4. I confirm that I give permission to use direct quotations, anonymously.

_____	_____	_____
Name of interviewee	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 7: Semi-structured interview schedules

Round 1

1. Could you tell me about your job?
 - a. Description of job title, duties and responsibilities
 - b. Length of time in current role
 - c. Place of qualification, working history

2. Could you describe the day surgery facilities at your Trust?
 - a. Related to infrastructure such as an isolated unit or combined with main hospital, number of theatres, dedicated day case lists or mixed lists
 - b. What is your equipment like?
 - c. What about staffing?
 - d. Identification of any problems they have experienced on a regular basis

3. Is there anything new happening in day surgery at your Trust?
 - a. Changes to infrastructure / moving into new building
 - b. Implementation of clinical pathways or protocols
 - c. Change to activity
 - d. What difference do you think this will make?

4. How much day surgery do you do personally?
 - a. Number of lists for general surgery
 - b. Scheduling
 - c. Types of operations performed
 - d. How do you feel about this?

5. What are the factors that affect how much day surgery you do?
 - a. Clinical outcome
 - b. Payment mechanisms affecting the way operations are booked – tariff
 - c. Impact on length of stay; national, local, trust related
 - d. Patient demand for day surgery
 - e. Personal interest
 - f. What about the role of other health professionals?

6. What are your views on laparoscopic cholecystectomy as a day case?
 - a. Clinical outcome

- b. Social circumstance
 - c. Acceptability of procedure to patients and surgeons
 - d. Adequate infrastructure for performing day surgery
 - e. Personal experiences influencing views and practice
 - f. Effect of anaesthetic techniques on day surgery
7. How is the decision to do day surgery made?
- a. Co-morbidities? ASA grading? BMI?
 - b. Complexity of cases?
 - c. Pre-op MRCP? Bile duct exploration? OTC?
 - d. Default booking?
8. What will happen next with laparoscopic cholecystectomy?
- a. Day case rates?
 - b. Why?
 - c. Change in payment mechanisms – tariff
 - d. Sub-specialisation

Are there any other points you would like to make?

If not mentioned in interview already, 'I have a further question. Where does money sit in all this?

Round 2

1. Establish rapport
 - a. Introduction and purpose of follow up interview
 - b. Confirmation of role
2. What changes have occurred?
 - a. External changes
 - i. Organisational circumstances
 - ii. Professional circumstances
 - iii. Personal circumstances
 - b. Day surgery facilities
 - i. Infrastructure
 - ii. Equipment
 - iii. Staffing
 - c. Protocols / pathways
 - i. Admissions
 - ii. Discharge process
 - iii. Nursing
 - iv. Anaesthetic guidelines or techniques
 - v. Back up arrangements
3. What is the impact of these changes? How have these affected your clinical practice at all
 - a. Use of facilities
 - b. Scheduling
 - c. Decision to perform day case laparoscopic cholecystectomy
 - d. An idea of numbers
 - e. Discharge of patients
 - f. Role of other health care professionals
4. What do you think will happen in the future? 12-24 months? 5 years?
 - a. Numbers of elective laparoscopic cholecystectomy
 - b. Numbers of day cases
 - c. Widespread adoption or rejection of day case laparoscopic cholecystectomy
 - d. Future changes
 - e. Impact of acute cholecystectomy
5. What other drivers for change are there?
 - a. Financial /tariff
 - b. National economic pressures
 - c. Trust pressures
 - d. GP consortia
 - e. Workforce issues/training

Are there any other points you would like to make?

Appendix 8: Framework layout used to insert coded qualitative data

Extract from spreadsheet for qualitative data collected during round 1 interviews for theme A, topics 1 and 2 for participants 1 and 2.

	A1	A2
1	<p>There is a day surgery facility at [redacted] not used by surgeon; cannot comment on how it works. DSU combined with endoscopy unit at [redacted]. Has experience at the [redacted] says that this is "well designed...has a fantastic atmosphere for people who work there and the patients". "Good experience" working there. Thinks that [redacted] is generally efficient. General layout is good in terms of theatres and ward area. Likes the staff room. Changing rooms are too small. Would prefer to have daylight in theatre. Gives importance to staff well being as well as the patients.</p>	<p>"Day surgery lap chole equipment at the [redacted] are crap". Refers to them as "useless". Most of the laparoscopic kit is old and inadequate. The sets are mixed. Feels that the instruments are so dangerous that he would not want to be operated there himself let alone on his patients. Equipment at [redacted] is newer and better.</p>
2	<p>For day case elective work currently uses the same facilities as gynae. This is separate from the main theatres. There are 4 theatres here. This is a separate theatre complex/unit. Has an attached ward. Previously only female patients were allowed in this unit because the ward was for gynae patients. Does not find that there are any issues with the flow of patients in this unit because the recovery area is big. Essential to ring fence beds - which has been promised but not sure if this will materialise.</p>	<p>Has not performed lap choles for the last month because of issues with equipment and staff (A3). Poor views on camera, which meant taking a new set from gynae preventing their clinical work. Comparing equipment with main theatres (used for hot choles) the standard of the stacks are much lower. Problems also extend to trays. Theatre units are territorial with their sets.</p>

Extract from spreadsheet for qualitative data collected during round 1 interviews for theme B, topics 1 and 2 for participants 4 and 5.

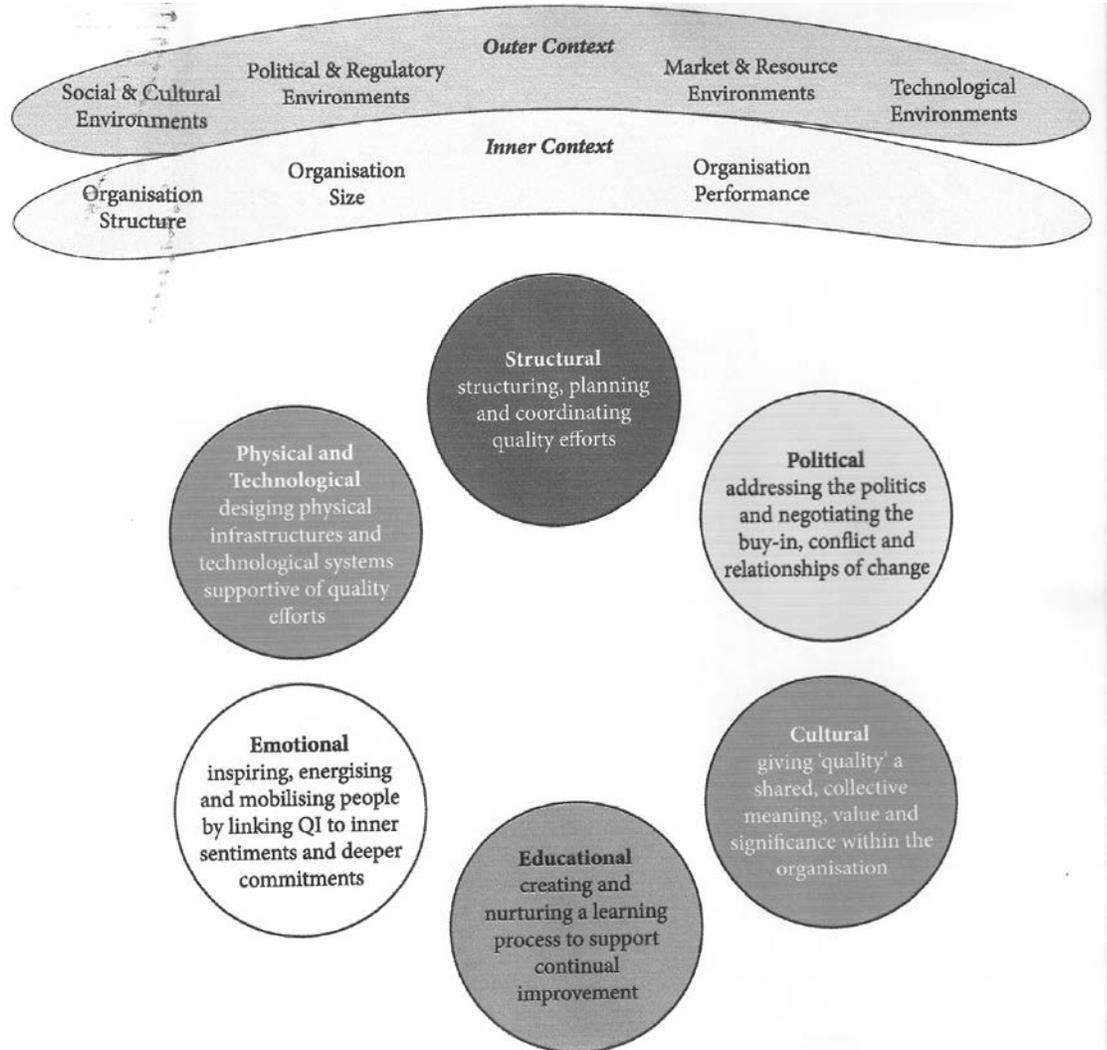
	B1	B2
1	<p>Does not currently have a day surgery list allocated to him. Does not appear to feel strongly about this. However he does say that about half of his workload would be suitable for a day case list. Feels strongly about operating on the patients he sees in clinic and therefore puts these on his main theatre list. These may still go home the same day, but are not classed as day surgery. Refers to this group of patients as "23 hour" stay. Does not believe that he will get a day case list so he will continue to practice as he does now.</p>	<p>Becomes hesitant with older patients, but it is the co-morbidities that affect practice more. Would not like to put over 65s on the day case list; ASA grade 1 and 2 are acceptable, ASA 3 is "borderline". Is cautious if patients are attending after 3-4 episodes of pancreatitis because the operation is likely to be difficult. Feels that there are a significant number of complex cases (for example post pancreatitis).</p>
2	<p>Has a half day pm list every other week for day surgery. Mainly used for benign breast conditions, herniae, lumps and bumps. Lap choles are scheduled on the main theatre list. This is also an afternoon list, so patients stay overnight. Has not attempted to do lap choles on day case list. Has 4 half day inpt lists in a 2 week period. Colleagues frequently have problems particularly on a Monday morning because there are no beds for elective cases.</p>	<p>Medical co-morbidities may determine whether patients are going to be day cases. These may mean that conversion to open is more likely. Age and BMI cannot be too prescriptive in this element because you can have a fit 70 year old and an unfit 50 year old. Many of the patients with complex disease or chronic liver disease would be sent on for tertiary referral. Hot choles are reducing the number of referrals for elective choles. Does not think there is a particularly complex case mix.</p>

Appendix 9: HES data fields collected

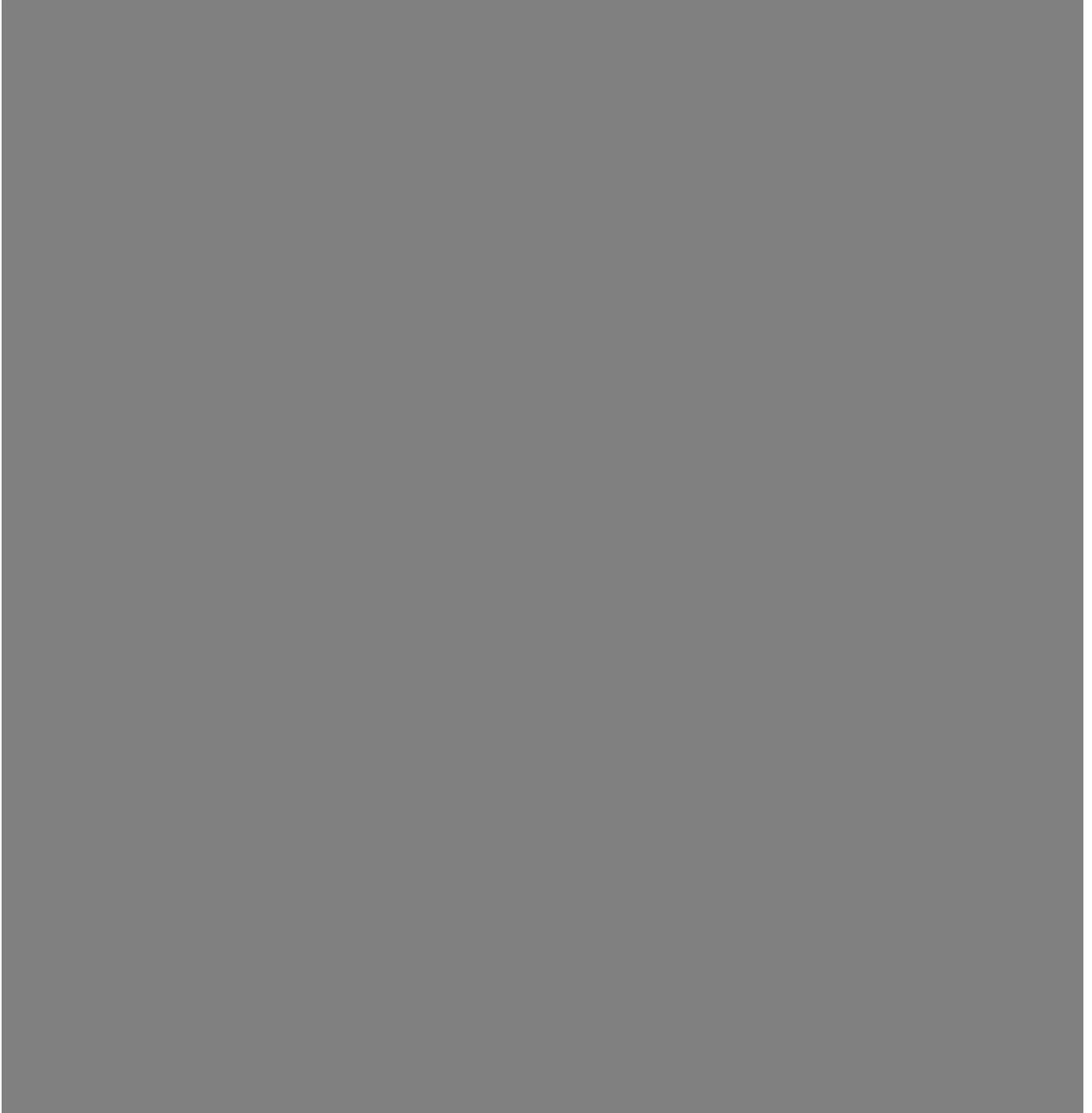
Field name	Description
susid	sus generated spell id (09/10-10/11 only)
provspno	unique provider generated spell identifier (07/08 - 08/09 only)
epikey	unique episode identifier
epiorder	number of the episode in the spell
spelbgin	did a spell begin with this episode? (2=yes 0=no)
spelend	did a spell end with this episode?
procode	5 digit hospital provider code
opdte_nn	date of main operation
resgor	government office region of residence
soal	Lower Level Super Output Area of residence
hrg_35	HRG code of the spell
admidate	date of admission
sex	sex
startage	age at start of episode
admimeth	method of admission
diag4	main diagnosis 4 character ICD10
pseudo_hesid	pseudonomised patient identifier
classpat	classification of patient
mainspef	main specialty under which admitted
oper3	main operation
dismeth	discharge method
disdest	discharge destination
disdate	discharge date
income_dep	income deprivation score (2010 base)
income_decile	income decile (England base)

Appendix 10: Bates

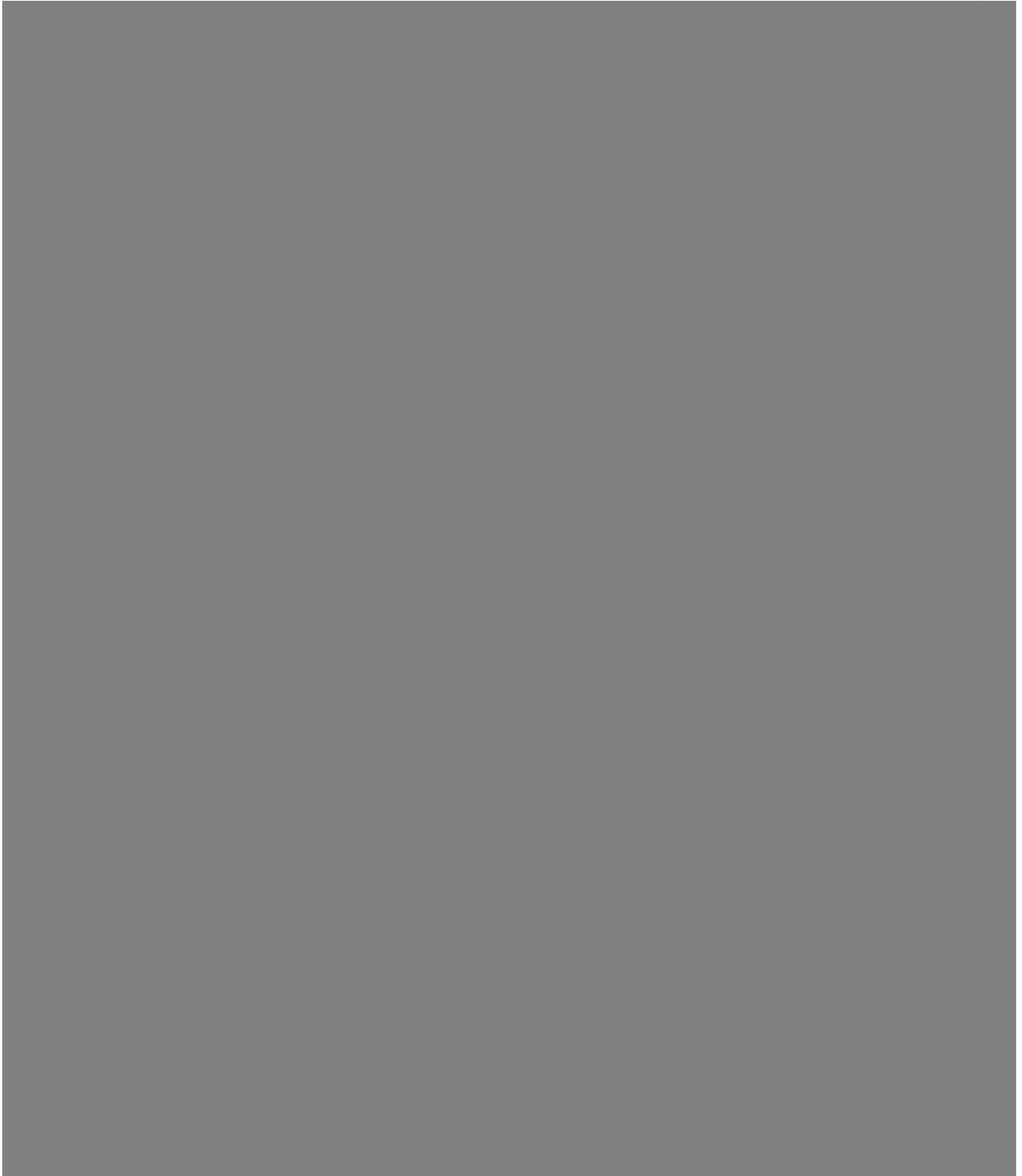
Bate, P. et al., 2014. *Perspectives on context*, Health Foundation.



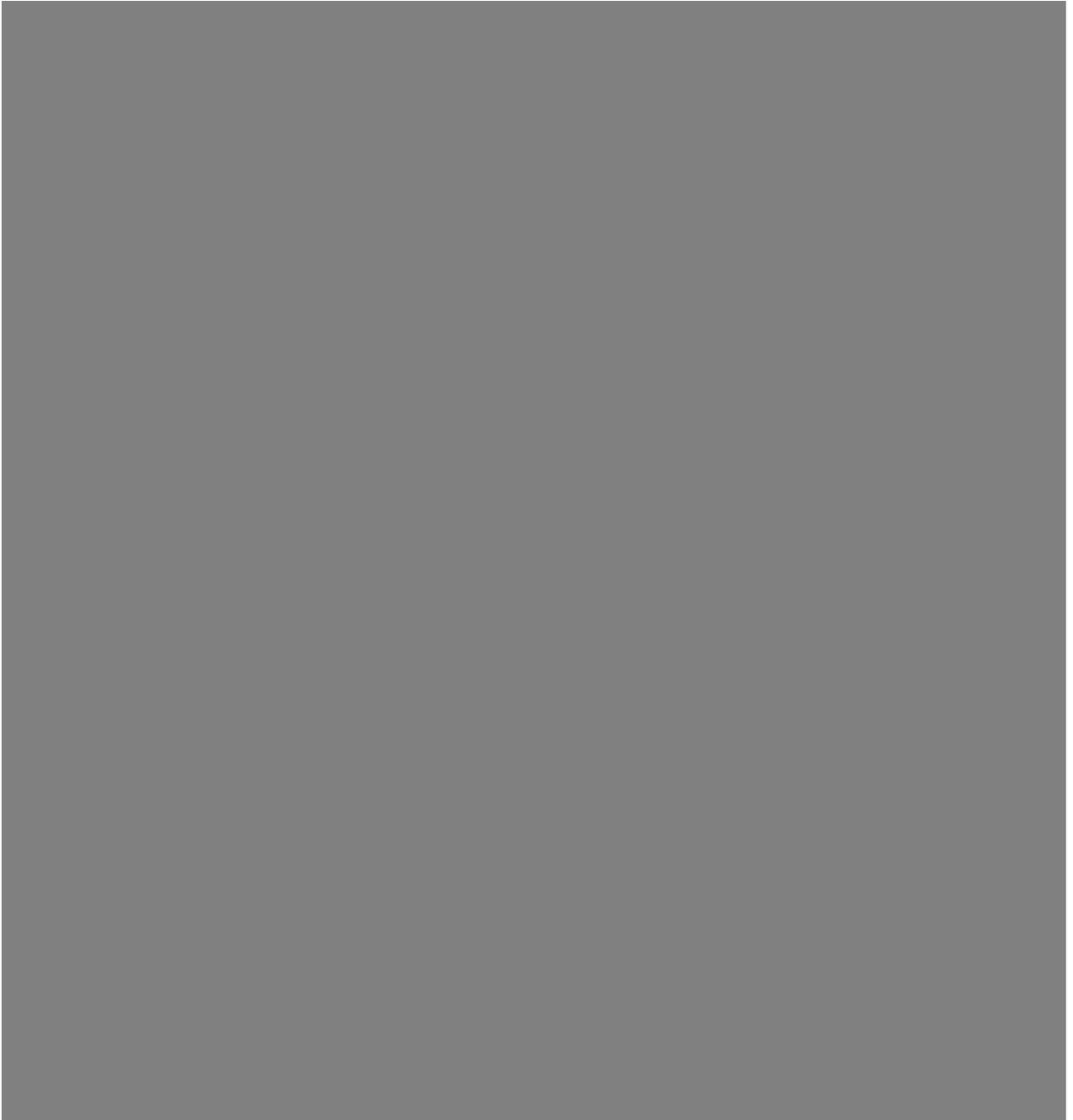
Appendix 11: Plan of trust A theatre suites
Not to scale



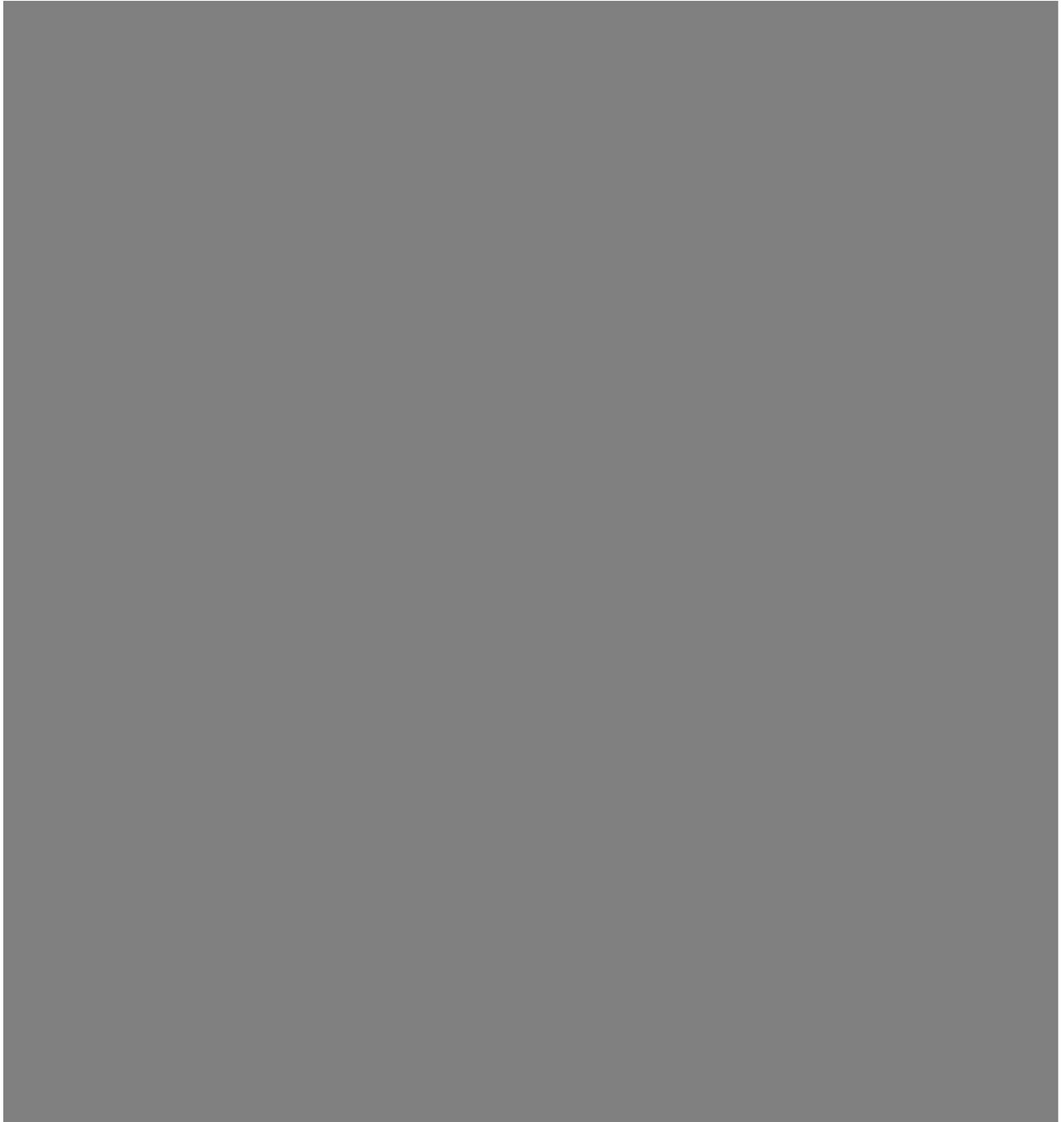
Appendix 12: Plan of trust B, site D diagnostic and treatment centre
Not to scale



Appendix 13: plan of trust B, site W day surgery unit
Not to scale



Appendix 14: plan of trust C day surgery unit
Not to scale



Appendix 15: Coded interview data entered into framework

Theme A: Context
Infrastructure (physical space)
Does not actually use site W DSU because has no allocated lists. There are 3 theatres and the unit closes overnight. Uses ward in the main spine to admit pts. Cannot comment on problems because does not use the unit, but does not hear other colleagues complaining about it. If the site W DSU was to be used for LC, it would need to extend opening hours. Fundamentally site D DTC is a good unit. Thinks there are issues with capacity.
Infrastructure (equipment)
Equipment at the site D DTC is of poor quality. This includes the laparoscopic stack and surgical instruments. This may be because the equipment at the site D DTC is older than that at site W. This is not standardised. He bases this on personal experience.
Infrastructure (staff)
DSU at site W has its own staff - separate pool of staff. Beginning to see a change in mind set of nursing staff as well. Nursing staff are thought to be key to the process. If they are able to encourage pts to get up and mobilise, eat and drink rather than letting them lie in bed and receive analgesia, then pts will respond to this.
Money
Not sure whether money has an effect. Doesn't directly influence clinical practice. Does what is right for the pt.
National targets
Doesn't feel like he is under pressure to hit certain targets. Publishing DCR is an exercise rather than exerting pressure.

Theme B: Mechanism	
Clinician's practice	Feels that his own mind set has changed since the introduction of the LC project. Tends to tell pts now that they are likely to go home the same day. Books LC as day cases unless there is a medical or social reason not to. Has no clinical concern with the procedure being performed as a day case. Comments that if a surgeon has performed a LC with ease, then you are more likely to push for discharge the same day. But if you have struggled, then you are less likely to push for discharge, because you are likely to worry about bleeding or bile leaks.
Scheduling	Discussions about moving LC into the day unit are moving forward slowly. Also mentions 3 session theatre days. Only has main theatre lists "I just don't happen to have a day case list", but puts day cases on this. Performs LC, herniae, anti-reflux surgery. Scheduling is based on waiting times. Thinks it would be better to have single type of cases on lists, e.g. all LC. because theatres function better. Describes an example of a list at site D DTC where 5 or 6 LC were done efficiently "because everyone was in the zone". "You'd probably have to do them in the morning". Recent list with 4 LC had 2 technically easy procedures and 2 difficult procedures, which is a reflection of the case mix that he gets. Finds it difficult to predict which cases will be more complex. Does 10-15 ble duct explorations a year.
Patient selection	Careful selection of pts will need to be made. Medical or social reasons may prevent booking as a day case. Feels that there are significant number of pts who present late and have advanced GB disease. This may mean that the procedure is more difficult. Thinks that about half of the cases are more difficult than 'normal'. BMI is not necessarily a factor for not performing day surgery. Previous diagnoses of pancreatitis or CBD stones or recurrent cholecystitis may not deter from doing a day LC, but cases may end up staying because they are technically more difficult.
Protocols	Guidance on using low pressures and local anaesthetic have already been in place. Having more structured protocols or pathways will help enable the process to be smoother and increase DCR.
Patient education	Patients are accepting of this. They are surprised to be told they will be going home the same day, but quite pleased. However translating this into a same discharge is not always the case.
Anaesthetic	

<p>Not sure if anaesthetists are "uniform in their approach; some are definitely better than others". Thinks that the anaesthetic does affect discharge. Feels that certain anaesthetists tailor their technique to LC and to day cases. Uses an example where the pt was given remifentanyl and no paralysis, which made the entire process quick and effective. Pt was ready for discharge within 2-3 hours. Wonders whether this has more of an influence than the surgery itself.</p>
<p>Pre-admission</p>
<p>No data</p>
<p>Discharge</p>
<p>Pain may be a reason for staying in and PONV. Describes himself as "not the hardest individual" so will let pts stay in if they don't feel up to going home. Feels that nurses need to be supported and feel happy if they are to discharge pts 3-4 hours post operatively and by building their confidence in this area, they are more likely to push for discharge. The staff at site D DTC are better at nurse led discharge than other areas. Part of this is the influence that a unit that has to close its doors overnight are more focussed on getting pts out than in other areas where pts can stay overnight.</p>
<p>Back-up facility</p>
<p>Refers to having a back up facility if LC are done in the day unit to provide confidence to the surgeon.</p>
<p>Project groups</p>
<p>Aware of the lap chole project. Consideration being given to introducing day case LC to the day unit at site W. The project has focussed people's minds on day case LC, but doesn't feel that it has made a "huge impact". The difficulty is in changing people's mindset. Regular review of day case rates encourages consultants to compare their practice with each other.</p>