

The psychological impact of surgical complications on patients and surgeons

A thesis presented for the degree of doctor of philosophy (PhD)

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Dedicated to my uncle

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Declaration

I hereby declare that the work presented in this thesis is my own and all contributions from other sources have been appropriately acknowledged and cited.

Thesis abstract

Adverse events constitute a significant challenge for healthcare organisations not only in terms of their prevention but also in terms of their after-effects on the injured patients and the staff involved. This PhD aims to investigate the psychological impact of surgical complications on patients and surgeons on the basis that the operating room is one of the highest risk areas for serious adverse events.

Chapter 1 presents background literature on the aftermath of patient safety incidents both from the patients' and the healthcare professionals' perspectives and outlines the gaps of knowledge in this area. Chapter 2 sets the scene for surgical complications and presents the limited existing data on patients' and surgeons' experiences of surgical adverse events. Chapter 3 provides an overview of relevant theoretical frameworks for the investigation and discussion of the psychological impact of surgical complications on patients and surgeons. A systematic review of the literature on the psychosocial impact of surgical complications on patients follows in Chapter 4. Chapters 5 and 6 present two empirical studies on surgeons' experiences of surgical complications. Chapter 5 reports an interview study with 27 surgeons which yielded a range of themes relevant to the personal and professional impact of complications on surgeons, the factors that affect their reactions, their coping, their perceptions of support as well as their perceptions of the institutional cultures in the aftermath of serious complications. Chapter 6 presents a cross-sectional survey study, which aims to quantify the psychological effects of serious surgical complications on surgeons and to identify their psychosocial correlates. Chapters 7 and 8 focus on patients' experiences of surgical complications. A two time-points interview study with 17 surgical patients who experienced complications of various levels of severity is reported in Chapter 7. This study presents findings relevant to the psychosocial effects of surgical complications on patients, the factors that affect their reactions as well as issues of patient-surgeon communication around complications. Informed by the

findings of the systematic review, the patient interview study and relevant literature, a longitudinal cohort study on the psychological impact of surgical complications on patients and the psychosocial predictors of this impact is presented in Chapter 8. Chapter 9 presents an online survey study with patient safety managers on the management of the aftermath of serious patient safety incidents in the NHS. This study investigates how the aftermath of patient safety incidents is managed by NHS organisations and describes the support that is typically available to patients and healthcare staff. Chapter 10 ends with an overview of the key findings from each study, their methodological limitations, directions for future research and implications for supporting surgeons and patients in the aftermath of surgical complications.

Thesis-related publications and presentations

Conference presentations

1. **Pinto A.**, Faiz O., Bicknell C. & Vincent C. A longitudinal cohort study on the association of surgical complications with patients' psychological wellbeing and psychosocial factors. 27th EHPS Conference. European Health Psychology Society. 16-20 July 2013. Bordeaux, France. Oral presentation.
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4. **Pinto A.**, Faiz O., Bicknell C. & Vincent C. Perceived major complications and surgeons' emotional wellbeing. 33rd STAR International Conference. Stress & Anxiety Research Society. July 2012. Palma, Spain. Oral presentation.
5. **Pinto A.**, Faiz O. & Vincent C. A questionnaire study on the management of the after-effects of medical errors in the English NHS trusts. 25th EHPS Conference. European Health Psychology Society. 20-24 September 2011. Crete, Greece. Oral presentation.
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8. **Pinto A.**, Faiz O. & Vincent C. Being open and supporting patients and staff when serious patient safety incidents occur: current state of practice in the NHS. International Society for Quality in Healthcare. ISQua International 28th Conference. September 2011. Hong Kong. Poster display.

Invited talks

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2. Vincent C. & **Pinto, A.** Patient Safety: recent developments in our understanding, and current research into the "double victims" of safety incidents. Invited talk at the *UCLPartners Quality Forum*. September 2012. London.
9. Vincent C. & **Pinto, A.** Medical error and disclosure. After the event: looking after patients and staff. Invited talk at the *Royal Society of Medicine Patient Safety Section launch meeting*. June 2010. London.

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Related publications

1. **Pinto, A.** & Vincent C. The Perspectives of the Patient and the Family. Book chapter in *Patient safety: Theory and Practice (Patientsäkerhet - teori och praktik)*. [edited by] S. Ödegård. In press.
2. Pichert, J.W., Hickson, G.B., **Pinto, A.**, and Vincent, C. Communicating outcomes, adverse events and errors. Book chapter in: *Handbook of human factors and ergonomics in health care and patient safety/ [edited by] Pascale Carayon*. 2nd ed. CRC Press. 2012.

Papers in the process of submission:

1. **Pinto A.**, Faiz O., Bicknell C. & Vincent C. Surgical complications and their implications for surgeons' wellbeing: An interview study.
2. **Pinto A.**, Faiz O., Bicknell C. & Vincent C. A survey study on surgeons' psychological wellbeing after their most recent major complication.
3. **Pinto A.**, Davis R., Almoudaris, A., Faiz O. & Vincent C. The psychosocial impact of surgical complications on patients: A systematic review of quantitative studies.
4. **Pinto A.**, Faiz O., Bicknell C. & Vincent C. An interview study on surgical complications and their implications for surgeons' wellbeing.

¹ This paper attracted media attention (*The Telegraph* and *The Evening Standard*).

5. **Pinto A.**, Faiz O., Bicknell C., Lear, R., Rayman, S, Jagger, E. & Vincent C. A longitudinal cohort study on the association of surgical complications with patients' psychological wellbeing and the contribution of psychosocial factors.

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List of abbreviations

ASD: Acute Stress Disorder

B-COPE: Brief COPE Inventory

Brief-IPQ: Brief Illness Perceptions Questionnaire

CABG: Coronary Artery Bypass Graft

CSM: Common Sense Model

DSM: Diagnostic and Statistical Manual of Mental Disorders

GI: Gastro-intestinal

HADS: Hospital Anxiety and Depression Scale

HDU: High Dependency Unit

HSPSC: Hospital Survey on Patient Safety Culture

IES: Impact of Events Scale

IPA: Interpretative Phenomenological Analysis

ITU: Intensive Therapy Unit

MBI: Maslach Burnout Inventory

MDSS: Multi-dimensional Support Scale

NHS: National Health Service

NHSLA: National Health Service Litigation Authority

NOS: Newcastle Ottawa Scale

NPSA: National Patient Safety Agency

PTSD: Post-traumatic Stress Disorder

QoL: Quality of Life

SF-36: Short Form Health Survey 36

SF-12: Short Form Health Survey 12

WHO: World Health Organisation

Chapter 1: Adverse events in healthcare and their aftermath

This chapter provides a general overview of the broad context of surgical complications. It starts with a summary of the scale of adverse events in healthcare and continues with a more extensive presentation of the existing literature on their aftermath. The aftermath of adverse events is discussed in relation to the effects of adverse events on patients and healthcare professionals, the potential factors of these effects and lastly patients' and healthcare professionals' needs for support.

1.1 Adverse events in healthcare

Medical error and medical harm have been at the core of quality improvement in healthcare over the last twenty years due to a growing number of reports on the incidence of adverse events in hospitals in the United States, Canada, Australia, United Kingdom and elsewhere (Leape et al. 1991; Wilson 1995; Schiøler et al. 2001; Vincent et al. 2001; Davis et al. 2003; Baker 2004; Brennan et al. 2004; Michel et al. 2007; Aranaz-Andrés et al. 2008; Soop et al. 2009; Zegers et al. 2009). Adverse events are "unintended injuries caused by medical management rather than the disease process that lead to prolonged hospital stay and/or temporary or permanent impairment or disability to the patient at time of discharge" (Brennan et al. 2004), while patient safety is "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" (Vincent 2010).

A large-scale medical record review of 51 acute care hospitals in New York State in the US, the so-called Harvard Medical Practice Study, a landmark study in the patient safety field, found that adverse events occurred in 3.7% of the hospitalisations with 6.5% of those having caused permanently disabling injuries and 13.6% having led to death (Leape et al. 1991; Brennan et al.

2004). The scale of medical harm was suggested to be much larger in a subsequent review of more than 14,000 medical records of 28 hospitals in New South Wales and South Australia which revealed that 16.6% of the studied admissions were associated with an adverse event which resulted in disability or longer hospital stay for the patient and was caused by health care management (Wilson 1995). In the UK, a retrospective review of 1,014 medical and nursing records of two acute hospitals found that 11.7% of patients had experienced some adverse event in their care with a third of them leading to moderate or greater disability or death (Vincent et al. 2001). The rates of adverse events that were suggested by later studies in other countries varied between 5.7% and 12.3% of hospital admissions (Schiøler et al. 2001; Davis et al. 2003; Baker 2004; Michel et al. 2007; Aranaz-Andrés et al. 2008; Soop et al. 2009; Zegers et al. 2009) confirming the significant degree of medical harm that is caused by medical management worldwide.

The emerging scale of adverse events in hospitals across the globe defined the context of the US Institute of Medicine's 1999 report 'To err is human' (Institute of Medicine 1999) as well as the later UK Department of Health document 'An Organisation with a Memory' (Department of Health 2000). Both documents put a great emphasis on learning from errors and healthcare systems improvement and stimulated research on medical harm prevention and the design of safe and reliable patient care. However, much less attention has been given to date on the *"amelioration of adverse outcomes or injuries stemming from the process of healthcare"*. By the term 'amelioration of adverse outcomes or injuries', Charles Vincent speaks of the need for rapid intervention to deal with the immediate crisis but also the need to care for injured patients and to support the staff involved (Vincent 2010).

1.2 Patients' experiences of adverse events in healthcare

The after-effects of adverse events on patients are multi-faceted and of various levels of severity. These are summarised below in the context of existing literature on the aftermath of medical harm, followed by a summary of the factors that potentially affect patients' experiences of adverse events. The last part of this section summarises the current developments around being open and supporting patients in the aftermath of serious patient safety incidents.

1.2.1 The effects of adverse events on patients

Patients and their relatives may suffer both physically and psychologically from medically induced injuries (Vincent 2010). The physical effects of adverse events vary from minor (e.g. discomfort or increased hospital stay) to quite major (e.g. severe disability or death). The psychological effects of adverse events are not very well documented but it has been suggested that psychological distress is common and under certain conditions it may turn into severe psychopathology such as depression or post-traumatic stress disorder (Vincent and Coulter 2002; Vincent 2010). Other likely after-effects of medically induced incidents on patients include burden on the patient's family and other social relationships, absence from work, lack of ability to care for one's family and financial strains (Vincent 2010).

Early findings from surgery suggest significant levels of suffering related with the experience of surgical adverse events such as higher levels of distress than people who had experienced serious accidents or bereavements, reported pain levels comparable, over a year after surgery, to untreated postoperative pain, and psychosocial adjustment worse than in patients with serious medical conditions (Vincent et al. 1993). A US study on the consequences of medical errors, as those were observed by family physicians, suggested significant health, time, and financial consequences on patients (Dovey et al. 2003). Two qualitative studies on patients' experiences of real adverse events

reported significant consequences as a result of these incidents (Gallagher et al. 2003; Duclos et al. 2005). Duclos et al. found that patients experienced physical, emotional and financial trauma as a result of their involvement in an adverse event (Duclos et al. 2005) while in the study by Gallagher et al. patients described feeling sad, anxious, depressed or often angry that their hospital stay was prolonged or that the incident was preventable or happened due to carelessness (Gallagher et al. 2003).

The above studies offer an indication of the ways in which serious adverse events may affect patients. However, empirical data on the association of adverse events with psychosocial outcomes such as anxiety, depression or post-traumatic stress are lacking. The only exception to this is the study of anaesthetic awareness. Anaesthetic awareness refers to the phenomenon 'when a patient under anaesthesia states or remembers that he or she had been awake at a time when consciousness was not intended' (Errando et al. 2008). A few recent studies showed that patients who reported having been aware under anaesthesia often experienced severe psychological distress and were commonly diagnosed with post-traumatic stress disorder (Schwender 1998; Osterman et al. 2001; Leslie 2010).

This type of psychopathology may also be common in patients who experience different types of adverse events in their care, however the evidence is lacking. Data of this kind will be useful for identifying the degree and types of psychological distress that is experienced by patients who suffer medical harm and for guiding healthcare professionals and organisations in their efforts to support patients in the aftermath of serious patient safety incidents.

1.2.2 Determinants of the effects of adverse events on patients

In addition to the effects that are attributable to the incident itself, patients who are harmed by their treatment may suffer further trauma if the incident is not handled sensitively (Vincent and Coulter 2002). A number of anecdotal reports and empirical studies highlight the need for honesty, compassion and apology in the aftermath of medically induced injuries as an ethical obligation on the part of the healthcare professionals which also allows patients to deal with the consequences of these incidents more effectively (Banja 2001; Vincent and Coulter 2002; Bismark and Paterson 2005).

Recent studies with patients and the general public on their attitudes to medical error disclosure have found that the great majority would like to be informed of any error; they would like to know what happened, how it happened, how it would be mitigated and what will be done to prevent recurrence even when the adverse event is minor (Hobgood et al. 2002; Gallagher et al. 2003). Full disclosure of errors to patients has been shown to correlate with higher patient satisfaction with quality of care (Duclos et al. 2005; Cleopas et al. 2006; Lopez et al. 2009), whereas non-disclosure has been associated with patients changing physicians or intending to seek legal advice (Mazor et al. 2006). Patients also express a desire for an apology from healthcare professionals when medical errors occur (Gallagher et al. 2003).

Healthcare organisations' and clinicians' failure to meet the needs of harmed patients may lead to patients' loss of trust and may motivate them to pursue legal action. For example, an early survey study with 277 patients and relatives who decided to take legal action due to their experience of a serious adverse event in their care found that their decision to sue was quite often the result of insensitive handling and poor communication after the original incident (Vincent et al. 1994). Since this key study on patients' views of litigation due to medical harm, our knowledge of patient's experiences of adverse events and the factors that determine patients' psychological reactions to them remains limited. This thesis will attempt to address this gap in the following chapters.

1.2.3 Supporting and being open with patients and families in the aftermath of serious adverse events

As it has already been argued, concealment, evasion and lack of prompt action to ameliorate both physical and psychological damage after medically induced injuries may cause immense distress and anger and lead to a breakdown of trust between family and staff (Vincent et al. 1994; Vincent 2010).

In the United States in 2001, the Joint Commission on Accreditation of Healthcare Organizations as part of its accreditation policies included a requirement that all unanticipated outcomes of care should be disclosed (Lamb et al. 2003). A national survey study of risk managers found that although the majority of hospitals reported disclosing harm to patients at least some of the time, only one-third of hospitals had board-approved policies in place (Lamb et al. 2003). Respondents were much less likely to disclose preventable harms than to disclose non-preventable harms of comparable severity partly because of fear of litigation.

In Britain the National Patient Safety Agency (NPSA) released guidance on 'Being Open' in 2005 and then, concerned about the lack of impact, re-released the document in 2009 (note that the NPSA has now been disbanded). The Being Open framework provides best practice guidance on how to create an open and honest environment where (a) patients, their families and carers receive the information they need to understand what went wrong, and the reassurance that everything possible will be done to prevent recurrence and (b) all involved, patients, families and healthcare professionals, feel supported. Since then considerable progress has been made in the development of policies to encourage and support organisations in providing effective support for patients, families and for staff who may also be affected by serious incidents. A number of government agencies and professional bodies in the UK have published guidelines and statements highlighting the importance of being open and of adopting a constructive and humanitarian response to harm,

rather than a defensive and legalistic approach (See Table 1 for an overview of existing principles and guidelines on being open in the UK). However, the extent to which NHS organisations have endorsed such guidelines and put them into practice is unknown.

Table 1: Existing UK guidelines of being open after healthcare-related adverse events

National Patient Safety Agency (NPSA): The NPSA issued the first guidance on <i>Being open</i> in 2005. The guidance was re-launched in 2009 after an independent review of the implementation of <i>Being open</i> which took place in 2008 with the aim of strengthening openness about patient safety incidents within healthcare organisations and supporting those involved (National Patient Safety Agency 2009). Department of Health (DH): In the Department of Health’s Safety First report (2006) there is a clear recommendation for all NHS organisations to develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and to provide required support. In the more recent report entitled ‘The NHS Constitution: The NHS belongs to us all’ (2010), staff’s duty to be open with patients, their families, carers or representatives when things go wrong is reiterated (Department of Health 2006). NHS Litigation Authority (NHSLA): Two out of the 50 criteria that the NHSLA uses to assess NHS trusts’ compliance with risk-related standards are pertinent to <i>being open with patients and families</i> (Criterion 5.10) and <i>supporting staff</i> (Criterion 3.09) when patient safety incidents occur (National Health Service Litigation Authority 2011). General Medical Council (GMC): One of the principles that the GMC has set in relation to <i>good medical practice</i> relates to healthcare professionals’ duty to offer an apology to the patient when things have gone wrong and to explain fully and promptly what has happened, and the likely short-term and long-term effects (General Medical Council 2009). Royal College of Surgeons (RCS): The Royal College of Surgeons published a position statement about doctors’ professional duty to be open and honest with their patients at all times and stated its support to the NPSA <i>Being open</i> guidelines (Royal College of Surgeons 2010). Nursing & Midwifery Council (NMC): Nurses’ and midwives’ code of conduct includes statements about the duty of putting ‘matters right if someone in their care has suffered harm for any reason’ and explaining ‘fully and promptly to the person affected what has happened and the likely effects’ (Nursing and Midwifery Council 2009).

A recent qualitative study on patients’ and family members’ perceptions of actual disclosures of adverse events in Australia has suggested that the way open discussions are enacted is very important and being open alone is not sufficient in meeting patients’ and their families’ needs (Iedema et al. 2008). Issues that have been highlighted by the above study as patient concerns were:

disclosure not occurring promptly or too informally; disclosure not being followed up with tangible support or change in practice; staff not offering an apology, and disclosure not providing opportunities for patients to meet with the staff originally involved in the adverse event (Iedema et al. 2008).

While being open with patients and their families is hugely important in the aftermath of serious patient safety incidents, patients may have broader needs that have not received as much attention in the literature. Offering tangible support such as timely psychological support or following up patients in the long-term could be further ways of supporting patients who have experienced harm from their care. Given that almost all existing research on patients' needs after adverse events focuses exclusively on being open, further research is needed to elucidate the full spectrum of needs that patients have after medical harm and to identify appropriate ways of supporting them.

1.3 Healthcare professionals' experiences of adverse events in healthcare

1.3.1 The effects of adverse events on healthcare professionals

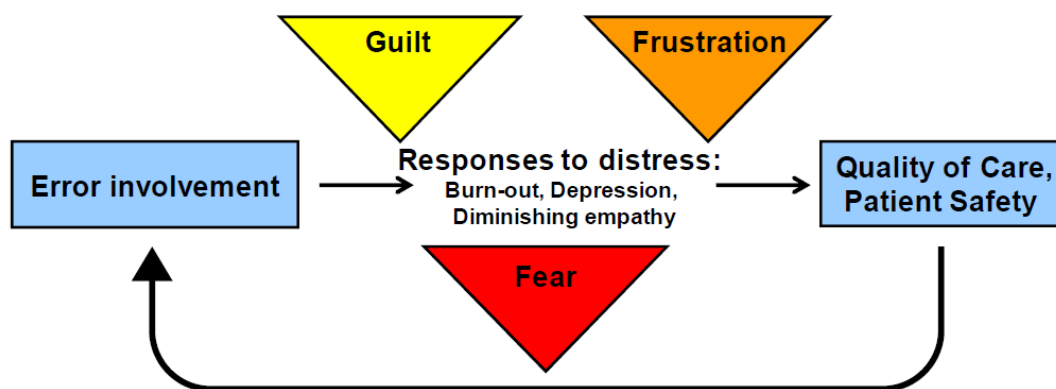
Healthcare staff may also experience severe consequences when they are involved in serious patient safety incidents especially when the incident is an error and even more so when the patient is harmed because of it (Vincent 2010). Recently, healthcare professionals have been called the 'second victims' of adverse events in healthcare (Wu 2000), and both anecdotal and empirical data have examined the experiences and the needs of clinical staff who are involved in such incidents (Goldberg et al. 2002; Giannetti 2003; Devencenzi 2006; Delbanco and Bell 2007).

A small number of early studies have shown profound emotional effects for doctors who are involved in serious patient safety incidents and particularly medical errors such as fear, guilt, anger, embarrassment, humiliation or even anxiety and depression symptoms (Wu et al. 1991; Christensen et al. 1992; Aasland and Forde 2005; White et al. 2008). One of the very first studies which used interviews to explore physicians' experiences of their mistakes reports that amongst the main emerging themes was the degree of emotional impact on the physician, so that some mistakes were remembered in great detail even after several years (Christensen et al. 1992). More recently, surveys of clinical staff show that the reactions described above are common responses to making a serious error (Aasland and Forde 2005; Engel et al. 2006; Waterman et al. 2007; Scott et al. 2009). Aasland et al. (2005) reported that 17% of the doctors who participated in a questionnaire study on the impact of feeling responsible for a medical injury expressed that the incident to which they were referring had a negative impact on their personal lives and 6% had needed professional help (Aasland and Forde 2005). A total of 22% of the participants reported that they did not receive adequate support from their colleagues. Scott et al. (2009) in their qualitative study on clinicians' stages of recovery after their involvement in a serious patient adverse event reported a stage of intrusive thoughts and self-reflection followed by a period of haunted re-enactments, often with feelings of internal inadequacy and periods of self-isolation (Scott et al. 2009).

Another important aspect of the impact of adverse events on healthcare professionals is their potential involvement in a reciprocal cycle of distressing symptoms leading to further suboptimal care and error. West et al. assessed the association of self-perceived medical errors with quality of life, burnout, depression, and empathy in a prospective longitudinal cohort study of internal medicine residents in the US, where surveys were sent out to the participants every 3 months over a three year period (West et al. 2006). Self-perceived major errors were associated with subsequent significant decreases in quality of life, higher scores in all dimensions of burnout and an increased likelihood of screening positive for depression at the subsequent assessment. Most importantly though the authors of the study report a potential reciprocal cycle of self-perceived error

involvement and distress as they found significant associations between distress at each survey point and a self-perceived error in the following 3 months. For example, a 1-point increase in the depersonalisation score of burnout was associated with a 10% increase in the odds of reporting an error in the next 3 months. These results suggest that personal distress and self-reported error involvement could be related in a reciprocal cycle, as Schwappach et al. illustrate in their systematic review of the emotional impact of errors on healthcare professionals (see Figure 1).

Figure 1: Reciprocal cycle of error involvement, emotional distress, and future errors (Schwappach & Boluarte, 2009)



1.3.2 Determinants of the effects of adverse events on healthcare professionals

Feelings of responsibility and acceptance of criticism from colleagues (Aasland and Forde 2005), perceptions of locus of control (Christensen et al. 1992), and most importantly the level of support that clinicians receive from colleagues and supervisors (Engel et al. 2006; Scott et al. 2009) have

been suggested as important determinants of the seriousness of clinicians' reactions to adverse events. Patient outcome is also an important determinant of healthcare professionals' reactions to their involvement in adverse events, with incidents leading to grave outcome such as death or severe impairment leading to high levels of distress (Engel et al. 2006; Muller 2007). Self-criticism is another potentially important factor of the impact of adverse events on clinicians' wellbeing. Jenny Firth-Cozens in a 10-year follow-up survey study of 302 4th year medical students, found that the tendency to self-criticism was highly predictive of depression amongst doctors (Firth-Cozens 1997). As Charles Vincent points out about the relationship between self-blame and the personal impact of medical mistakes, a heightened tendency amongst clinicians to criticise themselves about the mishaps of the care that they provide may place them at significant risk for severe distress in the aftermath of such incidents (Vincent 2010).

The ways in which adverse events are handled institutionally and the support offered by healthcare organisations is another crucial determinant of the impact of adverse events on healthcare professionals. Two recent systematic reviews on the emotional impact of medical errors on clinicians confirmed the emotional burden of errors on staff and highlighted the lack of institutional support for them (Schwappach and Boluarte 2009; Sirriyeh et al. 2010). Sirriyeh et al. report that support in the workplace was often described as inadequate and organisational response was sometimes detrimental for staff wellbeing. For example, Waterman et al. report that only 10% of their 3,171 participants agreed that healthcare organisations adequately support their staff in coping with stress due to medical errors (37% disagreed strongly). Physicians who perceived their institutions as unsupportive were more likely to report increased stress after being involved in serious errors (Waterman et al. 2007).

There are therefore some indications on the factors that may moderate the relationship between involvement in adverse events and healthcare professionals' emotional reactions. However, as Sirriyeh et al. point out in their systematic review of the literature on the effects of

medical errors on clinicians' wellbeing: *"To date, the potential moderators of the emotional response, which may include error severity, colleague relationships, workplace culture and individual characteristics such as personality, have not been studied explicitly. These factors could be central in understanding the circumstances in which support would be beneficial, and may alert both individuals and healthcare institutions of the circumstances in which an error may have the most severe repercussions"* (Sirriyeh et al. 2010). Sirriyeh et al. also point out that the lack of empirical data on healthcare professionals' coping and support in the face of serious adverse events, as well as various inconsistencies and weaknesses in the methodology of existing studies such as the absence of commonly used mental health measures, need to be addressed with future research. The authors finally advise that clinicians' reactions to adverse events may vary as a function of the clinical setting and professional group, a research question that warrants further investigation.

1.3.3 Supporting healthcare professionals in the aftermath of serious adverse events

The importance of institutional support emerged in most of the studies that explored clinicians' experiences of adverse events.

A qualitative interview study highlighted that junior physicians' ability to cope with the emotional sequelae of adverse events was very much dependent on available reassurance and opportunities for learning (Engel et al. 2006). Others have reported that a significant proportion of healthcare professionals are reluctant to discuss their errors with colleagues and seniors (Wu et al. 1991; Kaldjian 2008) or that they are often unable to find the support they wish for among colleagues (Christensen et al. 1992; Waterman et al. 2007). The qualitative study by Scott et al. on the natural stages of recovery of healthcare professionals after their involvement in a medical error

reported an inability of clinical staff to move forward when the event was followed by non-supportive, negative departmental gossip, which triggered additional memories and intensified the self-doubt and lack of clinical confidence (Scott et al. 2009). Similarly, Wu et al. found that nearly a third of surveyed house officers indicated that “the hospital atmosphere inhibited them from talking about the mistakes” and 20% reported that the “administration was judgmental about the mistakes” (Wu et al. 1991). Therefore, a tendency to immediate blame after adverse events on the part of healthcare institutions seems to be a significant barrier to seeking support in the aftermath of unintended medical harm.

These studies highlight the need to better understand how healthcare professionals wish to be supported in the aftermath of medically induced injuries. Supporting healthcare professionals in the aftermath of serious patient safety incidents is vital not only for their own personal and professional wellbeing but also for patient safety and quality of patient care (see previous comments on the reciprocal cycle of symptoms that can further compromise patient safety). More research is needed in order to identify how best to implement an effective system of support for clinical staff who are involved in medical harm. Mixed methods research designs using in-depth qualitative methods supplemented by surveys on healthcare professionals’ own preferences for support would be most appropriate for identifying what is likely to be most effective.

1.4 Conclusions

This chapter presented background literature on the occurrence of adverse events in healthcare and their challenges both for patients’ and healthcare professionals’ psychological wellbeing. It also summarised the limited existing data on factors that potentially affect patients’ and healthcare professionals’ reactions to adverse events such as the ways in which adverse events are handled

institutionally, patient outcome and self-blame. However, currently we know very little about the range of patients' and clinicians' psychological reactions to such incidents, the role of different factors in shaping these reactions and patients' and clinicians' needs for support. These gaps will be addressed in this thesis in the context of surgery as will be explained in Chapter 2.

Chapter 2: Surgical complications and their aftermath

This chapter presents background literature on surgical complications. It starts with a short summary of their prevalence followed by issues of definition and an overview of the different levels of severity of these incidents. The chapter closes with a synopsis of relevant, albeit limited, literature on the physical and psychosocial effects of surgical complications on patients as well as on their implications for surgeons' wellbeing.

2.1 Prevalence of surgical complications

The operating room is one of the highest risk areas for patient safety incidents (Leape 1997) with potentially profound consequences for the patients affected. Nearly half of the adverse events that were identified in the Harvard Medical Practice study were related to surgery (Leape et al. 1991). A later study by Gawande et al. on the incidence and nature of surgical adverse events in Colorado and Utah in 1992, which involved a retrospective review of 15,000 non-psychiatric discharges from a sample of representative hospitals in Utah and Colorado in 1992, found that 66% of all adverse events were surgical and 54% amongst them were preventable (Gawande et al. 1999). Among all surgical adverse events, 5.6% resulted in death, accounting for 12.2% of all hospital deaths in Utah and Colorado. Therefore, the implications of surgical adverse events for patients, surgeons and healthcare organisations are significant.

2.2 Definition of surgical complications

‘Surgical complications’ is the term that is commonly used to describe adverse events that happen in surgery. After decades of research on surgical procedures and their outcomes there is still lack of consensus in surgical literature in relation to what constitutes a surgical complication. Various attempts have been made recently to define and operationalise the term “surgical complications”.

Clavien (1992), two decades ago, noting the large variability in the reported rates of surgical complications due to significant disagreement in the surgical community about which events constitute complications, attempted to define surgical complications by making a distinction between different negative outcomes following surgery. Surgical complications were defined as “any deviation from the normal post-operative course, including asymptomatic complications such as arrhythmia and atelectases” and did not include sequelae which constitute after-effects of surgery that are inherent to the procedure (e.g. inability to walk after a leg amputation) and failure to treat which refers to the situation where the original purpose of the procedure was not fulfilled (e.g. cancer recurrence) (Clavien 1992). Clavien (1992) also proposed a classification system for grading the severity of surgical complications in order to facilitate consistency in the reporting of complications amongst different studies.

More than a decade later Dindo et al. (2004) noted that there was still limited consensus on how to define complications and how to stratify them by severity. As a result, the authors refined the Clavien classification system, tested it on a large cohort of patients and assessed its acceptability and reproducibility by surveying a large number of surgeons from different health systems in various countries (Dindo et al. 2004). The results of the validation process were very positive and the revised classification system was proposed by the authors as a compelling tool for the assessment of surgical outcome worldwide. Moreover, surgical complications were re-defined as “any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to

cure” (Dindo and Clavien 2008). More specifically, the term *normal post-operative course* of Clavien’s 1992 definition (Clavien 1992) was replaced with the term *ideal postoperative course* in order to minimise subjectivity in the interpretation of what a complication is. As the authors note, in an ideal postoperative course no pathological findings may be observed unless inherited from the procedure (Dindo and Clavien 2008), which is line with the definition of medical adverse events as “unintended injuries caused by medical management rather than the disease process” (Brennan et al. 2004).

The classification system of Dindo et al. is now used widely in surgical studies assessing outcomes after various surgical procedures and represents one of the most thoroughly validated tools for defining and grading the severity of surgical complications (Dindo et al. 2004). Therefore for the purposes of this thesis, surgical complications are defined as per Dindo and Clavien as “any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure” (Dindo and Clavien 2008).

2.3 Effects of surgical complications on patients

There are two main types of effects of surgical complications on patients: the physical and the psychosocial.

2.3.1 Physical effects of surgical complications on patients

The physical impact of surgical complications on patients may be of various degrees of severity. Dindo et al.’s severity grading system defines a range of surgical complications that vary from very

minor risk events that can be resolved relatively quickly without the need for pharmacological treatment or other intervention, to more grave events which can be life-threatening, require multiple interventions (e.g. return to theatre), delay patient's discharge and might lead to multi-organ failure or even death (Dindo et al. 2004).

Examples of relatively minor surgical complications that can be treated quite easily include wound infections, which require packing on the ward, or atrial fibrillation after cardiac surgery, which requires administration of a pharmacologic agent. An example of a serious complication in gastro-intestinal surgery is anastomotic leaks following bowel resections that might lead to sepsis and multi-organ failure and might require a second operation that could lead to the formation of a stoma. An example of a serious surgical complication in vascular surgery is an embolism of the lower limb arterial system after open aortic aneurysm repair requiring above knee amputation. The clinical implications of relatively minor surgical complications are much less grave and short-lived as opposed to the life-changing effects of major complications, which may lead to permanent disability or disfigurement.

2.3.2 Psychosocial impact of surgical complications on patients

Other than their physical effects surgical complications may also affect patients psychologically. They may contribute to the development of psychological distress such as depression or anxiety due to the challenges that are inherent to them in terms of prolonged recovery or long-lasting disability. An anastomotic leak following bowel surgery, which requires a re-operation and a permanent stoma or a knee amputation following an embolism after open aortic aneurysm repair will represent significant sources of stress for the affected patients.

Undergoing major surgery has been documented as a stressful life event, regardless of the experience of complications. For example, Triffaux et al. found that patients undergoing orthotopic heart transplantation (OHT) scored significantly worse on depression, anxiety and general psychological wellbeing compared to an age and gender-matched group of healthy individuals (Triffaux et al. 2001). Clarke et al. found that 27% of general surgery patients developed high scores of acute post-traumatic stress symptoms in the post-operative period which were associated with in-hospital stress (Clarke et al. 1997). Qualitative data suggests that some patients experience a significant loss of confidence and feelings of anxiety in the aftermath of major cardiac surgery due to feeling unable to do tasks and activities they had previously undertaken without problems (Dunckley et al. 2008). A fear about the future and a general apprehension about returning to normality was also reported by Gardner et al. in an interview study with patients who had undergone major cardio-thoracic surgery in the previous six months (Gardner et al. 2005).

When things go wrong with patients' recovery, their psychosocial wellbeing may be further affected. An early study on the aftermath of adverse events that was conducted with patients who had experienced a serious adverse event after surgery found that these patients experienced higher levels of distress than people who had experienced serious accidents or bereavements and psychosocial adjustment worse than in patients with serious medical conditions (Vincent et al. 1993). The authors of an interview study on patients' experiences following cardio-thoracic surgery reported that a small number of patients who had a long hospital stay due to the occurrence of numerous surgical complications expressed intense feelings of hopelessness and depression (Gardner et al. 2005). One patient who suffered several complications during his hospital stay described: "My mental state was terrible, at one point I gave up. . . my lowest point". Studies on patients' experiences of being treated in an Intensive Therapy Unit (ITU) after surgery also suggest that a complicated recovery following surgery may contribute to reduced psychosocial wellbeing. Bapat et al. evaluated patients' quality of life (QoL) following prolonged ITU stay after cardiac surgery and compared it to the QoL of a control group of surgical patients who were not treated in

ITU and found that ITU survivors scored significantly lower on all different dimensions of QoL, including mental health (Bapat 2005). This data suggests that a complicated recovery from surgery may be a significant source of psychological distress for patients.

2.4 Implications of complications for surgeons' wellbeing

As argued in Chapter 1, healthcare professionals may also be affected by their involvement in unintentional patient harm. Therefore, surgical complications are likely to affect not only patients but also surgeons.

Surgical complications represent an important aspect of surgeons' professional identity. Surgeons in the UK, US and elsewhere hold regular audit meetings, the so-called morbidity and mortality meetings, where surgeons discuss complications with their peers in order to learn and improve their practice (Campbell 1988; Orlander et al. 2002; Pierluissi et al. 2003). Other than their relevance for surgeons' professional development, surgical complications may also constitute a significant source of stress. Complications may be perceived by surgeons as a personal failure (Bosk 2003), a perception that could be the core of a series of other psychological reactions with various degrees of severity and significant implications for their personal and professional lives.

Atul Gawande, a surgeon, academic and writer, dedicated an entire book to surgical complications noting surgeons' fallibility in the practice of surgery and the often painful personal experiences of surgical adverse events, based not only on his personal experiences but also on observations of others, both colleagues and patients, as they went through such incidents (Gawande 2007). More than 30 years ago, Charles Bosk spent eighteen months observing a surgical training programme in the Pacific Hospital in the United States aiming to explore and understand the construction of surgeons' professional identity during their training. As part of this ethnological

study Bosk tried to explore surgeons' socialisation in relation to managing surgical failure and to document how a surgeon copes with what he describes as "*the existential problem of the limits of his skill and the limits of his knowledge*". This sociological study suggests various degrees and forms of impact of complications on surgical trainees (Bosk 2003).

Recently, two empirical studies have been published with regard to the experiences of surgeons after certain surgical complications. A survey study in the UK on surgeons' attitudes to intra-operative death, found that all five surgeons who had experienced the death of a patient during elective surgery thought that counselling should be offered. Four (80%) of those experiencing unexpected intra-operative death of a trauma patient and one (20%) of those experiencing expected intra-operative death of a trauma patient also thought that counselling should be offered (Smith and Jones 2001). The sample size of this study was far too small (n=16) to allow us to make any strong assumptions but it provides preliminary evidence, which suggests that surgeons experience significant distress when catastrophic complications happen in their practice.

Lastly, Shanafelt et al., in a large survey study of 7,900 American surgeons found that having been involved in a surgical error in the previous 3 months was associated with significantly lower mental quality of life, higher levels of burnout and higher risk of screening positive for depression. Reported errors were also related to lower career satisfaction, with those surgeons who reported recent errors being less likely to report that they would become a surgeon again and also less likely to recommend their children to pursue a career as a surgeon. The authors conclude that further research is needed on how to reduce surgeons' distress and how to support surgeons when errors occur (Shanafelt 2010).

2.5 Conclusions

The aftermath of adverse events in surgery is of critical importance not only because surgical complications are the most frequent type of healthcare-related adverse events but also because their consequences can be significant. Studies on patients' experiences of surgery or ITU treatment imply that complications may be a significant source of stress for patients. Surgeons also appear to be affected by surgical complications that happen in their practice. However, our understanding of the range of the psychological impact of surgical complications on patients and surgeons and the determinants of their psychological reactions is very limited due to the scarcity of primary data in this area. Further research is needed to identify the range and intensity of the psychological impact of surgical complications on patients and surgeons, the factors that affect their reactions, and optimal ways for supporting both patients and surgeons in the aftermath of such unfortunate incidents. This thesis will attempt to answer these questions in the light of relevant psychological literature that is presented in Chapter 3.

Chapter 3: Theoretical perspectives on the aftermath of surgical complications

This chapter reviews the theoretical frameworks and constructs that are relevant for the investigation of how surgeons' and patients' psychological wellbeing is affected by the experience of surgical complications. First, the psychological outcomes that are of relevance to patients' and surgeons' responses to surgical complications will be discussed, followed by an overview of the psychosocial factors that may affect the wellbeing of surgeons and patients in the aftermath of surgical complications. This chapter closes with the implications of the reviewed literature for understanding patients' and surgeons' experiences of surgical complications and a presentation of the aims of the thesis.

3.1 Psychological reactions to extreme stress

Surgical complications that result in severe disability, impairment or death are expected to cause significant amounts of stress both to patients and surgeons and may elicit responses similar to those that individuals exhibit after their exposure to traumatic events. Post-traumatic stress will therefore be discussed as a key psychological outcome for the investigation of the psychological impact of surgical complications on both patients and surgeons. Anxiety and depression are also commonly encountered after exposure to severe stress and are of relevance to patients' and surgeons' reactions to surgical complications. The psychological impact of surgical complications on surgeons could also manifest itself through symptoms of burnout, which is a work-related psychological

syndrome of high relevance to healthcare professionals. Finally, a relevant outcome for the assessment of the psychosocial impact of surgical complications on patients is health-related quality of life (QoL). Background information on each outcome is presented below in more detail.

3.1.1 Post-traumatic stress

3.1.1.1 Diagnosis of Post-Traumatic Stress Disorder (PTSD)

Post-traumatic stress disorder (PTSD) is the most common type of psychopathology that is associated with the experience of traumatic events (Yehuda 2002). PTSD was first introduced in the third edition of Diagnostic and Statistical Manual of Mental Disorders (DSM III) (American Psychiatric Association 1980) as a mental disorder requiring a stressor that would “evoke significant symptoms of distress in almost everyone” and that was generally “outside the range of usual human experience” (i.e. criterion A of PTSD) (American Psychiatric Association 1980). In the most recent edition of DSM (American Psychiatric Association 2000) the criterion A of PTSD was broadened so that one does not need to experience but can also witness or be confronted with a traumatic event with the capacity to provoke fear, helplessness or horror in response to the threat of injury or death, or in response to a threat to the physical integrity of self or others (DSM-IV). Green (1990) listed 7 dimensions that indicate the diversity of events that qualify as traumatic stressors: 1) threat to one’s life and body integrity, 2) severe physical harm or injury, 3) receipt of intentional injury/harm, 4) exposure to the grotesque, 5) witnessing or learning of violence to loved ones, 6) learning of exposure to a noxious agent, and 7) causing death or severe harm to another (Green 1990).

Even though PTSD was initially seen as relevant in the context of major traumatic events such as natural disasters, wars and terrorist attacks (McFarlane and De Girolamo 2007) epidemiological

research on the prevalence of PTSD revealed that traumatic events were much more prevalent than what was originally assumed and that PTSD may also follow less major events such as road accidents (Mayou 1993; Mayou et al. 1997), medical procedures (Shalev et al. 1993), myocardial infarctions (Kutz et al. 1994), bereavement, or employment-related stressors (Rosen and Lilienfeld 2008). Moreover, other than horror, helplessness and fear, a wide range of reactions to trauma are now associated with PTSD, including shame, a sense of violation of trust and emotional numbing (Rosen and Lilienfeld 2008; Brewin et al. 2009).

A diagnosis of PTSD is given when a person has three clusters of symptoms: (a) re-experiencing the event, (b) avoiding reminders of it and (c) experiencing increased hyperarousal. All three clusters need to be present together for longer than one month (DSM-IV) (American Psychiatric Association 2000). Re-experiencing the event refers to intrusive recollections of the event (e.g. nightmares, flashbacks or vivid memories) accompanied by intense psychological distress as a response to these reminders. Avoidance symptoms refer to actively avoiding people, places or other cues that remind the person of the event, while increased hyper-arousal refers to physiological manifestations such as insomnia, concentration problems, irritability and outbursts of anger, tendency to become more vigilant and concerned about safety and increased startle reactions (Yehuda 2002).

When these symptoms are experienced within one month after a traumatic event, the individuals are diagnosed with acute stress disorder (ASD) which has been linked with increased odds of developing chronic PTSD (Yehuda 2002; Brewin et al. 2003).

3.1.1.2 Theories of PTSD

A number of psychological theories exist that describe the processes of PTSD development (Brewin 2003). The best known is the *Stress response theory* (Horowitz 1986) which focuses on the conflict that exists between trauma-related information and key assumptions about oneself, the world and the future. According to Horowitz, there are two opposing processes that are involved in the development of PTSD: one that tries to protect the individual from the overload of trauma-related information that is in conflict with his/her prior knowledge and one that results from a fundamental psychological need to reconcile new and old information. The first process leads to the avoidance of trauma-related cues while the second leads to intrusive memories. When the individual fails to process the trauma-related information in a coherent way, chronic post-traumatic stress develops (Horowitz 1998).

3.1.2 Anxiety and depression

Post-traumatic stress is not the only type of psychopathology that is encountered in the aftermath of extreme stress. Depression and anxiety disorders are also associated with exposure to trauma (Shalev and Yehuda 1998; Rosen and Lilienfeld 2008; Brewin et al. 2009). A prospective study of psychological wellbeing after trauma found that major depression and PTSD were independent outcomes of traumatic events with similar prognoses (Shalev et al. 1998). In another study, civilian trauma survivors were diagnosed with major depression and anxiety disorders four months after the traumatic event (Shalev et al. 1997). Therefore, depression and anxiety are also commonly encountered after exposure to traumatic stressors.

Depression is a psychological state which is defined by the following attributes: (a) a significant alteration in mood such as sadness, loneliness and apathy, (b) a negative self-concept associated with self-reproach and blame, (c) regressive and self-punitive wishes such as desire to escape, hide or die, (d) vegetative changes such as anorexia, insomnia, loss of libido and (e) change in activity level such as retardation or agitation (Beck and Alford 2008). Anxiety is defined as an emotional response to perceived threats (Spielberger, 1972) while general anxiety disorder is defined as excessive worry about a variety of topics including minor matters, accompanied by at least three of the following: restlessness, fatigue, difficulty concentrating, irritability, muscle tension, and difficulty sleeping (American Psychiatric Association 2000).

3.1.3 Burnout

3.1.3.1 Definition of burnout

Burnout is a psychological syndrome that has been linked with job-related interpersonal stressors and is one of the most extensively studied markers of wellbeing in the work-place with very high relevance to healthcare professionals (Maslach et al. 2001; Schaufeli 2007). It consists of three dimensions: an overwhelming exhaustion, feelings of cynicism and detachment from the job, and a sense of ineffectiveness and lack of accomplishment (Maslach et al. 2001).

Exhaustion is the main aspect of burnout and has been suggested to result from the emotional demands of the work, which can compromise a service provider's engagement with the needs of service recipients. Depersonalisation is the attempt to distance oneself from service recipients as a way of managing their emotionally exhausting demands. Reduced accomplishment refers to feelings

of incompetence at work and seems to arise from the lack of resources for coping with the emotional demands of the job (Maslach et al. 2001).

The consequences of burnout are varied. First, it has been linked with reduced job performance such as absenteeism, intention to leave one's job, turnover, reduced productivity and reduced job satisfaction (Parker and Kulik 1995; Schaufeli et al. 2009). It has also been linked with negative health outcomes such as standard stress-related physiological indexes (De Vente et al. 2003; Grossi et al. 2003). Finally, burnout might contribute to the development of affective disorders such as anxiety and depression (Maslach et al. 2001).

3.1.3.2 Prevalence of burnout

Numerous studies in various countries suggest that a substantial proportion of healthcare professionals suffer from the burnout syndrome (Spickard et al. 2002; Embriaco et al. 2007; Trufelli et al. 2008). Schaufeli, in a recent review of burnout research, estimated the prevalence of burnout at about 4%-7% of the working population, reaching about 10% in healthcare professionals (Schaufeli 2007). Surgeons also suffer from high levels of burnout and score particularly high on emotional exhaustion (Campbell Jr 2001; Bertges Yost et al. 2005; Sharma et al. 2008; Shanafelt et al. 2009). The prevalence of burnout could be even higher than the existing estimates especially in consideration of the "healthy worker effect" (i.e. a bias resulting from the fact that only working members of staff are usually researched, who are expected to be healthier than those who are not working) (Schaufeli 2007).

3.1.3.3 Theories of burnout

To date there is no overarching, all encompassing theory of burnout (Schaufeli 2007). The traditional approach to burnout suggests that emotional overload which results from emotionally demanding relationships with the recipients of one's work is the root cause of burnout (Field 2011). The main mechanism behind emotionally exhausting relationships at work is the existence of a negative social exchange dynamic with employees investing too much and too long in their relationships with others or the organisation and not receiving enough back in return (Schaufeli 2006). This model has received significant support in a variety of occupations including healthcare professionals (Schaufeli 2006).

Another popular organisational approach to burnout is the *"Job Demand-Resources"* model (Demerouti et al. 2001). This model postulates that emotional exhaustion is primarily related to excessive job demands, whereas lack of job resources leads to symptoms of disengagement. Personal accomplishment is not considered a genuine component of burnout in this approach (Bakker et al. 2004). This model highlights the important role of job resources (e.g. social support) in buffering the effects of excessive demands (Bakker et al. 2004).

Finally, a theoretical framework on burnout that moves beyond the job-person paradigm to a more complex conceptualisation of the person within the job context has recently been proposed (Maslach and Leiter 1997). The proponents of this framework suggest that burnout is the result of the mismatch between the person and six domains of his/her job environment (i.e. workload, control, rewards, community, fairness and values). The greater the mismatch, the higher the likelihood of burnout (Maslach et al. 2001). For instance, a mismatch in workload is observed when there is excessive overload from the wrong kind of work or when the job requires a display of emotions inconsistent with one's feelings and it is directly associated with the exhaustion aspect of burnout.

3.1.4 Quality of Life (QoL)

While the focus of medical research has traditionally been on clinical outcomes such as mortality and morbidity, the last few decades have seen a significant increase of studies that assess the impact of medical interventions on patients' quality of life (QoL) (Paykel 1994). Health-related quality of life is defined by the World Health Organisation (WHO) as: *"An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals and expectations, standards and concerns. It is a broad ranging concept affected in a complex way by a person's physical health, psychological state, level of independence and their relationships to salient features of their environment"* (Halbesleben 2006).

QoL has been adopted as an outcome in clinical studies for three main purposes: (a) to assist in evaluations about the best uses of healthcare resources, (b) to facilitate clinical decision-making by allowing comparisons of treatments especially when these are equal in terms of clinical outcomes, and (c) to facilitate patients' autonomous decision-making in relation to treatment choice (Häyry 1991).

QoL is a dynamic construct as the individuals' perceptions of it vary with time and experience and are modified by psychological factors such as adaptation, coping, expectancy, optimism and self-control (Allison et al. 1997). A response shift can occur in perceptions of past and present QoL as a result of: (a) a change in the respondent's internal standards of measurement (i.e. scale recalibration); (b) a change in the respondent's values (i.e. the importance of domains constituting QoL) or (c) a redefinition of QoL itself (Schwartz and Sprangers 1999).

3.2 Predictors of psychological reactions to extreme stress

Recent studies on the epidemiology of post-traumatic stress suggest that less than 10% of those exposed to traumatic stressors will develop the full syndrome of PTSD (Breslau 2009). The factors that explain why certain people experience severe psychological distress in the aftermath of extreme stressors while others do not are therefore important for our understanding of patients' and surgeons' psychological reactions to surgical complications. Reactions to extreme stress are powerfully moderated by three major factors: how people appraise the threat, how they cope with stress and the support that is available to them. These factors are discussed below.

3.2.1 Appraisals

Cognitive appraisals are key determinants of the individuals' response to stressful life events. Lazarus & Folkman's model on stress and coping proposes that the selection of coping strategies is guided by two types of appraisal (i.e. a primary appraisal of the stimulus which determines whether it represents a stressor, followed by a secondary appraisal of the best course of action in order to deal with the stressor). Weiner's causal attribution theory proposes three major dimensions of causal attributions that individuals make about stressors: locus of causality (whether the cause is seen as pertinent to the person or external factors), controllability (whether the cause is seen as controllable or not) and stability (whether the cause is seen as lasting or transient) (Weiner 1986). Different combinations of these dimensions are associated with different coping strategies and wellbeing outcomes. In a meta-analysis of the relations between causal attributions, coping, and psychological adjustment in individuals with physical illnesses or undergoing medical procedures, perceptions that the cause of the illness is stable and uncontrollable were associated with the use of avoidance and low psychological wellbeing whereas attributions to internal and controllable causes were associated with problem-focused and emotion-focused coping and positive psychological adjustment (Roesch and Weiner 2001).

Cognitive appraisals are important factors in the development of psychopathology such as PTSD. An internal locus of causality has been associated with more symptoms of PTSD (Joseph et al. 1991; Joseph et al. 1993). Attributing negative outcomes to internal and controllable factors has been suggested to lead to feelings of guilt which exacerbate negative emotions (Joseph et al. 1993). Other studies suggest that an external locus of causality is associated with increased risk of PTSD. For example, among road accident survivors who met the criteria for PTSD those who blamed themselves for their accident had significantly less PTSD symptoms than those who attributed responsibility to someone else (Delahanty et al. 1997; Hickling et al. 1999). Interactions with perceptions of controllability and stability of the threat possibly explain these divergent findings.

3.2.2 Coping

Lazarus and Folkman propose that the extent to which a potential stressor will impact on the person's experience of stress will depend on the interactions between his/her appraisals of the situation and the coping strategies that he/she will employ in order to respond to the stressful situation (Lazarus and Folkman 1984; Lazarus and Folkman 1987). Coping is defined as: *"constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person"*.

According to this model, a cognitive appraisal precedes the selection of coping strategies. During the primary appraisal the individual assesses the extent to which a stimulus represents a stressor. If the stimulus is perceived as threatening, then the person evaluates the most appropriate coping strategies in order to make a response to the stressful situation. The appraisal of the controllability, the duration and the type of stressor have been found to predict the selection of coping strategies (Penley 2002). Problem-focused coping, which is directed towards changing the

relationship between the demands of the situation and the resources available, has mainly been linked with controllable and changeable stressors. On the other hand, emotion-focused coping which is directed towards managing the emotional consequences of the stressor has been associated with situations where the scope for individual control is limited (Newsom and Schulz 1996).

Coping strategies have also been linked with the development of PTSD. For example, greater avoidance or suppression of thoughts related to the incident is associated with higher PTSD symptoms and slower recovery from PTSD (Brewin 2003). Rumination and increased use of safety behaviours has also been linked with a greater risk of PTSD (Brewin 2003). A study of the relationship between coping and PTSD amongst ambulance service workers found that wishful thinking, mental disengagement, negative interpretations of intrusive memories, rumination, suppression and dissociation correlated with PTSD severity (Clohessy and Ehlers 1999).

3.2.3 Social support

Social support is *“the function and quality of social relationships, such as perceived availability of help or support actually received”* (Schwarzer and Leppin 1991; Schwarzer et al. 2004). A subjective operationalisation of social support is not only concerned with the existence of relationships, but with the functions that an individual's relationships are perceived to serve. This definition has been consistently linked with psychological wellbeing and health outcomes (McNally and Newman 1999).

It has been suggested that social support positively impacts on health under conditions of stress by functioning as a buffer to stressful conditions (Schwarzer and Leppin 1991). Social support has also been conceptualised as a coping strategy and the mechanism of seeking support is a key component of most tools that assess coping (Schwarzer et al. 2004). More recently researchers have also started investigating the negative aspects of perceived social support. For instance, a meta-

analysis of the relationship between coping strategies and health outcomes found that seeking emotional support was significantly related with negative physical outcomes and unrelated with psychological outcomes. A possible explanation is that while perceived adequacy of support is associated with fewer psychological symptoms, high support utilisation is associated with worse psychosocial wellbeing due to stress leading to tendency to seek more support (Monroe and Steiner 1986).

Social support is an important factor for the development of psychopathology after traumatic stress. A meta-analysis of 14 risk factors for PTSD found that social support had the strongest effect size (Brewin et al. 2000). It is not only the positive elements of social support that are of relevance to the development of PTSD (e.g. perceived emotional and practical support) but also the existence of a negative social environment (e.g. indifference, criticism or blame) (Brewin 2003). Ullman and Filipas (2001) found that among the strongest correlates of PTSD severity in sexual assault victims was the receipt of negative social reactions upon disclosing assault (Ullman and Filipas 2001). There is strong evidence suggesting that perceived social support also mediates the effects of stress on anxiety (Mercer and Ferketich 1988), depression (Paykel 1994), burn-out (Maslach et al. 2001) and quality of life (Newsom and Schulz 1996).

3.3 Implications for patients with surgical complications

In this section I discuss the implications of the above presented literature for patients' experiences of surgical complications.

3.3.1 Implications of PTSD, anxiety, depression and impaired QoL for patients who suffer surgical complications

When patients experience serious complications as part of their surgery, it is expected that some will develop the types of psychological distress that are encountered after major traumatic events. 'Threat to one's life and body integrity' and 'severe physical harm' which are key dimensions of traumatic stressors (Green 1990) are defining criteria of life-threatening complications after surgery. Fear and intense worry for one's life are expected patient reactions after major surgical accidents. Patients who suffer serious unexpected complications are expected to experience a conflict between their pre-operative assumptions of surgery as beneficial and the unexpected harm that they experience as a result of it. It is this conflict between trauma-related information and key assumptions of the world and oneself that leads to experience of post-traumatic stress according to the Stress Response Theory (Horowitz 1986). Therefore, post-traumatic stress is a relevant psychological outcome for patients who suffer serious surgical complications.

Anxiety and depression symptoms are also relevant outcomes after patients' experiences of surgical complications. Other than the fact that they are common reactions to extreme stress as it was described above, they are also often encountered in the aftermath of surgical treatment (Johnston 1980; Wallace 1986; Magni G and et al. 1987; Burker et al. 1995; Rymaszewska et al. 2003; Carr et al. 2005). Surgical complications are also expected to impair patients' perceived quality of life due to the consequences of surgical complications on all aspects of patients' lives including their psychological and social welfare. Moreover, QoL is one of the main outcomes that are used in the evaluation of surgical treatments with a substantial amount of QoL research now existing in relation to various types of surgery (Duits et al. 1997) (Ethgen et al. 2004) (Sprangers et al. 1993; Pusic et al. 2007). Therefore, QoL, anxiety and depression are of high relevance to the investigation of the psychosocial impact of surgical complications on patients' wellbeing.

3.3.2 Implications of appraisals, coping and social support for patients who suffer surgical complications

Patients' appraisals of their condition, the surgery and the associated complications may affect their feelings in the aftermath of complicated surgery. The *Self-regulation model of illness cognition and behaviour*, otherwise known as the *Common Sense Model (CSM)*, emphasises the importance of common sense beliefs about illness as determinants of patients' experiences (Leventhal et al. 1984). The CSM proposes that individuals create cognitive representations of their condition's identity (i.e. beliefs about the diagnosis and the symptoms), the cause (i.e. beliefs about factors that have led to the disease), the timeline (i.e. beliefs about the duration of the illness), the consequences (i.e. perceptions of the effects of an illness on wellbeing) and control/cure (i.e. perceptions of the extent to which treatment or specific behaviours can manage the illness). These representations contribute to the self-regulation of health threats by guiding the selection of coping behaviours. The CSM has been applied with surgical patients and findings lend support to the important contribution of patients' illness representations to their post-operative psychosocial adjustment. For instance, patients who underwent surgery for osteoarthritis and believed that their symptoms were under their control gained more function after discharge and patients who were pessimistic about the benefits of surgery reported significantly higher depression levels (Orbell et al. 1998). Pre-surgery negative illness beliefs amongst cardiac surgery patients predicted disability, physical functioning, and depressive symptoms three months post-surgery even after controlling for variables of illness severity (Juergens et al. 2010). These findings suggest that illness representations are important determinants of patients' psychosocial adjustment in the post-operative period and may therefore moderate the effects of surgical complications on patients' wellbeing. Patients' pre-operative expectations of the benefits of surgery in particular are of high relevance in the context of complicated surgery. Patients who have high expectations from their surgery and who experience

serious complications may be more distressed than patients who have lower pre-operative expectations from their surgery. Patients' causal attributions of the complications that they experience may also be of relevance to their post-operative psychological wellbeing.

The ways in which patients cope with the challenges of the surgical complications are also expected to affect their psychological wellbeing. Coping strategies are well known predictors of patients' wellbeing after surgery. For example, Boehmer et al. found that active and meaning-focused coping was a significant mediator of self-efficacy beliefs on health-related quality of life after surgery for head and neck cancer (Boehmer et al. 2007), while depressive symptoms were related to less adaptive coping methods in patients who had undergone surgery for lung cancer (Walker et al. 2006). In other words the coping strategies that patients employ in order to deal with the stress of their surgery may also moderate the impact of surgical complications on their post-operative wellbeing.

Lastly, patients who suffer surgical complications are expected to rely on the support of their loved ones and the healthcare professionals who care for them. Patients' needs of support may be practical, emotional or informational. We saw earlier that perceived social support is one of the key factors for the development of PTSD after traumatic stress (Brewin et al. 2000). Perceptions of social support are also significant correlates of patients' wellbeing after major surgery both in terms of physical (Kulik and Mahler 1989; Bastone 1995; Schröder et al. 1998; Boehmer et al. 2007) and psychological outcomes (Neuling and Winefield 1988; Schröder et al. 1998; Walker et al. 2006; Boehmer et al. 2007). Therefore, patients' perceptions of the support that they receive in the aftermath of surgical complications represent an important contextual factor for the investigation of the impact of surgical adverse events on patients' wellbeing.

3.4 Implications for surgeons who are involved in surgical complications

In this section I discuss the implications of the above presented literature for surgeons' experiences of surgical complications.

3.4.1 Implications of PTSD, anxiety, depression and burnout for surgeons who experience complications in their patients' care

Serious surgical complications are important work-related stressors for surgeons. 'Causing death or severe harm to another' is a painful experience and constitutes one of the core aspects of traumatic incidents (Green 1990). Surgeons who are confronted with serious complications are expected to experience fear, anger and shame (Wu et al. 1991; Christensen et al. 1992; Aasland and Forde 2005; White et al. 2008) all of which are associated with PTSD. Complications may also haunt surgeons for a long time after their occurrence in the form of intrusive reflections (Scott et al. 2009). Surgeons who experience a conflict between their expectations of a successful outcome and the occurrence of serious complications could be at risk for post-traumatic stress based on the Stress Response Theory (Horowitz 1986). Therefore, under certain conditions post-traumatic stress may be one of the consequences of surgeons' involvement in serious surgical complications.

Depression may also be a relevant psychological outcome for surgeons in the aftermath of surgical complications as it has recently been associated with healthcare professionals' involvement in adverse events (West et al. 2006; Fahrenkopf et al. 2008; Shanafelt et al. 2009). Moreover, surgeons who were involved in a medical error in the previous 3 months were significantly more likely to exhibit symptoms of depression (Shanafelt 2010). Surgeons are also expected to report

increased levels of anxiety in the aftermath of surgical complications especially when these are of a serious nature and even more so when they are followed by institutional repercussions.

Burnout is also a potential consequence of surgeons' involvement in surgical complications. Burnout was recently found to be associated with perceived medical errors among American surgeons (Shanafelt 2010). Even though the study was cross-sectional this finding suggests that adverse events may contribute to the development of burnout. The underlying mechanisms behind this association may be a series of mismatches that happen when surgical complications occur. There may be a mismatch with surgeons' sense of control over patient outcomes or with their community of peers due to feelings of incompetence and embarrassment. A mismatch may also occur with a sense of fairness due to lack of institutional support for staff after adverse events or a mismatch with the surgeons' own values (i.e. do no harm). Mismatches such as the above are suggested to lead to burnout (Maslach et al. 2001). The combination of the high demands of surgical complications (i.e. manage their consequences, comfort patients and offer explanations) with the lack of adequate support may exacerbate feelings of exhaustion and cynicism (Demerouti et al. 2001).

3.4.2 Implications of appraisals, coping and social support for surgeons who experience complications in their patients' care

Appraisals of the factors that lead to complications, especially if the complications are seen as related to the surgeons' own actions, are expected to exert an important impact on how seriously surgeons are affected by complications. Preliminary qualitative data suggest that greater perceived personal responsibility is associated with higher levels of distress (Engel et al. 2006). Therefore, surgeons' appraisals of the locus of causality of the factors that lead to surgical adverse events are

important contextual factors for our understanding of their emotional responses to surgical complications.

The ways in which surgeons cope with the stress of surgical complications are also expected to be associated with their psychological wellbeing in the aftermath of these incidents. The literature on healthcare professionals' coping with adverse events is limited. Early findings suggest that denial, discounting and emotional distancing are common coping strategies of junior clinical staff in the aftermath of adverse events (Mizrahi 1984). Considering that coping is one of the key correlates of psychological outcomes in the aftermath of extreme stress and that use of specific coping strategies such as avoidance are correlated with higher levels of post-traumatic stress (Brewin 2003), an investigation of surgeons' coping mechanisms in the aftermath of major surgical complications will shed light on why some surgeons may be more affected more than others.

Social support is also an expected predictor of surgeons' emotional distress in the aftermath of surgical complications. Lack of adequate institutional support for staff after adverse events is unfortunately common and is expected to negatively impact on staff's wellbeing (Schwappach and Boluarte 2009; Sirriyeh et al. 2010). Support from colleagues and supervisors is also an important factor of clinicians' reactions to adverse events (Engel et al. 2006; Scott et al. 2009). Therefore, the perceived support that surgeons receive from their institutions, their peers, as well as their own personal networks of friends and family is likely to moderate the impact of complications on their emotional wellbeing.

3.5 Summary of relevant theoretical perspectives

In summary, post-traumatic stress, anxiety, depression, burnout and quality of life are relevant psychological outcomes for the investigation of patients' and surgeons' emotional wellbeing after

surgical complications. Appraisals, coping and perceptions of support are evidence-based correlates of wellbeing in the context of extreme stress and useful theoretical constructs for the aims of this thesis. This thesis will aim to identify the relationship between the occurrence of surgical complications and most of the psychological outcomes that were presented above. Moreover, it will investigate the role of cognitive appraisals, coping and perceived support as predictors of the psychological impact of complications on patients and surgeons. The aims of the thesis are listed below.

3.6 Thesis aims and rationale

We saw in Chapter 1 that adverse events in healthcare pose significant challenges both for patients and healthcare professionals. Chapter 2 presented data which suggest that the aftermath of surgical complications is particularly important due to the prevalence of surgical adverse events in healthcare as well as due to their profound consequences on patients. However, the range of patients' and surgeons' psychological reactions to surgical complications and the factors that affect their psychological wellbeing in the aftermath of these incidents are unclear. This thesis will address these questions by drawing upon relevant psychological literature that was presented in Chapter 3. In summary, this thesis aims:

1. To understand the range of patients' psychological reactions to surgical complications.
2. To identify the psychosocial factors that moderate patients' psychological reactions to surgical complications.
3. To understand the range of surgeons' psychological reactions to surgical complications.

4. To identify the psychosocial factors that moderate surgeons' psychological reactions to surgical complications.

As a first step, an understanding of the types, extent and duration of the psychosocial impact of surgical complications on patients is required. Therefore, the following chapter presents a systematic review of existing literature on the association of surgical complications with patients' psychosocial wellbeing.

Chapter 4: The psychosocial impact of surgical complications on patients: A systematic review of quantitative studies

This chapter presents a systematic review of quantitative studies on the psychosocial impact of surgical complications on patients after major gastro-intestinal, vascular or cardio-thoracic surgery. The findings of 50 studies that were found to be eligible for the final stage of this review are summarised in relation to the types of impact of surgical complications on patients' wellbeing, their effect sizes and their duration. The findings are discussed with regard to the quality of the included studies, as well as the methodological limitations and strengths of the review.

4.1 Introduction

Surgical complications pose significant challenges for surgical patients. Complications vary from very minor risk events that can be resolved relatively quickly without the need for pharmacological treatment or other intervention, to more grave events which can be life-threatening, require multiple interventions (e.g. return to theatre), delay patient's discharge and lead to multi-organ failure or even death (Dindo et al. 2004).

The existing research on surgical complications has mostly focused on the types and rates of surgical complications after specific procedures (Lawrence et al. 1995; Ridderstolpe et al. 2001), their clinical or financial implications (Dimick et al. 2004), or how they can be prevented (Clagett 1988; Bratzler and Hunt 2006). Surgical complications are also expected to affect patient's psychosocial wellbeing and may contribute to the development of severe psychological distress such as depression or anxiety due to the challenges that are inherent to them in terms of prolonged

recovery or long-lasting disability (e.g. severe chronic post-operative pain, permanent disfigurement). Psychological distress could further delay patients' recovery from surgery in an almost reciprocal manner, as there is strong empirical evidence on the negative relationship between stress and physical recovery which suggests that increased levels of stress delay wound healing (Ebrecht et al. 2004; Walburn et al. 2009) and compromise immunity through established psycho-bio-neurological avenues (Herbert and Cohen 1993; Kiecolt-Glaser et al. 2002). Increased levels of stress have also been linked with delayed recovery from surgery (Kiecolt-Glaser et al. 1998), and therefore psychological distress resulting from the experience of surgical complications could further compromise patients' convalescence.

However, the implications of surgical complications for patients' psychosocial wellbeing above and beyond the effects of surgery are not well understood. As a first step, a review of the relevant literature is required in order to identify the types, magnitude and duration of the psychosocial impact of surgical complications on patients.

4.1.1 Aims

This review aims to critically review and synthesize the existing literature on the psychosocial impact of surgical complications on adult surgical patients and to estimate the types of impact, their degree and duration. For this purpose, empirical studies, which quantitatively assess the association of surgical complications with adult patients' psycho-social wellbeing post-surgery were reviewed. The research questions that this systematic review aims to answer are:

- Do surgical complications impact negatively on patients' psychosocial wellbeing and how?
- What is the degree of this impact?

- Is the psychosocial impact transitory or long-term?

4.2 Methods

4.2.1 Electronic databases

The following databases were used for the retrieval of literature relevant to the research questions of this systematic review: 'PsychINFO', 'MEDLINE-in-process-and-other-non-indexed-citations and Medline' and 'Classic Embase + Embase'; all three were searched through OvidSP. On the basis that to my knowledge there is no other systematic review of the literature on the above-listed research questions, it was initially decided that the searches would not be restricted by time of publication. All three databases were searched from the beginnings of their collections (i.e. 'PsychINFO' was searched from 1967 to date, 'Classic Embase + Embase' from 1947 to date and 'MEDLINE-in-process-and-other-non-indexed-citations and Medline' from 1948 to date).

4.2.2 Search strategy

A search strategy was developed after a long iterative process specific to each database. Each version of the search strategy was constructed to include both standardised subject headings (i.e. MESH terms) and text words for each facet of the research question. The three main facets of the research question were:

A. Population: Adult surgical patient

Adult patients only (i.e. above 18 years old) were included in this review as it is expected that the ways in which adults are affected by surgical complications are different, both qualitatively and quantitatively, from the ways in which children and adolescents experience such incidents. Terms such as patients, inpatients, outpatients, men, women were used for this facet.

B. Outcomes: Patient psychosocial outcomes

Key psychosocial outcomes that are commonly used to assess patients' wellbeing in medical literature include anxiety, depression and quality of life (see Chapter 3). Terms for post-traumatic stress were also included in the search strategy due to the relevance of this psychological outcome in situations where a person is exposed to extreme stress as explained in Chapter 3. Generic terms such as wellbeing and emotions were also used.

C. Setting: Complications in surgery

Surgery-related complications were defined as any adverse event in relation to the surgical procedure including search terms for complications (e.g. adverse events, untoward incidents) and terms about the surgical setting (e.g. surgical, post-operative, intra-operative).

Each of the facets was expanded into a list of search terms truncated as appropriate and combined with each other using Boolean operators, and also by mapping those to their relevant MeSH headings in each database. In order for the search strategy to be comprehensive enough each of the

relevant MeSH headings were exploded so that their sub-headings were also included in the search. The search was restricted to titles and abstracts, and the results were limited to studies that used human participants and were written in English. Appendix 1 presents the search strategies that were used in each of the electronic databases.

The last search was run on the 28th of September 2010. An update literature search was performed from the 29th of September 2010 to the 25th of May 2012.

4.2.3 Eligibility criteria

Due to the large amount of retrieved literature the inclusion criteria were further narrowed down by limiting results to articles that were published after the year 2000 and also with the majority of patients recruited after the year 2000. The adoption of a current approach in the selection of literature was also expected to reduce any bias that results from studies that report outcomes of out-dated surgical practices. We also decided to restrict the results to surgical specialties that include high-risk procedures where complications are more likely to occur, i.e. cardio-thoracic, gastro-intestinal and vascular surgery (Gawande et al. 1999). Table 2 presents the inclusion criteria that were used for deciding which articles were eligible for inclusion in the final stage of the systematic review.

Table 2: Study eligibility criteria for inclusion in the final stage of the systematic review

Inclusion criteria	Definition
Population	Adult surgical patients: Patients above 18 years old who underwent cardio-thoracic, general gastro-intestinal or vascular surgery.
Outcomes	Psychosocial wellbeing: i.e. anxiety, depression, quality of life, post-traumatic stress, general wellbeing, assessed with validated patient reported measures or formal psychological assessment. We excluded studies that assessed patients' wellbeing based on clinical judgement only or non-validated measures.

Study aims	To measure the association of surgical complications with patient psychosocial outcomes after surgery. This aim could be either primary or secondary. Studies that measured psychosocial outcomes as predictors of the occurrence of surgical complications were excluded.
Setting	Surgical complications: adverse events associated with surgery in cardio-thoracic, general gastro-intestinal and vascular surgical procedures. Studies looking at neuropsychological complications (e.g. delirium) were excluded, as their direct relationship with surgery is not always clear. Studies on transplantation procedures were also excluded as the issues around transplant donor-recipient may confound the relationship between surgical complications and patients' wellbeing.
Design	Any quantitative design. Qualitative studies and case studies were excluded.
Article type	Empirical studies only. Conference proceedings and non-empirical data were excluded.
Language	English
Publication year	Later than the year 2000
Patient recruitment dates	The majority of patients should have been recruited after year 2000.

4.2.4 Study selection process

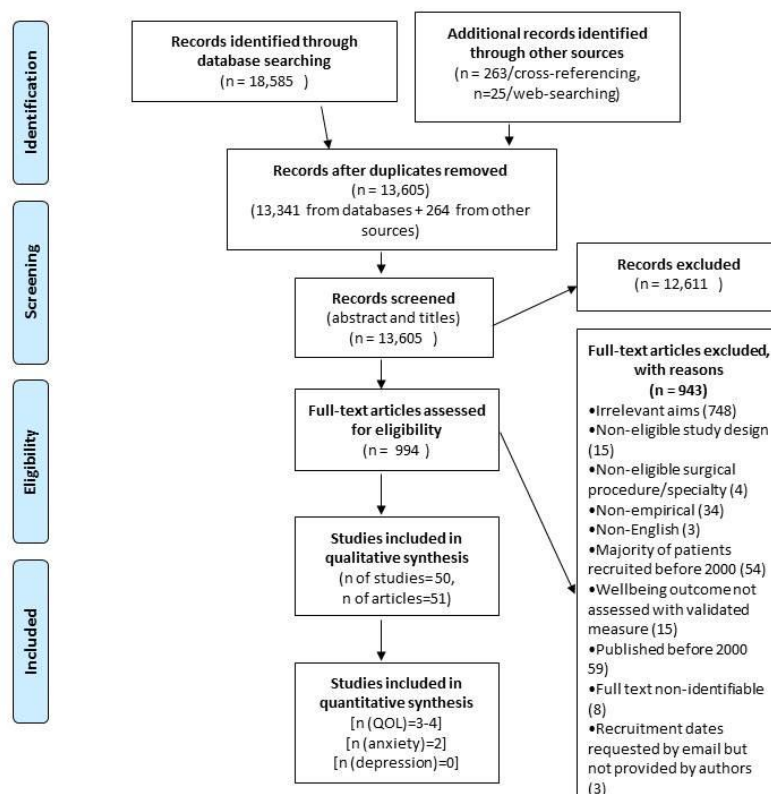
18,585 articles were retrieved in total across the three databases (Embase=10925, MEDLINE=7206, PsychINFO=454). Database searching was complemented by scoping searches of the web and scanning the reference lists of articles that were found to be eligible for full text review. This yielded another 288 eligible papers (most of those were retrieved from cross-referencing). After removing duplicate references, a total of 13,605 papers were reviewed at abstract and title level. A total of 50% of the abstracts were reviewed independently by two researchers (AP and RD) and any disagreements were resolved by consensus. The remaining half of the retrieved abstracts were reviewed by the primary researcher (AP) based on the consensus that was achieved for the first half.

Each of the retrieved abstracts was screened against the eligibility criteria that were described above. The following codes were used to indicate whether the study was eligible for full text review.

- NO: the study did not meet the eligibility criteria
- YES: the study met the eligibility criteria
- MAYBE: the study partly met the eligibility criteria but further information was required

Articles that were given a 'YES' or 'MAYBE' code qualified for full text review. This left 994 articles for full text review. The eligibility criteria were applied again on each article and the same codes were used to decide whether the article was eligible for inclusion in the final stage of the review. Reasons for exclusion were coded. Articles that were given a 'MAYBE' code were discussed between the primary researcher (AP), a researcher with background in psychology (RD) and a researcher with background in surgery (AA). Any disagreements were resolved by consensus. A total of 51 articles (50 studies) were eligible for inclusion in the final stage of the review. The PRISMA diagram in Figure 2 shows the selection process, and the numbers of articles accepted and rejected at each stage.

Figure 2: PRISMA flow diagram of study selection



4.2.5 Data extraction

For data extraction, a spreadsheet was developed on Microsoft Excel which included a number of fields based on guidance by the Centre for Reviews and Dissemination, University of York (Centre for Reviews and Dissemination 2009) (see Appendix 2 for a screenshot of the data extraction spreadsheet). The spreadsheet was pilot-tested on 5 randomly selected articles and was refined accordingly. The primary researcher (AP) and a researcher with a background in surgery (AA) independently extracted data from 20 articles, which they reviewed for any disagreements. Disagreements were resolved by consensus or referral to a third senior researcher (OF). Data were extracted from the remaining articles by the primary researcher and were later checked by the second reviewer (AA). A total of 10 authors were contacted by email to provide information that was not included in the manuscript (e.g. dates of patient recruitment). A total of 7 authors replied and provided the requested information and 3 articles were not included in the analysis, as the authors did not respond to my requests for further information. Information was extracted from each article on:

- Year of publication
- Years of patient recruitment
- Country where the study was conducted
- Study aims (including primary and secondary aims)
- Participant characteristics (including, where available, total number of participants approached, total number of enrolled participants, number of participants per comparison groups, drop-out rates, indication for surgery, inclusion and exclusion criteria)

- Study design (i.e. prospective vs. retrospective, cohort vs. case control, observational vs. experimental, cross-sectional vs. longitudinal)
- Type of surgery (i.e. surgical procedure(s), major vs. minor surgery and surgical specialty)
- Surgical complications [i.e. complications recorded and definitions and method of recording, where available]
- Wellbeing outcomes (i.e. wellbeing outcomes, method and time-points of measurement)
- Findings relevant to the aims of the review (including where available means/standard deviations or medians/odds ratios of wellbeing outcomes for groups of patients with complications vs. group of patients without complications, p values, beta values of multivariate analyses on predictive value of complications on wellbeing outcomes)

4.2.6 Quality assessment

The quality of the included studies was thoroughly assessed in accordance with systematic review guidelines (Deeks et al. 2003; Moja 2005; Liberati et al. 2009; Moher et al. 2009). I reviewed a selection of existing checklists for the assessment of risk of bias in systematic reviews and meta-analyses (Deeks et al. 2003) and concluded that the Newcastle Ottawa scales (NOS) for cohort and case-control studies (Wells G.A. et al.) were the most suitable. NOS was rated among the 14 best tools for the assessment of risk of bias in non-randomised interventional studies and is easy to use, taking only 5–10 minutes to complete (Deeks et al. 2003).

Both versions of the scale contain eight items grouped into three categories: selection, comparability and outcome. For each item a series of response options are provided. For example, for the representativeness of the exposed cohort, response options include truly representative,

somewhat representative, selected group or no description of exposed cohort. Highest quality studies are awarded a maximum of one star for each item within the selection and outcome categories and a maximum of two stars for comparability. The maximum score of stars that one study can achieve is 9. For the purposes of this systematic review the scales were modified in order to reflect the research aims of the review. Items that were not applicable to the aims of this systematic review were removed which changed the maximum score of stars that could be achieved by each study from 9 to 8. Appendix 3 presents the modified versions of the NOS scales that were used in this review.

4.2.7 Data synthesis

The included studies were first synthesised and discussed qualitatively. In order to quantify the degree of the impact of surgical complications on patients' wellbeing meta-analytic procedures were also used. A separate meta-analysis was conducted for each wellbeing outcome (i.e. quality of life, anxiety and depression). I^2 was used to calculate the extent of heterogeneity present in the meta-analyses. Heterogeneity was considered low when it was below 25% and high above 50% (Higgins and Green 2011). A random effects approach was chosen for all the meta-analyses, as a degree of heterogeneity between studies should always be assumed in social sciences (Field and Gillett 2010). Due to the very small number of studies with sufficient data for quantitative synthesis, funnel plots (which are an easy way of assessing publication bias) are not reported. Where multiple assessments were conducted in one single study, only the one furthest from the participants' surgery was included in the meta-analysis.

4.3 Results

4.3.1 Study characteristics

4.3.1.1 General characteristics

Out of the 50 studies 29 were in gastro-intestinal (Anthony et al. 2003; Delaney et al. 2003; Targarona et al. 2004; Viklund et al. 2005; Avery et al. 2006; Champault et al. 2006; Dubernard et al. 2006; Hawn et al. 2006; Lim et al. 2006; Menten et al. 2006; Rea et al. 2007; Sharma 2007; Bitzer et al. 2008; Dasgupta et al. 2008; Pittman et al. 2008; Rutegard et al. 2008; Bloemen et al. 2009; El-Awady and Elkholy 2009; Kalliomaki et al. 2009; Scarpa et al. 2009; Siassi et al. 2009; Bruns et al. 2010; Chang et al. 2010; Liu et al. 2010; Douma et al. 2011; Ince et al. 2011; Kement et al. 2011; Riss et al. 2011; Polese et al. 2012); 17 in cardio-thoracic (Myles et al. 2001; Jarvinen et al. 2004; Hata et al. 2006; Landoni et al. 2006; Le Grande et al. 2006; Myles 2006; El Baz et al. 2008; Martin et al. 2008; Peric et al. 2008; Rodriguez et al. 2008; Deaton and Thourani 2009; Ferguson et al. 2009; Jideus et al. 2009; Merkouris et al. 2009; Gjeilo et al. 2010; Tully et al. 2011; Kinney et al. 2012; Moller and Sartipy 2012) and 4 in vascular surgery (Subramonia and Lees 2005; Nguyen et al. 2006; Nguyen et al. 2007; Lohse et al. 2009). A total of 28 studies were conducted in Europe, 14 in the US, 3 in Australia, 2 in Turkey, 1 in Egypt, 1 in Japan and 1 in Taiwan.

4.3.1.2 Surgical procedures

Out of the 29 studies in gastro-intestinal surgery, 21 assessed colorectal procedures, 5 upper-gastro-intestinal and 3 bariatric procedures. A total of 13 studies assessed cardiac procedures [i.e. mostly Coronary Artery Bypass Graft (CABG)], 4 studies assessed thoracic procedures (e.g. lung resection, thoroscopic sympathectomy, thoracotomy), and 3 assessed vascular procedures (i.e. lower extremity vein bypass, aorta replacement and low saphenous vein stripping).

The majority of the studies assessed major procedures, apart from 8 studies in gastro-intestinal surgery (e.g. hernia repairs, cholecystectomies), one study in thoracic surgery (i.e. thoroscopic sympathectomy for hyperhidrosis) and one study in vascular surgery (i.e. conventional low saphenous vein stripping for varicose veins).

The most common indications for surgery were heart conditions, followed by different types of cancer. Other diagnoses included hernias, Crohn's Disease, chronic anal fissure, colorectal endometriosis, familial adenomatous polyposis, palmar and axillary hyperhidrosis, critical limb ischaemia and varicose veins.

4.3.1.3 Research aims

Of the studies included, 23 examined the association between surgical complications and patients' wellbeing as a primary research aim. The remaining examined this relationship as a secondary aim whereas their primary aim was usually a generic exploration of the association of different clinical factors with patients' postoperative wellbeing.

4.3.1.4 Wellbeing outcomes

Quality of life was the main outcome that was used for the examination of the relationship of surgical complications with patients' psycho-social wellbeing. Three studies assessed anxiety, four studies assessed depression and one study assessed mood states. No other psychosocial outcomes were studied.

The SF-36 (and its associated versions, i.e. SF-12, SF-20) was the most commonly used measure for the assessment of QOL, followed by the European Organisation for Research and Treatment of Cancer core Questionnaires (EORTC QLQ-C30) and its versions that are specific to different types of cancer. Other (mostly condition-specific) quality of life questionnaires included: the Gastro Intestinal Quality of Life Index (GIQLI), the City of Hope Quality of Life for Ostomates Questionnaire (mCOH-QOL-Ostomy), the Assessment of Cancer Therapy Questionnaire with the colorectal module (FACT-C), Cleveland Global Quality of Life (CGQL), EuroQol (EQ-5D), RAND-36, Fecal Incontinence Quality of Life Instrument (FIQL), the World Health Organization Quality of Life – Brief (WHOQOL-BREF), the Glasgow Dyspepsia Severity Score (GDSS), the Social Functioning subscale of the Inflammatory Bowel Disease Questionnaire (IBDQ), the MacNew Heart Disease HRQOL questionnaire, the Nottingham Health Profile Questionnaire, VascuQOL and the Aberdeen Varicose Vein Questionnaire 2.

Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale (HADS) and the Depression Anxiety Stress Scales (DASS-21). One study used a formal psychological assessment and the Center for Epidemiological Studies Depression (CES-D) scale test for the diagnosis of depression. The Positive and Negative Affect Schedule (PANAS) and the Mood Rating Scale (MRS) were used for the assessment of mood states.

4.3.1.5 Research designs

All the studies were observational. The majority were cohort population studies (i.e. comparisons were made between patients who experienced post-operative complications to patients who did not). Four studies used a case-control design (i.e. the cases were patients who had suffered surgical complications and the controls were patients who had not experienced the complications under investigation).

A total of 31 studies were longitudinal and the time-points of the assessment of patients' wellbeing varied from 2 (one preoperative and one post-operative assessment) to 5 (1 preoperative and 4 postoperative assessments). Most of the longitudinal studies included only 1 or 2 post-operative assessments, and only five studies included more than two post-operative assessments.

4.3.1.6 Assessment of surgical complications

The types and the definitions of surgical complications varied. The vast majority of the studies used a-priori definitions of complications. For example, Bloemen et al. recorded only severe complications based on the grading system of surgical operations in Dindo et al. (i.e. grade III or IV). Dasgupta et al., also recorded major complications which were defined as "those associated with systemic illness requiring transfer to a higher level of care or requiring relaparotomy, or complications needing interventional radiology". Others used pre-defined categories of complications such as infections, respiratory complications, chronic postoperative pain or perioperative myocardial infarctions. A total of 14 studies did not explain how complications were operationalised for the purposes of the study.

The majority of the included studies were interested in the full range of postoperative complications that patients had experienced. A total of 13 studies focused only on one type of complications (e.g. anastomotic leaks following colorectal surgery, serious wound infections after cardiopulmonary bypass or graft-related events after lower extremity vein bypass).

Complications were mostly recorded through medical records review, followed by clinical examinations and review of administrative databases, and less often through patient reports. A total of 15 studies did not describe the methods that they used for the recording of complications. Appendix 4, Appendix 5 and Appendix 6 present the complications that were examined in each study and the methods of their recording.

4.3.1.7 Quality assessment

The maximum score that a study could achieve on the quality assessment scales was 8. The scores of the included studies ranged from 2 to 8, with a mean score of 5.9 across all specialties. Only 4 studies scored 8 out of 8. The majority of the included studies scored 5 to 7. Only 7 studies scored exceptionally low (i.e. 4 or less). Studies were not excluded from the final stage of the review based on their quality assessment. Appendix 7, Appendix 8 and Appendix 9 present three tables (one per surgical specialty) with information on how each study scored against the modified criteria of the NOS scales.

Points were deducted from the included studies for the following reasons: a) the authors did not explain how surgical complications were recorded (n=15) or complications were assessed with patient reports when clinical sources would have been more appropriate (n=2), b) the sample's representativeness was doubtful either due to a very small response rate (less than 50%) (n=6) or due to lack of information on response rates (n=13), c) patients' preoperative levels of wellbeing

were not assessed (n=23) or were not accounted for statistically (n=3), d) patient demographics (i.e. age, sex) were not controlled for in the investigation of the association between complications and patient's post-operative wellbeing (n=11) or cases and controls were not comparable in terms of key characteristics (n=1), e) the period of follow-up was too short (i.e. less than 1 month for minor surgery and less than 3 months for major surgery) (n=6), or the range of the follow-up period was very big (n=10), f) loss to follow-up in longitudinal studies could not be established due to lack of information on the number of participants at first assessment (n=3) and g) there was no information on the response rates of cases and controls (n=3).

The characteristics of each study are presented separately for each surgical specialty in Table 3, Table 4 and Table 5.

Table 3: Key characteristics of studies in gastro-intestinal surgery

Citation	Year	Country	Study aims	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Severity of surgery	Psychosocial outcome & time-points	Measure of psychosocial outcome
1. Bruns	2010	Germany	-To assess postoperative QOL of patients who underwent curative liver resection.	Secondary	N=96/188 Nc(any morbidity)=30 Nc(wound infections)=10	Patients who underwent curative hepatic resection for malignant or non malignant diseases, disease free at time of assessment	Observational, cross-sectional	Hepatectomy	Major & minor	QOL/at least 3 months post-op (range: 3-36 months post-op)	SF-12
2. Liu	2010	US	-To understand the impact of complications on total HRQOL for patients who underwent CRC (colorectal cancer) surgery	Primary	N=679/1308 Nc(early comps/anast)=54 Nc(late comps/anast)=126 Nc(early comps/anast/rectal cancer only)=42 Nc(late comps/ostom/rectal cancer only)=105	Long-term Colorectal Cancer patients (284 patients with ostomies and 395 with anastomoses matched to ostomy cases)	Observational, cross-sectional	Colorectal cancer surgery	Major	QOL/ 5-15 years post-op	mCOH-QOL-Ostomy ²
3. Bloemen	2009	Netherlands	-To assess the impact of postoperative complications and the presence of a stoma on long-term QOL after surgery for rectal cancer.	Primary	N=121/170 Nc=33	Rectal cancer patients	Observational, cross-sectional	Surgical treatment for adenocarcinoma of the rectum	Major	QOL/The median duration of follow-up after surgery of the responders was 36 (range, 16–51) months	EORTC QLQ-C30 ³ & CR38 ⁴
4. El-Awady	2009	Egypt	-To evaluate the effect of inguinal hernioplasty in Egyptian patients on testicular perfusion and their sexual function.	Secondary	N=40/? Nc=14	40 patients with inguinal hernia	Observational, prospective, cohort	Anterior open Lichtenstein tension free hernioplasty	Minor	QOL/pre-op, 3, 6 & 12 months post-op	SF-36
5. Scarpa	2009	Italy	-To analyse the impact of different surgical techniques on patients who underwent intestinal surgery for Crohn's Disease (CD) in terms of recovery, QOL, and direct and indirect costs	Secondary	N=47/? Nc=?	Patients admitted for intestinal surgery for Crohn's Disease	Observational, cross-sectional	Bowel resection through midline laparotomy or with laparoscopic assistance, end ileostomy, stricturoplasty	Major	QOL/3 months post-op	CGQLI ⁵
6. Siassi	2009	Germany	-To compare the influences of clinical factors, especially the formation of a stoma, and psychological variables on QOL in patients undergoing colorectal surgery for benign and malignant disease	Secondary	N=79/113 Nt1=93 Nt2,t3=79Nc=26	Patients undergoing colorectal surgery for benign and malignant disease	Observational, prospective, cohort	Resection of the sigmoid colon or rectum	Major	QOL/pre-op, 3 & 12 months post-op	SF-36 & GLQI ⁶

² City of Hope Quality of Life for Ostomates questionnaire

³ European Organisation for Research and Treatment of Cancer core

⁴ European Organisation for Research and Treatment of colorectal cancer

⁵ Cleveland Global Quality of Life

⁶ Gastrointestinal Quality of Life Index

7. Dasgupta	2008	UK	-To test the hypothesis that symptoms, functioning and QOL would deteriorate in the short term after liver surgery for liver cancer, with recovery by 12 months, and that patients without cancer recurrence would maintain their QOL beyond 3 years after operation.	Secondary	Nt1=102/122 Nt2=87 Nt3=80 Nt4=33 Nc=44	Consecutive, patients undergoing liver surgery for liver cancer	Observational, prospective, cohort	Liver resection for hepatic malignancies	Major	QOL/pre-op, 6, 12, 36-48 months post-op	EORTC QLQ-C30 version 3
8. Rutegard	2008	Sweden	-To assess the impact of surgical approach, type of resection, extent of lymphadenectomy, size of proximal resection margin, type of oesophageal substitute, type of anastomosis, perioperative blood loss, duration of operation and early technical surgical complications on QOL.	Secondary	N=355/ 446 (79.6 %) Nc=56	Patients diagnosed with an oesophageal or cardia cancer who underwent macroscopically and microscopically radical resection	Observational, cross-sectional	Oesophageal resection	Major	QOL/6months post-op	EORT QLQ-C30 (version 3.0), & QLQ-OES1812 ⁷
9. Pittman	2008	US	-To determine relationships among demographic variables, clinical factors, QOL, and stomal or peristomal complications in US veterans living with a fecal ostomy.	Primary	N=239/322 Nc=56	Veterans who were living with an ostomy after major gastro-intestinal surgery requiring an intestinal stoma	Observational, case-control, cross-sectional	Gastro-intestinal surgery requiring an intestinal stoma	Major	QOL/6months post-op	mCOH-QOL-Ostomy
10. Rea	2007	US	-To address HRQL in patients who suffer postoperative complications or experience 50% EWL (excess body weight loss) after Roux-en-Y gastric bypass (LRYGB).	Primary	Nt1=505/? Nt2=237 Nt3=106 Nc(t2)=41 Nc(t3)=23	Patients who underwent LRYGB by one surgeon for morbid obesity	Observational, prospective, cohort	LRYGB for morbid obesity without conversion to an open procedure.	Major	QOL/baseline, 1 & 2 years	SF-36
11. Sharma	2007	UK	-To record preoperative and postoperative QOL and evaluate the factors which predict postoperative QOL at 6-8 weeks after surgery in patients undergoing elective resection for colorectal cancer.	Secondary	Nt1=104 /110 Nt2=92 Nc=41	Consecutive patients with newly diagnosed colorectal cancer scheduled for elective open resection in one hospital trust	Observational, prospective, cohort	Elective resection for colorectal cancer	Major	QOL, anxiety, depression, positive vs. negative affectivity, mood states/pre-op (5-12 days pre-op) & 6-8 weeks post-op	FACT-C ⁸ , EuroQOL (EQ-5D), HADS, PANAS ⁹ , MRS ¹⁰
12. Avery	2006	UK	-To investigate associations between patient satisfaction and QOL and major morbidity and type of treatment after in-hospital treatment for oesophageal and gastric cancer.	Primary	N=139/162 Nc=37	Patients with esophageal or gastric cancer who underwent upper gastro-intestinal surgical treatment	Observational, cross-sectional	Upper gastro-intestinal surgical treatment for esophageal or gastric cancer	Major	QOL/39.6days after treatment (range,6-105)	EORTC QLQ-C30
13. Dubernard	2006	France	-To evaluate the QOL after laparoscopic segmental colorectal resection for endometriosis	Secondary	Nt1=58/? Nt2=58 Nc=9	Women with colorectal endometriosis who underwent a segmental colorectal resection	Observational, prospective, cohort	Laparoscopic segmental colorectal resection for endometriosis	Major	QOL/pre & post-op	SF-36

⁷ oesophageal cancer-specific questionnaire

⁸ Functional assessment of cancer therapy questionnaire with the colorectal module

⁹ positive and negative affect schedule

¹⁰ mood rating scale

14. Lim	2006	UK	-To examine sub-clinical leaks and their effect on bowel function and QOL -To examine the significance of features seen on WCE (water-soluble contrast enemas) in prediction of subsequent anastomotic healing after subclinical and clinical leaks.	Primary	N=92/112 Nc(leaks)=23 Nc(clinical leaks)=13 Nc(sub-clinical leaks)=10	Consecutive patients under the care of three consultant surgeons who underwent procedures with LRA	Observational, cross-sectional	Low rectal anastomosis (LRA)	Major	QOL/10-18 months post-op	EORTC QOL
15. Montes	2006	Turkey	-To investigate the effects of lateral internal sphincterotomy (LIS) on QOL in a selected group of patients with chronic anal fissure (CAF). -To identify patient subgroups who developed surgical complications and to determine the possible impact of these complications on QOL.	Primary	Nt1=253/302 Nt2=244 Nc(anal fistula/abscess)=3 Nc(FISI>0)=7 Nc(FISI, 0->4, 21, 7)=3	Patients who underwent Lateral internal sphincterotomy (LIS) for chronic anal fissure (CAF)	Observational, prospective, cohort	Lateral internal sphincterotomy (LIS) for chronic anal fissure (CAF)	Minor	QOL/pre-op (admission) & 12 months post-op	GIQLI & FIQL ¹¹
16. Viklund	2005	Sweden	-To investigate how various factors related to esophageal resection surgery for cancer influenced different measures of QOL and esophagus-specific symptoms in a nationwide population-based study.	Secondary	N=100/146 Nc=44	Patients newly diagnosed with a histologically verified adenocarcinoma or squamous-cell carcinoma of the esophagus or adenocarcinoma of the gastric cardia that underwent macroscopically and microscopically radical tumor resection.	Observational, cross-sectional	Esophageal resection surgery for cancer	Major	QOL/6 months post-discharge	QLQ-C30 & OES-24 ¹²
17. Delaney	2003	US	-To evaluate the effect of surgery for Crohn's Disease (CD) on QOL	Secondary	Nt1=109/109 Nt2=82/109 Nc(any)=19 Nc(major)=9	Patients with Crohn's Disease	Observational, prospective, cohort	Surgery for CD (abdominal perineal, loop or end stoma)	Major	QOL/pre-op & 30 days post-op	CGQL
18. Kalliomaki	2009	Sweden	-To present an analysis of persistent post-herniorrhaphy pain, whether nociceptive or neuropathic -To determine the influence of persistent postoperative pain on QOL.	Primary	N(total)=184/423 N1=92 N2=92	Patients who had been operated on for groin hernia. Controls matched for age, gender and method of surgical repair were allotted from the group of persons without persisting pain (Grade 1 in IPQ)	Observational, cross-sectional, case-control	Hernia repair	Minor	QOL, anxiety, depression/(on average 4.9 years post-op, range > 7 years)	SF-36, HADS
19. Bitzer	2008	Germany	-To assess the feasibility, validity, and usefulness of a quality monitoring system based on patient-reported outcomes in cholecystectomy within a short-stay surgery setting.	Secondary	Nt1=151/205 Nt2=130 (86.1%) Nc(complaints)=49 Nc(wound infection)=5 Nc(seroma)=13 Nc(pneumonia)=1 Nc(other)=28	Patients undergoing cholecystectomy	Observational, prospective, cohort	Cholecystectomy	Minor	QOL/T0 = 14 days pre-op, T1 = 14 days post-op, and T2 = 6 months post-op	SF-36

¹¹ Fecal Incontinence Quality of Life Instrument

¹² symptoms specific to oesophageal cancer

20. Hawn	2006	US	-To better understand how a recurrence or complication after inguinal hernia surgery affects long-term functional outcomes and patient satisfaction	Primary	Nt1=1983/3518 Nt2=1526 (77%) Nt3=1603 (81%) Nc(neuralgia t1)=94 Nc(hematoma t1)=51 Nc(orchitis t1)=13 Nc(recurrence t1)=76 Nc(other)=124 Nc(neuralgia t2)=105 Nc(hematoma t2)=55 Nc(orchitis t2)=18 Nc(other t2)=150	Men who received a hernia repair.	Observational, prospective, cohort	Inguinal herniorrhaphy	Minor	QOL/pre-op, 1 & 2 years post-op	SF-36
21. Anthony	2003	US	-To identify patient-, tumor-, and treatment-related factors that were associated with HRQL after the completion of therapy for colorectal cancer	Secondary	Nt1=71/? Nt2=63 Nc=16	Colorectal cancer, male patients who underwent open surgical therapy	Observational, prospective, cohort	Open surgical therapy for colorectal cancer	Major	QOL/at time of diagnosis and 12 months later (after surgical therapy)	FACT-C
22. Champault	2006	France	-To analyse the results of a prospective study on obesity surgery, with respect to safety, efficiency of weight loss, complication rate, and QOL during a 2-year follow-up	Secondary	Nt1=152/? Nt(4)=139 Nc=(unclear)	Consecutive patients operated on for morbid obesity.	Observational, prospective, cohort	Laparoscopic placement of a gastric band	Minor	QOL/pre-op, 1, 3 months & at least 2 years post-op	GIQLI
23. Chang, et al.	2010	Taiwan	-To evaluate the effects of bariatric surgery on changes in health-related QOL, comorbidities and loss of excess BMI during the year after operation.	Secondary	N=102/218 Nc(anastomotic stricture)=12 Nc(gastrojejunal anastomotic ulcer)=9 Nc(upper gastro-intestinal bleeding)=1 N(GORD)=2	Patients undergoing bariatric surgery.	Observational, case-control, longitudinal	Roux-en-Y bypass	Major	QOL/pre-op, 1, 3, 6 and 12 months post-op	WHOQOL-BREF ¹³
24. Douma, et al.	2011	Netherlands	-To investigate the HRQOL of FAP family members and to identify the socio-demographic and clinical factors significantly associated with HRQOL. -To investigate the consequences of FAP on several practical aspects of daily life, including education, employment and insurance.	Secondary	N=296/? Nc=?	296 patients with FAP who had been surgically treated	Observational, cross-sectional	Surgery for familial adenomatous polyposis (FAP)	Major	QOL/0 to >10 years post-op	SF-36, EORTC-QLQ-C38, Social Functioning (SF) subscale of the Dutch version of IBDQ ¹⁴
25. Ince, et al.	2011	US	-To evaluate whether the minimally invasive approach leads to recovery of QOL early after surgery and to evaluate factors specifically associated with the change in QOL in patients undergoing lap colorectal resection	Secondary	Nt1=?/568 Nt2=166 Nc=?	Patients who underwent colorectal resection for benign and malignant diseases.	Observational, retrospective, cohort	Laparoscopic colorectal resection	Major	QOL/pre-op, 4 weeks post-op	SF-36

¹³ World Health Organization Quality of Life – Brief

¹⁴ Inflammatory Bowel Disease Questionnaire

26. Riss	2011	Austria	-To investigate the impact of anastomotic leakage after rectal resection for malignancies on overall pelvic organ function and QOL	Primary	N1=16/36 N2=16/?	Patients who were operated for rectal cancer and developed anastomotic leak. Patients, who underwent rectal cancer resection at the same time period and had an uneventful postoperative course served as controls for each case and were matched by sex, age (± 5 years), type of resection, and neoadjuvant therapy (yes/no).	Observational, cross-sectional	Rectal resection for malignancies on overall pelvic organ function	Major	QOL/106.8 months post-op (32.4–170.4)	SF-12
27. Polese	2012	Italy	-To prospectively analyse the incidence of colorectal anastomotic stenoses in consecutive patients who underwent surgery for neoplastic or inflammatory diseases Risk factors associated with their formation and the impact on QOL.	Primary	N=147/211 Nc(anastomotic stenoses)=22	All the patients who underwent elective left colonic or rectal resection and colorectal anastomosis for neoplastic or inflammatory disease.	Observational, cross-sectional	Left colonic or rectal resection and colorectal anastomosis	Major	QOL/mean 58 (SD ± 31) months after surgery	SF-36
28. Kement	2011	Turkey	To evaluate the risk factors for incontinence after (open lateral internal sphincterotomy) LIS and assess the anatomic findings and QOL in patients with different levels of incontinence.	Primary	N=253/351 N(incontinence)=28 N(severe incont)=9 N(mild incont)=19	Consecutive patients with chronic anal fissure who underwent open LIS.	Observational, cross-sectional	(Open lateral internal sphincterotomy) LIS	Minor	QOL/23.3 $\pm$ 7.1 months after the operations	SF-36
29. Targarona	2004	Spain	To evaluate prospectively the rate of anatomic and/or symptomatic recurrence after paraesophageal or large sliding hernia repair, and then to investigate the correlation between the repair and the patients' QOL.	Primary	N=37/46 Nc(recurrent hernias)=3	Patients diagnosed with paraesophageal or mixed hiatal hernia (types II, III, and IV) with >50% of the stomach in the chest.	Observational, cross-sectional	Laparoscopic repair of paraesophageal hiatal hernia	Minor	QOL/ ≥ 6 months post-op (median, 24; range, 6–50)	SF-36, GDSS ¹⁵ and GIQLI

Table 4: Key characteristics of studies in cardio-thoracic surgery

Citation	Year	Country	Study aims	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Severity of surgery	Psychosocial outcome & timepoints	Measure of psychosocial outcome
1. Gjeilo	2010	Norway	-To assess chronic pain 6 and 12 months after cardiac surgery and to measure HRQOL in relation to chronic pain.	Primary	Nt1=534/631 Nt2=462 Nt3=465 Nc(t2)=52	Patients undergoing cardiac surgery	Observational, prospective, cohort	Midline sternotomy	Major	QOL/pre-op, 6 & 12 months post-op	SF-36
2. Merkouris	2009	Greece	-To explore the QOL of elderly patients (>65 years) before, 4 months and 12 months after CABG surgery.	Secondary	Nt1=63/63 Nt2=59 Nt3=56 Nc=42	All patients over 65 presenting a 1, 2 or 3 vessel disease treated with CABG without concurrent procedures (e.g. valve replacement), ability to communicate and absence of any serious postoperative complications.	Observational, prospective, cohort	CABG	Major	QOL/pre-op, 4 & 12 months post-op	MacNew Heart Disease HRQOL questionnaire
3. Peric	2008	Serbia & Montenegro	-To evaluate changes in QOL after coronary artery bypass surgery -To discover the preoperative and perioperative predictors of worsening of QOL after coronary artery bypass surgery.	Secondary	Nt1=208/? Nt2=192 Nc=60	Consecutive patients who underwent elective CABG	Observational, prospective, cohort	CABG	Major	QOL/pre-op, 6 months post-op	Nottingham Health Profile Questionnaire (NHP)
4. Le Grande	2006	Australia	-To identify the general form of change of HRQOL over time -To identify the different trajectories of HRQOL over a six month period for both physical health and mental health -To identify the socio-demographic, medical, psychological or cognitive variables that predict group membership of HRQOL trajectories in patients undergoing CABG	Secondary	Nt1=182/444 Nt2=128 Nt3=114 Nc=?	Adults on the waiting list for CABG	Observational, prospective, cohort	CABG	Major	QOL/pre-op, 2 & 6 months post-op	SF-36
5. El Baz	2008	Netherlands	-To determine whether EuroScore is associated with physical and mental HRQOL before and 6 months after CABG -To determine whether EuroScore is a predictor of physical and mental domains of HRQOL 6 months after CABG	Secondary	Nt1=198/256 Nt2=168 Nc=?	Consecutive patients who were scheduled for CABG following a coronary angiography	Observational, prospective, cohort	CABG	Major	QOL/pre-op & 6 months post-op	SF-36
6a. Myles	2001	Australia	-To measure, in cardiac surgical patients, the association between quality of recovery in the days after surgery with QOL up to 3 months postoperatively -To further evaluate the QoR-40 (quality of recovery) in cardiac surgical practice	Secondary	Nt1=120/125 Nt2=120 (days 1,2,3) Nt3=108 Nc=69	Adult cardiac surgical patients	Observational, cohort, prospective, longitudinal	Cardiac surgery (specific procedures not specified)	Major	QOL/pre-op, 1 & 3 months post-op	SF-36
6b. Myles	2006	Australia	-To measure QOL in subjects who had undergone cardiac surgery three years earlier (see Myles a) -To determine whether quality of recovery had predictive ability for patients' long-term health status	Secondary	Nt1=120/125 Nt4=94 Nc=?	Adult cardiac surgical patients	Observational, cohort, prospective, longitudinal	Cardiac surgery	Major	QOL/pre-op, 3 months post-op, 3 years post-op	SF-36

7. Jarvinen	2004	Finland	-To assess the impact of perioperative myocardial infarction (PMI) on health-related QOL following CABG.	Primary	Nt1=501/1128 Nt2=485 Nc=80	Patients who underwent CABG	Observational, prospective, cohort	CABG [89% via sternotomy incision with cardiopulmonary bypass (CPB; on-pump) and 11% without CPB (off-pump)]	Major	QOL/pre-op & 12 months post-op	RAND-36
8. Martin	2008	US	-To assess the relationship between perioperative complications and HRQL at 1 year after elective open-heart surgery	Primary	Nt1=836/2,007 Nt2=2,007 Nc=189	Patients undergoing elective open heart surgery	Observational, prospective, cohort	Open heart surgery (133 valve procedure; 620 CABG; 67 CABG plus valve procedure; 15 CABG plus other cardiac procedure; and 1 closure of an atrial septal defect)	Major	QOL/pre-op, 1 year post-op	SF-20
9. Jideus	2009	Sweden	-To evaluate QOL in sternal wound infection patients	Primary	N=73/84 (cases) N=42/? (controls)	-Cases: patients who developed sternal wound infection (SWI) after cardiopulmonary bypass. -Controls: patients prior to CABG and evaluated 1 year postoperative and matched for time of the operation, age and sex + Swedish normal population matched for age	Observational, case-control, cross-sectional	Cardiopulmonary bypass	Major	QOL/20 months post-op (range 7-40).	SF-36
10. Deaton	2009	US	-To determine if pre-hospital management of diabetes (including insulin therapy) and CHD risk factors affect short- and mid-term outcomes in patients with Type 2 Diabetes (T2DM) undergoing CABG, and to compare insulin-treated and non-insulin-treated patients	Secondary	Nt1= 317/442 Nt2=270 Nc=44% (130)	Patients with documented T2DM undergoing CABG	Observational, prospective, cohort	CABG	Major	QOL/post-op recovery, 3 months post-op	SF-36
11. Hata	2006	Japan	-To determine independent predictors for post cardiovascular surgery depression, and evaluate how it affects the patient's prognosis.	Secondary	N=452/452 Nc=?	Consecutive adult patients who underwent open heart surgery.	Observational, cross-sectional	CABG	Major	Depression/5-7 days post surgery	Interviewed by a psychiatrist and CES-D scale ¹⁶
12. Landoni	2006	Italy	-To assess long-term survival and QOL in survivors after ARF (acute renal failure) and RRT (renal replacement therapy) after cardiac surgery	Primary	N1=22/42 N2=40/42	-Cases: patients who underwent cardiac surgery and developed ARF requiring RRT and left the hospital alive. -Controls: matched controls who did not develop ARF and did not receive RRT.	Observational, case-control, cross-sectional	Cardiac surgery (procedures not specified)	Major	QOL/23-42 months post-op	SF-36

13. Ferguson	2009	US	-To assess the influence of age, preoperative comorbid factors, and postoperative complications on postoperative QOL and mood, and to identify predictors of poor postoperative QOL and mood.	Primary	N=124/221 Nc=22	Prospective patients who underwent major lung resection for early stage lung cancer.	Observational, cross-sectional	Major lung resection for early stage lung cancer (lobectomy, bilobectomy, pneumonectomy)	Major	QOL/average of 2.6 years after surgery (3 months to 6.4 years)	EORTC QLQ-C30 and EORTC QLQ-LC13 ¹⁷ -DASS-21 ¹⁸ for patients who underwent surgery during the years 2003 to 2006
14. Rodriguez	2008	US	-To follow-up on the complications and side effects of thoracoscopic sympathectomy (TS) for palmar and axillary hyperhidrosis (HH).	Secondary	Nt1=397/? Nt2=? Nt3=? Nt4=? Nc=23	Patients diagnosed with upper extremity HH treated with TS.	Observational, prospective, cohort	Thoracoscopic sympathectomy for palmar and axillary hyperhidrosis	Minor	QOL/pre-op, discharge, 6 & 12 months post-op	SF-36
15. Tully	2011	Australia	-To examine whether cognitive-affective or somatic symptoms of anxiety were associated with atrial fibrillation (AF) after CABG, -To determine whether anxiety was associated with AF after adjustment for general distress and depression.	Primary	Nt1=226/238 Nt2=222 Nc=56	Patients undergoing first-time CABG surgery	Observational, prospective, cohort	CABG	Major	Anxiety, Depression, Stress/pre-op (mean=2 days, SD=2 days) & post-op (mean=6 days, SD=2 days)	Depression Anxiety Stress Scales (DASS)
16. Moller	2012	Sweden	-To analyse the association between selected patient and tumor characteristics and QOL 6 months after surgery for lung cancer.	Secondary	Nt1=249/? Nt2=213 Nc=?	Prospective patients scheduled for lung surgery for lung cancer	Observational, prospective, cohort	Lung surgery	Major	QOL/pre-op, 6 months post-op	SF-36
17. Kinney	2012	US	-To examine the specific impact of persistent postthoracotomy pain on health-related QOL. -To describe quantitatively and qualitatively patients' postthoracotomy pain symptoms and analgesic medication use.	Primary	N=99 Nt1=120/? Nt2=99 Nc=75	Patients aged 45 to 75 years undergoing elective thoracotomy	Observational, prospective, cohort	Serratus-sparing posterolateral thoracotomy or limited thoracotomy	Major	QOL/pre-op, 3 months post-op	SF-36

¹⁷ EORTC Lung Cancer Questionnaire

¹⁸ Short version of the Depression Anxiety Stress Scales

Table 5: Key characteristics of studies in vascular surgery

Citation	Year	Country	Study aims	Primary or Secondary aim	Sample (N=number of patients in analysis/eligible patients, Nt(i)=sample size per time-point, Nc=patients with complications, N1=Cases vs. N2=controls)	Patient inclusion criteria	Study Design	Type of surgery	Severity of surgery	Psychosocial outcome & timepoints	Measure of psychosocial outcome
1. Nguyen ^a	2007	US & Canada	-To evaluate the incidence of Wound Complications (WC) -To identify significant predictors of WC; -To assess if WC affect traditional Infrainguinal Bypass (IB) endpoints including primary, primary-assisted, and secondary patency, and limb salvage and survival rates; -To estimate the wound related economic burden imposed on the health care system through examining RU; -To determine how QOL is affected by WC	Primary	Nt1=1296/1404 Nt2=862 Nt3=732 Nc=543	Patients who underwent IB for Critical Limb Ischaemia (CLI) in community and university hospitals across the US and Canada	Observational, prospective, cohort	Lower extremity vein bypass for limb salvage in critical limb ischemia (CLI) patients	Major	QOL/baseline, 3 & 12 months post-op	VascuQol ¹⁹
2. Nguyen ^b	2006	US & Canada	-To assess the effect of infrainguinal vein grafting for limb salvage in Critical Limb Ischaemia (CLI) patients on health-related QoL.	Secondary	N1=1296/1404 (92.3%) N2=862 (61.4%) N3=732 (52.1%) Nc=	Patients who underwent IB for Critical Limb Ischaemia (CLI) in community and university hospitals across the US and Canada	Observational, prospective, cohort	Infrainguinal vein grafting for limb salvage in critical limb ischemia (CLI) patients	Major	QOL/pre-op, 3 & 12 months	VascuQol
3. Subramonia	2005	UK	-To study the extent of bruising and the extent and pattern of sensory abnormalities after conventional long saphenous vein (LSV) stripping -To investigate their effect on short-term QOL	Primary	Nt1=70/70 Nt2=59 Nt3=62 Nc(sensory abnormalities)=25 Nc(bruising at t1)=58 Nc(bruising at t2)=16	Patients with varicose veins, either symptomatic or with skin changes, resulting from incompetence of the LSV as confirmed by handheld Doppler examination or duplex ultrasonography or both and requiring surgical intervention (both day cases and inpatients).	Observational, prospective, cohort	Conventional LSV stripping	Minor	QOL/pre-op, discharge & 6 weeks post-op	Aberdeen Varicose Vein Questionnaire 2
4. Lohse	2009	Germany	-To analyse the operative outcome and quality of life among patients who have had the ascending aorta replaced, in comparison with quality of life among the general German population.	Secondary	N=110/124 Nc=?	Consecutive patients who received a replacement of the dilated ascending aorta.	Observational, cross-sectional	Ascending aorta replacement	Major	QOL/36.4 ± 15.5 months post-op (11–58 months)	SF-36

¹⁹

A validated instrument assessing pain, symptoms, activities, social life and emotional state in patients with vascular disease

4.3.2 The impact of surgical complications on patients' wellbeing

The vast majority of the included studies (n=31) found a significant association between some or all of the surgical complications under investigation and worse patient wellbeing outcomes. More than half of those (n=18) found a significant relationship between surgical complications and worse postoperative wellbeing even after controlling for baseline levels of patients' wellbeing. A total of 21 studies found a significant association of surgical complications with patients' wellbeing in both univariate and multivariate analyses which suggests that complications remained a significant independent predictor of patients' postoperative wellbeing even after controlling for a range of clinical and demographic factors. Complications that were found to be significantly associated with worse patient wellbeing included both major events such as perioperative myocardial infarctions after CABG or severe incontinence after internal sphincterectomy and relatively minor complications such as wound infections after hepatic resection or new cardiac arrhythmias after CABG.

A total of 13 studies did not find a significant association of surgical complications with patients' postoperative wellbeing. Four of them suffered from very small sample sizes, which could potentially explain the lack of observed effects (Dubernard et al. 2006; Menten et al. 2006; El-Awady and Elkholy 2009; Riss et al. 2011).

Six studies reported a confounding association between surgical complications and patients' wellbeing. Champault, who examined surgical complications in the context of laparoscopic placement of a gastric band, found that surgical complications did not influence patients' QoL when weight loss was achieved. However, in patients without adequate weight loss, complications were associated with lower QoL improvement following surgery (Champault et al. 2006). Scarpa reported a significant association between surgical complications and QoL after bowel resection for Crohn's disease in univariate analysis, but in multivariate regression analysis only disability status at

admission was shown to be an independent predictor of QoL at follow-up (Scarpa et al. 2009). Lim found a significant association of low QoL with the presence of clinical leaks without ileostomy closure but not with clinical leaks (CL) with ileostomy closure (Lim et al. 2006). Myles found that postoperative respiratory complications and post-operative strokes were associated with lower QoL in univariate analysis of patients' postoperative wellbeing at 3 months but not in further multivariate logistic regression analyses (Myles et al. 2001). Similarly, Hata found that post-operative minor strokes and pneumonia were associated with postoperative depression in univariate analysis, but not in multivariate analysis where female gender, emergency surgery and being over 70 were the only significant predictors for postoperative depression (Hata et al. 2006). Nguyen found that serious wound infections (SWCs) after lower extremity vein bypass were associated with lower QoL 3 months after surgery in univariate analysis but not at 12 months in multivariate analysis (Nguyen et al. 2006).

Table 6 summarises the significant findings by measurement tool and by domain of wellbeing that was significantly affected by surgical complications (see also Appendix 10, Appendix 11, Appendix 12).

Table 6: Summary of domains of patient wellbeing that were significantly affected by surgical complications

		Studies																																	
Measures		Bruns	Liu	Bloemen	Siassi	Rutegard	Pittman	Sharma	Avery	Lim	Mentes	Viklund	Delaney	Kalliomaki	Hawn	Anthony	Chang	Douma	Kement	Targarona	Peric	El Baz	Jarvinen	Deaton	Ferguson	Tully	Gjello	Jideus	Kinney	Polese	Rea	Bitzer	Jarvinen	Moller	
Short Form scales (e.g. SF-36, SF-12 RAND-36)	Physical-Component	✓			✓										✓			✓	✓				✓	✓									✓		
	Mental Component														✓				✓					✓											
	Physical functioning													✓												✓	✓	✓					✓	✓	
	Bodily pain													✓					✓								✓		✓	✓	✓	✓			
	Role physical													✓												✓			✓	✓	✓	✓			
	Role emotional													✓																✓					
	General health													✓					✓								✓	✓		✓	✓		✓	✓	
	Mental health													✓								✓				✓			✓	✓					
	Social functioning													✓						✓							✓	✓		✓	✓				
	Vitality													✓						✓			✓				✓		✓		✓				✓
EORTC QLQ-C30+	Physical Functioning			✓		✓			✓	✓		✓						✓							✓										
	Global QOL					✓				✓		✓																							
	Social Functioning								✓		✓																								
	Fatigue			✓		✓																													
	Role functioning					✓			✓																										
	Pain			✓																															
	Weight loss			✓																															

[illegible]

4.3.3 The degree of the impact of surgical complications on patients' wellbeing

This research question required meta-analytic procedures. The results of the quantitative synthesis are presented below separately for each wellbeing outcome (see also Table 7).

4.3.3.1 Quality of life

Due to the vast variety of measurement tools that were used for the assessment of quality of life and the different domains that each of these tools assesses, it was decided that a meta-analysis would be more meaningful if it was conducted only on the studies that used the SF-tools. These were the most commonly used tools for the assessment of QoL, they are not condition-specific and they use the same measurement scale. Moreover, all of them yield the same summary component scores (i.e. physical and mental) and the same sub-scores. A separate meta-analysis was conducted on each sub-score. The effect sizes are expressed as mean differences (MD) on a scale ranging from 0 to 100.

Only three studies provided sufficient data for a meta-analysis on the physical and mental component scores of quality of life between patients with complications and patients without complications (Hawn et al. 2006; Deaton and Thourani 2009; Kement et al. 2011). The pooled mean differences for the physical and mental summary scores between the two groups were significant indicating significantly lower levels of physical and mental quality of life in patients who suffered complications compared to patients without complications (see Table 7).

Only three studies (Rea et al. 2007; Gjeilo et al. 2010; Polese et al. 2012) provided sufficient data for a quantitative synthesis on physical functioning, bodily pain, role limitations due to physical health problems and role limitations due to emotional health problems. The pooled mean

differences between the two groups were significant and large (i.e. more than 5 points) indicating significant and clinically important adverse effects of complications on each of the above domains of quality of life (see Table 7). Four studies (Rea et al. 2007; Gjeilo et al. 2010; Kement et al. 2011; Polese et al. 2012) provided sufficient data for a meta-analysis of the differences on general health, social role functioning, mental health and vitality. The pooled mean differences between the two groups were again significant and large indicating significant and clinically important adverse effects of surgical complications on each of the above domains of quality of life (see Table 7).

The estimates of heterogeneity (I^2) were low for the majority of the SF scores (<25%). High heterogeneity was observed only for mental health (78%), bodily pain (70%) and general health (81%). A sensitivity analysis by the methodological quality of the included studies revealed that when a study that scored low in quality assessment was excluded (Kement et al. 2011), the pooled mean differences for mental health and general health increased indicating even higher adverse effects of complications on these two sub-scores of the Short Form Health Surveys.

4.3.3.2 Anxiety and Depression

Two studies out of the three that assessed anxiety provided sufficient data for a meta-analysis of the differences in anxiety levels between patients who suffered complications and patients who did not (Kalliomaki et al. 2009; Tully et al. 2011). Each study used a different scale, therefore, the effect sizes are expressed as standardised mean differences (SMD). The pooled SMD for anxiety was 0.27 [-0.21, 0.75, $p=.26$] and was not significant indicating a lack of population effect in terms of the complications' impact on patients' anxiety levels. The estimate of heterogeneity was high ($I^2=81\%$), however a sensitivity analysis by the methodological quality of the included studies did not alter the results.

Only one study out of the four that assessed depression provided sufficient data for a meta-analysis of the differences in depression levels between patients who suffered complications and patients who did not (Kalliomaki et al. 2009). Therefore a meta-analysis on depression was not possible.

Appendix 13 presents the forest plots for each meta-analysis.

Table 7: Meta-analysis of psychosocial impact of surgical complications on patients

Wellbeing outcome	Sub-score	Comparison	k	N	Z	P	MD (SMD/anxiety)	95% CI	I ²
Quality of life (SF-tools)	Physical component	Complications vs.	3	244	4.51	0.00001	-3.28	-4.71, -1.86	20%
		No complications		1638					
	Mental component	Complications vs.	3	244	6.52	0.00001	-3.82	-4.97, -2.67	0%
		No complications		1638					
	Physical functioning	Complications vs.	3	97	2.34	0.02	-5.26	-9.67, -0.85	20%
		No complications		610					
	Bodily pain	Complications vs.	3	97	3.70	0.0002	-15.05	-23.04, -7.07	70%
		No complications		610					
	Role physical	Complications vs.	3	97	2.58	0.010	-11.56	-20.33, -2.78	48%
		No complications		610					
	Role emotional	Complications vs.	3	97	2.65	0.008	-8.63	-15.00, -2.25	25%
		No complications		610					
	General health	Complications vs.	4	106	2.51	0.01	-13.71	-24.40, -3.02	82%
		No complications		629					
	Mental health	Complications vs.	4	106	5.01	0.00001	-9.33	-12.97, -5.68	0%
		No complications		629					
	Social functioning	Complications vs.	4	106	6.93	0.00001	-9.95	-12.76, -7.14	0%
		No complications		629					
	Vitality	Complications vs.	4	106	5.15	0.00001	-10.63	-14.67, -6.58	0%
		No complications		629					
Anxiety		Complications vs.	2	148	1.12	0.26	0.27	-0.21, 0.75	81%
		No complications		262					

4.3.4 The duration of the impact of surgical complications on patients' wellbeing

Out of the 37 studies that found a significant association between surgical complications and patients' wellbeing (including those that found confounding associations), 18 reported a significant relationship of the presence of post-operative complications with worse wellbeing at later than 12 months post-surgery. In fact 11 studies reported a significant relationship between postoperative surgical complications and patients' wellbeing more than 1.5 years post-surgery. Ten of those were longitudinal and had controlled for patients' preoperative wellbeing. It is worth noting that the time-points of patients' assessment varied considerably in nine studies, which may have affected the observed effects. For example, Bruns asked patients to complete the QoL questionnaire between 3 and 36 months post-surgery, Bloemen between 16 and 51 months post-surgery, Lim between 10 and 18 months, Kalliomaki a mean of 4.9 years post surgery with a wide range of years since operation, Douma between 0 and 10 years post-surgery and Polese a mean of 58 months after surgery with a standard deviation of 31 months.

The remaining 19 studies reported a significant association of complications with worse patient wellbeing less than 12 months post surgery. Of those, 12 were longitudinal and had accounted for patients' baseline wellbeing (see also Appendix 10, Appendix 11 and Appendix 12).

4.4 Discussion

4.4.1 Summary of included studies

This systematic review aimed to identify whether surgical complications secondary to high-risk surgery are associated with worse post-operative psychosocial wellbeing and to identify the degree and duration of this association.

Out of the 50 studies that were included in this review less than half explored this association as a primary aim with the majority investigating this association as part of a broader exploration of the clinical predictors of patients' wellbeing post-surgery. The majority of the studies were conducted in general gastro-intestinal surgery followed by cardio-thoracic surgery with only four studies in vascular surgery. There was high heterogeneity in the types and definitions of surgical complications that were assessed, with the majority of the studies examining a range of complications and a few investigating only one type. Quality of life was the most commonly used outcome for the exploration of the complications' impact on patients' wellbeing while mental health specific outcomes (i.e. anxiety and depression) were rarely assessed. None of the studies looked at any other mental health outcomes such as post-traumatic stress.

4.4.2 Key findings

The majority of the included studies found a significant association of surgical complications with patients' postoperative wellbeing (31 out of 50). Of those, 21 did so at both univariate and multivariate analyses, suggesting that complications are an independent predictor of patients' postoperative wellbeing above and beyond clinical or surgical parameters and demographic variables.

Significant associations were reported between surgical complications and worse scores on physical, mental and social dimensions of the various QoL measures. A meta-analysis of the studies that used the generic Short Form Health Surveys for the assessment of QoL confirmed the existence

of significant and clinically important adverse effects of complications on various domains of patients' quality of life with the largest effects being on bodily pain, general health, role limitations due to physical health problems, mental health and social functioning. Surgical complications were also significantly associated with higher post-operative anxiety and depression in individual studies even though a population effect could not be shown in meta-analysis. Complications that were found to be significantly associated with patients' low post-operative wellbeing ranged from relatively minor complications such as wound infections or atrial fibrillation, to more severe complications such as anastomotic leaks after gastro-intestinal surgery, perioperative myocardial infarctions after cardiac surgery, or graft-related events after major vascular surgery. Significant associations were reported between complications and patients' wellbeing from a few days to a few years post-surgery. A considerable number of studies found a significant association 12 months post-surgery (often later than 1.5 years post-surgery).

Note should also be taken of the studies that did not find a significant association between complications and patients' postoperative wellbeing (n=13) or found significant associations at univariate analyses which were not confirmed with multivariate models (n=6). Even though these were proportionally fewer (38% of the included studies), they suggest that complications do not always affect patients' wellbeing or that often other factors may moderate their impact. None of the included studies examined the potential confounding effects of psychosocial factors such as coping, cognitive appraisals and social support.

4.4.3 Quality of findings

The quality of the included studies needs to be considered when interpreting the findings of this review. Firstly, a substantial number of studies assessed patients' pre-operative wellbeing and

accounted for it in their statistical analyses. This confirms that surgical complications were an independent predictor of worse levels of postoperative wellbeing above and beyond any baseline differences between patients who suffered complications and patients who did not.

Secondly, more than half of the included studies which found a significant relationship between complications and patients' postoperative wellbeing employed multivariate statistical techniques in which complications were a significant independent predictor of wellbeing outcomes above and beyond clinical or demographic factors. This further validates the independent contribution of surgical complications on the impairment of patients' psychosocial wellbeing after surgery.

The robustness of the findings is also reinforced by the fact that all the included studies used validated self-report measures or formal psychological assessment for the assessment of patients' wellbeing. SF-36 was the most commonly used tool and it is one of the most thoroughly validated and most extensively used generic measures of quality of life in various patient and healthy populations (Ware and Sherbourne 1992; Garratt 1993; Jenkinson 1993). Anxiety and depression were assessed with HADS (Zigmond 1983; Crawford et al. 2001; Bjelland et al. 2002) and DASS (Lovibond and Lovibond 1995; Antony et al. 1998) both of which have excellent psychometric properties and have been used widely for the assessment of depression and anxiety in clinical and community samples.

Certain methodological limitations of the included studies should also be considered. First, even though the majority of the studies used predefined lists and definitions of complications almost one third of them did not describe their methods for the recording of complications. Moreover, one third of the studies did not state their response rates, which does not allow us to make inferences about the representativeness of their samples.

4.4.4 Limitations of the review

There are certain limitations in the methodology of this systematic review that need to be taken into consideration in the interpretation of the findings. First, the facet of surgical complications was based on generic search terms and synonyms of the term *complications* and as a result it may have not picked up studies which use terminology specific to certain complications. It is expected though that through the extensive use and the explosion of MESH terms this limitation has been adequately compensated for.

Secondly, a contemporary approach was chosen in the selection of eligible studies, as studies that were published before the year 2000, or with the majority of their patients recruited before the year 2000, were excluded from the review. This was partly due to the vast amount of literature that was retrieved by the search strategy that did not allow a meaningful synthesis of the studies but most importantly because we believe that limiting this review to literature that was published in the last decade is more reflective of current surgical practices and their associated complications. Similarly, the review was limited in the selection of literature from four high-risk specialties (i.e. gastro-intestinal, cardiac, thoracic and vascular procedures). These four specialties were selected on the basis that they include high-risk procedures where the potential for complications is higher; therefore the examination of the association of complications with patients' wellbeing in these specialties is highly relevant. Caution should be taken when interpreting these findings to other surgical specialties as the clinical setting at which complications occur may affect the extent to which they impact on patients' postoperative wellbeing. However, the consistency with which complications were significantly associated with wellbeing outcomes across all four specialties suggests that these findings are highly generalisable across most surgical specialties.

An important limitation concerning the use of meta-analysis was the very small number of studies with sufficient data for a quantitative synthesis as well as the difficulty of synthesising data

from different QoL measures. The latter resulted in restricting the QoL meta-analyses on data collected only with the SF-tools. The exclusion of studies that used different tools or that did not have adequate data may have biased the results of the meta-analyses.

Another limitation, which is common in most systematic reviews, is the potential for publication bias, where studies with significant results and big effect sizes are more easily published than studies with non-significant findings and small effect sizes (Easterbrook et al. 1991; Dickersin and Min 1993; Dwan et al. 2008). The potential omission of studies with non-significant findings or small effect sizes might have led us to overestimate the observed effects of surgical complications on patients' post-operative wellbeing.

4.4.5 Strengths of the review

This is, to my knowledge, the first systematic review and meta-analysis of the literature which aims to answer if surgical complications affect patients' psychosocial wellbeing and to identify the degree and duration of this impact. One of the most important strengths of this systematic review is that it is based on a very comprehensive search strategy, where keywords were complemented by MESH terms specific to each database, and where each MESH term was exploded in order to include all possible headings and subheadings under each facet. Moreover, the quality of each study has been thoroughly assessed with modified versions of the Newcastle-Ottawa tools (Wells G.A. et al.) which have been highly rated (Deeks et al. 2003). Another strength of this review is that it includes literature from four different surgical specialties, which increases the generalisability of the findings to surgical patients as a whole. Moreover, meta-analytic techniques were used in order to quantify the effects of surgical complications beyond each study, which adds to the robustness of the identified effects. Finally, one of the inclusion criteria of the retrieved studies was that patients'

wellbeing had to be assessed with validated measures or formal psychological assessment, which increases the validity of the reported findings.

4.5 Conclusions

This systematic review suggests that surgical complications are a significant independent predictor of patients' impaired post-operative psychosocial wellbeing often for a very long time post-surgery. It is not only major complications such as anastomotic leaks after colorectal surgery or perioperative myocardial infarctions after cardiac surgery that compromise patients' quality of life and emotional wellbeing but also relatively minor adverse events such as wound infections and atrial fibrillation. Patients who experience complications from their surgery report worse quality of life or higher anxiety and depression than patients with uncomplicated recovery, even later than 2 years post-surgery. However, none of the included studies investigated the role of psychosocial factors in the association of complications with patients' wellbeing and only a very small minority assessed mental health specific outcomes such as anxiety and depression.

The implications of these findings are significant for the delivery of surgical care as the results highlight the importance of supporting patients in the aftermath of complicated surgery not only in relation to their physical needs but also from a psychological perspective. Mixed-methods research is needed in order to understand how surgical complications influence patients' wellbeing, the various psychosocial mechanisms that moderate their effects and how to support surgical patients who have a complicated post-operative recovery. These issues will be addressed in Chapters 7 and 8. In the meantime, Chapters 5 and 6 are investigating the implications of surgical complications for surgeons' wellbeing.

Chapter 5: An interview study on surgical complications and their implications for surgeons' wellbeing

This chapter presents an in-depth exploration of the implications of surgical complications for surgeons' wellbeing using qualitative methods (i.e. semi-structured interviews). Five overarching themes are presented which are pertinent to the different types of impact of surgical complications on surgeons' wellbeing, the factors that affect surgeons' reactions, their ways of coping with the stress of complications, their perceptions of support and lastly their perceptions of the institutional cultures around surgical complications. These findings are discussed in relation to existing literature on the aftermath of healthcare-related adverse events as well as in relation to wider literature on psychological reactions to stress. The findings of this interview study set the scene for a hypothesis driven investigation of surgeons' psychological wellbeing after their involvement in major complications that follows in Chapter 6.

5.1 Background

Healthcare professionals' involvement in a healthcare-related adverse event, particularly if a patient is harmed and more so if they are seen as primarily responsible for the outcome, may have profound consequences for the staff involved (Vincent 2010). Healthcare professionals have been called the 'second victims' of adverse events in healthcare (Wu 2000) and a growing number of empirical studies suggest that the stakes of patient safety incidents for healthcare professionals' wellbeing are significant (Schwappach and Boluarte 2009; Sirriyeh et al. 2010) (see also Chapter 1).

As we saw in Chapter 2, the operating room is one of the highest risk areas for serious adverse events (Leape et al. 1991; Gawande et al. 1999), with potentially profound consequences for patients and the professionals involved but little is known about the response of surgeons to serious complications or how best to support staff in the aftermath of such events. A recent survey study of 7,900 surgeons found that those reporting a surgical error during the last 3 months were more likely to have a lower quality of life and increased probability of symptoms of burnout and depression (Shanafelt 2010). Grief and guilt about patient death or unsatisfactory outcome are amongst the factors that have been suggested to predict high levels of distress and burnout in surgeons (Balch 2009). Little is known however about surgeons' broader experiences of surgical adverse events and the determinants of their reactions to them.

Understanding how surgeons are affected by surgical complications and the wider issues is not only important for surgeons and their families but also for their patients as evidence suggests that healthcare professionals are often involved in a reciprocal cycle of symptoms with distress experienced due to their involvement in adverse events leading to more errors (West et al. 2006). Existing evidence suggests that high levels of stress adversely affects clinical performance and patient safety (Firth-Cozens and Greenhalgh 1997; Taylor et al. 2007; Fahrenkopf et al. 2008), which further confirms the importance of understanding surgeons' psychological reactions to surgical complications and how these could be mitigated.

5.1.1 Study aims

In the present study the aim is to explore in depth the impact of surgical complications on surgeons. More specifically, this study aims to examine how surgeons are affected by patient complications on

both a personal and professional level, the factors that affect surgeons' reactions, how they cope with their consequences and their perceptions of support.

5.2 Methods

5.2.1 Design

A one time-point design using in-depth, semi-structured, individual interviews was used. Semi-structured interviews were used as the most appropriate method for the aims of this study because they constitute a very flexible method of data collection leading to rich narratives that permit the researcher to analyse in detail how the participants make sense of the topic under investigation. This is achieved through a *“dialogue whereby initial questions are modified in the light of the participants’ responses and the investigator is able to probe interesting and important areas which arise”* (Smith and Osborn 2003).

5.2.2 Setting and participants

A purposive sampling technique was used so that the participants had experience in high-risk surgery where patient complications are more common and also had personal involvement in different types of surgical adverse events. Surgeons with this profile have a more extensive pool of relevant experiences to draw upon, hence they were considered more suitable for an in-depth exploration of how surgeons perceive and make sense of surgical complications. Surgeons were therefore eligible to participate if:

- They were practising gastro-intestinal or vascular surgery, both of which are associated with high risks of serious complications (Gawande et al. 1999).
- Above registrar level with at least 3 years of experience, which implied exposure to a range of surgical complications.

The participants were recruited from two large teaching trusts in London, UK, which provide for a large number of patients undergoing general or vascular surgery.

5.2.3 Procedure and materials

5.2.3.1 Participant recruitment

The participants were identified through clinical contacts from the two participating trusts. All the surgeons who worked for the two participating NHS trusts and met the eligibility criteria (n=41) were sent an invitation email which included information on the study aims and procedures and invited the surgeons to an interview with the researcher (AP). The invited surgeons were reassured that the interviews would be strictly confidential and that the data would be reported anonymously.

5.2.3.2 Interviews

The interviews were semi-structured. A standard topic guide was used which was developed based on a review of existing literature on healthcare professionals' experiences of patient safety incidents (see Chapters 1 and 2) and through consultation with surgeons, psychologists and academics in

patient safety. The guide was pilot-tested with 4 surgeons (two consultants and two registrars) for comprehensibility and relevance and included general topics of investigation and relevant prompts. Changes were made on the sequence of the questions based on feedback from the pilot participants. The general topics that were covered in the interview schedule were:

- How surgeons are affected by complications
- What factors determine the seriousness of their reactions
- How they cope with their impact
- Their views on support experienced and support required

Under each general topic a list of prompts was included. The wording of the questions was kept very open in order to avoid leading the participants towards the researcher's prior concerns. When the initial general questions were not sufficient to elicit a comprehensive response from the participants, more explicit prompts were employed. This technique is called "funnelling" (Smith and Osborn 2003). The interview schedule is presented in Appendix 14.

The interviews were conducted in private between December 2010 and April 2011. They were conducted face to face, by a researcher with a background in psychology and patient safety research (i.e. by myself). They lasted 45-60mins, were audio-recorded and professionally transcribed verbatim for analysis. Participants' consent to being interviewed was recorded. Ethics approval for the study was granted by the North West London REC 1.

5.2.3.3 Interviews analysis

The interview data were analysed in QSR NVivo qualitative analysis software (version 8) using Interpretative Phenomenological Analysis (IPA). The aim of IPA is to explore in detail how participants are making sense of their personal and social world with a strong emphasis on the meanings particular experiences, events or states hold for participants (Smith and Osborn 2003). This paradigm of qualitative analysis was chosen as the most appropriate for the aims of this study due to its phenomenological approach (i.e. detailed exploration of personal perceptions and meanings).

An idiographic iterative approach to analysis was followed starting from coding the detail of each transcript and slowly working up to more general categorisations and statements (Smith and Osborn 2003). The text was initially divided into small units of meaning, which were assigned a code describing the particular excerpt. As the analysis of the various transcripts progressed, emerging higher-level themes were noted reflecting more general psychological entities (e.g. coping, emotional reactions). The emergent themes were assessed for connections, which led to organising emerging themes in a hierarchical tree of super-ordinate and sub-ordinate themes. The emerging tree was used as a guide in the analysis of the remaining transcripts with a continuous assessment and incorporation of convergent and divergent data. A final table of super-ordinate themes was produced where themes were reduced to key overarching thematic areas based on the prevalence of the themes but also the richness of the included passages in terms of highlighting aspects of the research questions.

In order to ensure the validity of the study findings, two methods of triangulation were employed. Triangulation refers to the process of adding validity to qualitative studies. First, samples of the transcripts were independently coded by two researchers [i.e. the researcher who conducted the interviews (AP) and a researcher with a psychology and patient safety background (RD) who had

not been involved in the interviews]. The codings of the two researchers were compared and discussed in detail to ensure multiple perspectives, consistency and coherence in the analysis (Yardley 2013). The second method of triangulation involved seeking the participants' feedback on the analysis. All the interviewees were individually emailed a report of the analysis and were asked to offer feedback on how well the emerging themes captured their personal meanings of surgical complications. Several participants provided feedback and all indicated that they fully related to the analysis of the data.

Finally, even though IPA is not concerned with the frequencies of the emerging themes because the focus is on the personal meanings and constructs that emerge from the interviewees' narratives, tables of frequencies at which each super-ordinate theme and its sub-themes were discussed were produced as a way of visualising the overall weight of each theme across the total of the interviews. These frequencies should not be interpreted as quantitative prevalence data because they are not based on a structured interview schedule with a prescribed list of items. However, they offer an indication of those themes that were most frequently discussed by the interviewees in a semi-structured interview context.

The participants' personal data were de-identified to ensure anonymity and confidentiality.

5.3 Results

5.3.1 Participants' characteristics

A total of 27 consultants and senior registrars in general or vascular surgery agreed to be interviewed which corresponds to a response rate of 66%. Further participant recruitment was not

considered necessary as saturation was achieved (i.e. no new themes emerged in further interviews, so new interviews would not contribute any significant new insight in the investigation of the research aims) (Glaser and Strauss 1967). The participants' characteristics are described in Table 8.

Table 8: Participants' characteristics

ID	Role	Specialty	Experience in current job
01	Consultant	General surgery	3 years
02	Consultant	Vascular surgery	2 years
03	Registrar	Vascular surgery	6 years
04	Consultant	General surgery	3 years
05	Registrar	Vascular surgery	6 years
06	Consultant	Vascular surgery	17 years
07	Registrar	General surgery	3 years
08	Consultant	Vascular surgery	6 years
09	Consultant	Vascular surgery	3 years
10	Registrar	General surgery	5 years
11	Consultant	Vascular surgery	5 years
12	Registrar	General surgery	Not available
13	Registrar	General surgery	7,5 years
14	Consultant	General surgery	18 years
15	Consultant	General surgery	4 years
16	Consultant	General surgery	7 years
17	Consultant	General surgery	4 years
18	Specialist	General surgery	Not available
19	Consultant	General surgery	3 years
20	Consultant	Vascular surgery	15 years
21	Registrar	General surgery	6 years
22	Registrar	General surgery	7 years
23	Registrar	Vascular surgery	5 years
24	Consultant	General surgery	13 years
26	Consultant	General surgery	11 years
25	Consultant	General surgery	5 years
27	Consultant	General surgery	8 years

5.3.2 Emerging themes

The following 5 overarching themes emerged from the analysis:

- The different types of impact of complications on surgeons
- Factors affecting surgeons' reactions
- Coping mechanisms of surgeons
- Support for surgeons when complications occur
- Institutional cultures around surgical complications

Two more overarching themes that were related to issues of communication with patients about complications and surgeons' perceptions' of support for patients were omitted from this chapter. These two themes were beyond the scope of this thesis' aims, which are pertinent to understanding the impact of surgical complications on surgeons, the contextual factors of this impact and ways of supporting them.

5.3.2.1 The impact of surgical complications on surgeons

All of the participants referred to at least one case in their practice where a complication affected them significantly on a personal and professional level. In the majority of those cases the complication was perceived as preventable and had happened early in the participants' career during their training. The participants also described a range of effects on their lives, which have been grouped under five general spheres of impact: 'emotional', 'behavioural', 'cognitive', 'social' and 'other types of' impact (see Table 9 for an overview of the various types of impact and

Table 10 for more illustrative quotes). A summary of the different types of impact is given below.

Almost all of the participants (96%) admitted that surgical complications affected them on an emotional level and that these effects were often long-lasting. The most common reactions were guilt, anxiety, anger, a crisis of confidence, worrying about one's reputation, and worrying about the patient. Some surgeons reported lasting rumination and difficulty in maintaining concentration. A strong sense of personal responsibility and guilt in the aftermath of complications was a frequent theme: *"...you obviously blame that particular lapse that you had committed before and it makes you feel bad, although sometimes difficult to bring in the direct connection...But I think it's usually about feeling like you have personally missed something..."* (15, Consultant).

A few junior surgeons reported that they were fearful of the reaction of their superiors: *"...quite often you think what have I done wrong, am I in trouble for this...is this like an error that I've made that's unforgivable and is it going to affect people's professional opinion of me..."* (07, Registrar). Younger surgeons were also more likely to experience anger, often against their supervisors for inadequate supervision, or a crisis of confidence as opposed to consultants who were more likely to report feelings of guilt and anxiety. Strong emotional reactions usually faded but memories of significant complications often lasted for years. *"...The direct emotional impact does fade. Over what period of time? Who knows because it still has an impact five years later. I'm sure in 20 years time I'll still be able to remember this case and what it taught me..."* (23, Registrar)

More than two thirds of the interviewees (67%) stated that serious complications had an impact on their clinical practice. Even though complications were often seen as a positive learning experience, many interviewees admitted that the impact of complications was not always in the best interest of patients. The most commonly reported impact on surgeons' practice was the tendency to become more conservative and risk-averse in the management of patients (67%). For instance: *"...Well it might make me much more conservative and much less prone to taking any form of risk at all...and sometimes that's not necessarily in the best interest of the patient...and I see this behaviour in my colleagues at a consultant level and down through to the registrars and even the SHOs..."* (07, Registrar).

Table 9: Emerging themes of the complications' impact on surgeons

Theme	Sub-themes	N (%) of participants
Emotional Impact		
	Guilt	15 (55%)
	Crisis of confidence	8 (30%)
	Worry about one's reputation	8 (30%)
	Worry for the patient	6 (22%)
	Anger (i.e. at one's self or at seniors for inadequate supervision)	6 (22%)
	Anxiety	6 (22%)
	Disappointment	3 (11%)
	Sadness	3 (11%)
Behavioural Impact		
	Surgical practice is affected (e.g. become more cautious/risk-averse)	18 (67%)
	Increasing efforts to improve	4 (15%)
	Becoming aggressive in interactions with colleagues	4 (15%)
Cognitive Impact		
	Rumination	6 (22%)
	Reflection on what went wrong	6 (22%)
	Loss of concentration	3 (11%)
Social Impact		
	Interference with personal life	6 (22%)
	Relationships with colleagues are enhanced	3 (11%)
Other Impact		
	Learning	11 (40%)
	Physical reactions	2 (7%)

Table 10: Illustrative quotes on the complications' impact on surgeons

- **Crisis of confidence**

"...as a result of what happened, my confidence got shaken and then there was a next case that I would have done very easily, had this thing not happened, but because I had that in the back of my mind, I feel that it had shaken my confidence, whereas I knew I had the ability and the technical skills to not commit that error, but I did..." (09, Consultant)

- **Anger**

"...I remember feeling great anger, both at myself as in not being strong enough because I didn't know and I should have been stronger to stick up for what I thought needed to happen, but also that I'd been essentially led down this pathway which went wrong and made me look bad to my consultant ..." (05, Registrar)

- **Rumination**

"... I'll wake in the middle of the night only thinking about it... it does dwell on my mind for a period of time afterwards certainly...you can't just walk away from a big complication particularly if the outcome is bad..." (20, Consultant)

- **Disruption of social life**

"...it doesn't enable you to fully enjoy your day off as you would like to, because you've still got that nagging worry all the time... there is an inability to completely relax, whilst you're doing whatever that social activity is..." (14, Consultant)

5.3.2.2 Factors affecting surgeons' reactions to surgical complications

Factors that were discussed as determinants of surgeons' reactions to complications were grouped under case-, surgeon-, patient/family-, team- and institution-related factors (see Table 11 for an overview of the various factors of impact and Table 12 for more illustrative quotes). The most prevalent factors from each overarching category are discussed below.

5.3.2.2.1 Case-related factors: expectations and preventability

Two thirds of the participants reported that preventable complications (59%) have a greater personal impact: *"...what do most surgeons like about surgery? It's the technical aspect of it... And if by your own hand, own error and judgement someone has suffered, then of course you're going to bear that complication as a greater burden than say there was some unexpected anatomy... putting in a stitch badly that tears a vein, you're going to kick yourself for that a bit more..."* (23, Registrar). Complications that happen in the context of high-risk complicated cases where the expectations of complications are higher are less likely to cause strong emotional reactions among surgeons. Similarly, eight interviewees suggested that complications in elective surgery are more stressful than in emergency operations because the expectations of mortality or serious morbidity are lower.

5.3.2.2.2 Surgeon-related factors: personality and experience

The great majority of the interviewees (78%) referred to the importance of personality whereby surgeons with different personalities cope with the stress of complications in very different manners: *"...I have worked with people who complications seem like water off a duck's back...and I have worked with people who completely fall to pieces when there's a complication...the first is a defence mechanism, which may well be their character..."* (26, Consultant). Surgical experience was also discussed by the great majority of the participants (78%), with many suggesting that senior surgeons are affected less due to their higher confidence and a better record of outcomes: *"...it's pretty common knowledge that it's the junior consultants who suffer the most at them [complications]...as far as the trust is concerned, you're appointed a Consultant and the buck stops with you, but they actually haven't got the maturity to have pretty much seen everything and done everything...and I have no doubt that there is higher psychological morbidity amongst that group than amongst the wise old birds who've been there and done it*

all...” (14, Consultant). Of course, a few participants noted that the impact might sometimes be as severe for senior surgeons due to their higher expectations from themselves, the expectations of others and the higher accountability for their outcomes. For example: “...as a trainee I think I was far more dispassionate about morbidity, I was able to be more objective about it. Because the responsibility was in theory somebody else’s, even if I’d done the surgery somebody else would support me if there was a problem, my consultant.... But as a responsible independent practitioner, everything is a problem...” (19, Consultant).

5.3.2.2.3 Patient-related factors: patient outcome and patients’ reactions

Patient outcome (63%) and patient/family reactions (48%) were also commonly reported determinants of surgeons’ reactions. Complications that lead to severe disability or death have the strongest emotional impact: *“...repairing someone’s aneurysm, giving them a stroke and then rendering them paraplegic it would be a terrible outcome and maybe they would be better off had they not survived that procedure...Death, limb loss, paralysis, they’re huge and probably affect the impact of complication on your emotions...” (23, Consultant).*

The interviewees also reported that when patients and families are understanding, complications are easier to deal with emotionally as opposed to when patients are in an adversarial mood. For instance: *“...There are some patients who you can tell them you’ve made a serious complication and they’ll come to clinic with a box of chocolates for you. And there’s some patients who have what I would consider, a relatively minor complication and they go absolutely mad... So, clearly the patient and the family’s reaction is of paramount importance to my levels of stress and anxiety about the situation...” (22, Registrar).* A patient deciding to take legal action was reported by many participants as a particularly stressful experience. Words such as “frightening”, “demoralising” and “devastating for one’s career” were used to describe the experience of litigation. For instance, a consultant surgeon described his view of litigation: *“I don’t know whether it gets easier with time, but the first time that happens it’s very horrifying*

and frightening, really. You have no idea of the system, the process. What does it mean? You just see your name bandied around, you know, all this legal jargon. And it feels very, very solitary, that you and the institution are not necessarily fighting the same corners...” (1, Consultant). Complaints were also quoted as a significant source of stress for surgeons, especially the more junior ones.

5.3.2.2.4 Team and institutional factors: colleagues’ reactions and blame culture

Colleagues’ reactions and the level of support that colleagues offer were also commonly cited by the interviewees as determinants of their reactions. *“...In my own experience it tends to be colleagues...if you discuss a complication within a multi-disciplinary environment and one of your colleagues is in a more adversarial mood...that can make it more stressful than if it’s done in a fair and open way...” (20, Consultant)*

Finally, many interviewees discussed the existence of a blame culture as a factor that exacerbates the emotional toll of complications: *“...If you feel that you're working in a blame environment ... then that is really difficult...you wouldn't be performing to your optimal anyway because you're watching your back the whole time...You might feel that you want to keep things to yourself...” (22, Registrar).* The institutional culture emerged as an overarching theme and therefore it will be discussed in more detail on page 126.

Table 11: Factors of the complications’ impact on surgeons

Theme	Sub-themes	N (%) of participants
Case-related	Expected vs. unexpected complications	18 (66%)
	Preventable vs. less preventable complications	16 (59%)
	Elective vs. emergency surgery	8 (30%)
	Intraoperative vs. postoperative complications	6 (22%)
	Life-saving vs. lifestyle surgery	3 (11%)
Surgeon-related		

Personality	21 (78%)
Experience	21 (78%)
Self-confidence in surgical technique or decision-making	10 (37%)
Level of responsibility on the case	7 (26%)
Other personal troubles	5 (18%)
Management of complication	3 (11%)
Sense of responsibility to the patients	2 (7%)
Personal expectations about the outcome	2 (7%)
Lack of insight about one's operative ability	1 (4%)
Communication with patient	1 (4%)
Gender	1 (4%)
Patient or family-related	
Patient outcome	17 (63%)
Patient/family reactions	13 (48%)
Empathy with patient	9 (33%)
Patient consent	1 (4%)
Patient expectations of how patients should react	1 (4%)
Team-related	
Colleagues' reactions	9 (33%)
Support during/after surgery	4 (15%)
Institution-related	
Blame culture	10 (37%)
Teamwork structures	4 (15%)
Other support structures	2 (7%)
Quality of training	2 (7%)
Institutional politics	1 (3%)
Competitiveness between surgeons	1 (3%)

Table 12: Illustrative quotes on factors that affect surgeons' reactions

- Expectations of complications**

"...If you have a sick patient or you're doing something that's a very big operation, a complicated, risky operation, then I think you're far more likely to expect there to be a complication. And therefore you're more mentally prepared for it when it happens. If you do something on a patient who is young and fit - what should be a straightforward operation, then it tends to have more impact because you're not expecting it so much..." (16, Consultant)

- **Preventability/controllability of complications**

"...avoidable complications, I do not like because there is no easy way of dealing with them if you have any empathy for patients or pride in what you do, if something stupid happens, it's hard to live with..." (26, Consultant)

- **Seniority**

"... I've found it does become easier as you get more senior because when you first start, particularly as a consultant, you sort of think I've got this complication, am I actually adequately trained to be doing this? You need to do a certain critical mass of operations to start knowing what your complication rates are. And the more you do the less one complication alters your complication rates. So you have the fallback of knowing that actually you have a body of practice under your belt, that you have performed to the standards, that you haven't had bad complications. That gives you much more confidence, it's when you start off and you have no idea..." (16, Consultant)

- **Patient outcome**

"...repairing someone's aneurysm, giving them a stroke and then rendering them paraplegic it would be a terrible outcome for some people and who's to judge, but maybe they would be better off had they not survived that procedure. The impact on the patient, the impact on the patient's family. Death, limb loss, paralysis, they're huge and probably affect the impact of complication on your emotions..." (23, Consultant)

- **Teamwork**

"...if you've got a well-functioning hospital with good clinical support, everybody will come and give you help should you require it, whether it's a cardiologist, physician, respiratory physician, anaesthetist, ITU. If you know you've got that support and that they're going to give you a good clinical opinion when they come, and they will come if you ask them to, then you feel very comfortable, very supported and you can function as a surgeon well..." (06, Consultant)

5.3.2.3 Coping with surgical complications

The interviewees used a variety of coping mechanisms in the aftermath of complications. These were grouped under two general types of coping which reflect the distinction between problem-focused coping (i.e. directed towards changing the relationship between the demands of the situation and the sources available) and emotion-focused coping (i.e. directed towards managing the emotional consequences of the stressor) (Lazarus and Folkman 1984; Lazarus and Folkman 1987). A list of the coping strategies that the interviewees reported is presented in Table 13.

The most commonly reported problem-focused coping strategies were: discussing the complications with peers for advice, deconstructing and evaluating the complication and ensuring that one's skills are up to scratch. For example: *"...the helpful thing about discussing problems with seniors or with colleagues is eventually you get advice from people who had the same problems in the past. And you can learn..."* (18, Registrar). In terms of evaluating one's practice: *"...I suppose what you do is you privately, just deconstruct it and replay it in your mind until you really thoroughly evaluate it, what the complication was, how a big a complication it is and your personal responsibility for it...You do that quite quickly even on the way home..."* (05, Registrar).

The most common emotion-focused coping strategy was rationalising by putting what happened into perspective, as this consultant surgeon explains: *"...the stress tends to dissipate because you've put things into perspective...because if you recognise that complications happen, no matter how good a surgeon you are, then it should become part of your working life..."* (14, Consultant). Other commonly quoted emotion-focused coping strategies were talking openly to patients as a way of finding closure and seeking reassurance from colleagues. For instance: *"...you discuss the case and see their [colleagues'] reaction...and if they are shocked, that would be quite powerful in your interpretation of that complication and vice versa, so 'oh well you know cases don't always go that way do they, yeah I had a case like that once', all those sorts of statements are very reassuring and allow you to get quickly over..."* (05, Registrar).

Table 13: Coping strategies used in the aftermath of serious surgical complications

Theme	Sub-themes	N (%) of participants
Problem-focused coping		
	Discussing the complications with others for advice	25 (92%)
	Deconstructing the complication and identifying learning lessons	17 (63%)
	Ensuring that one's practice is as good as possible	8 (30%)
	Ensuring best management of the complication	7 (25%)
	Involving patients and families in management of complication	6 (22%)
	Using colleagues' help	5 (18%)
	Over-investigating patient cases	2 (7%)
	Consenting patients carefully	2 (7%)
Emotion-focused coping		
	Rationalising	11 (40%)
	Seeking reassurance	9 (33%)
	Being open with patients & families	8 (30%)
	Getting on with one's life	8 (30%)
	Disassociation from emotional aspects of complications	6 (22%)
	Alcohol	4 (15%)
	Distracting one's self with other activities	4 (15%)
	Internalising	3 (11%)
	Acceptance	3 (11%)
	Blaming other factors	3 (11%)
	Self-blame	2 (7%)
	Becoming authoritative	2 (7%)

5.3.2.4 Support

The discussions about support in the aftermath of surgical complications evolved around the forms of support that are commonly available, the forms of support that are lacking, barriers to seeking support, and suggestions for the improvement of existing support arrangements. The support-related themes are presented in Table 14 and more illustrative quotes are presented in Table 15. A summary of the support-related discussions is presented below.

Almost unanimously (96%) the participants reported that peers are the most commonly available and most sought after source of support. Discussions with colleagues happen informally and offer reassurance. Senior surgeons' support was greatly appreciated by junior surgeons. One senior consultant describes an example of an informal team structure which allows young surgeons to deal with complications more effectively: *"...We have a team of three, we do a ward round together and we bounce opinions off each other... We will happily discuss complex cases and complications of cases. And that's a very good stress reliever, especially if you're relatively junior and there's a very senior person who's probably seen it all before, that's very reassuring..."* (26, Consultant). Other available sources of support that were quoted less frequently were one's loved ones (e.g. family, partner), institutional structures such as various surgical meetings and psychological services.

However, more than two thirds of the participants (70%) suggested that support from employing organisations is inadequate. Debriefing or effective mentoring in the aftermath of serious incidents was rarely available. Organisations typically reacted in a punitive manner and with little understanding of the wider systemic problems that can contribute to complications: *"...I don't think the institutions have any knowledge of the difficulties that their Consultants face and to my knowledge there are no mechanisms for support, at all. If a Surgeon mucks up the trust's response is to suspend them..."* (14, Consultant)

The majority of the participants also suggested that support for surgeons in the aftermath of serious complications needs to be improved. The need for a better mentoring system was discussed extensively (40%): “...For consultants, it's very good to have someone a little more senior that if you have a problem you can say, 'What am I going to do?' or 'What happens next?' That's very, very unofficial and it would be nice if it could be made more structured in the Health Service...” (26, Consultant) Other suggestions included a time-break after serious complications, teamwork structures (e.g. operating in pairs), structures aimed at human aspects of complications (e.g. facilitating communication with patients when things go wrong), and psychological services (with mixed views about their acceptance within the surgical community). Specific references were made to how seniors should support their juniors when things go wrong. “...I hope that we're not so aloof that our juniors can't actually talk to us about issues that they have...” (20, Consultant)

Table 14: Themes regarding support for surgeons in the aftermath of complications

Theme	Sub-themes	N (%) of participants
Available support		
	Peers	26 (96%)
	Senior surgeons	12 (44%)
	Close ones (i.e. partners, family, outside work friends)	10 (37%)
	Institution (e.g. M&M meetings, managers, help with complaints)	7 (26%)
	Psychological/counselling services	4 (15%)
Inadequate support		
	Institution	21 (78%)
	Colleagues	4 (14%)
Barriers to seeking support		
	Machismo culture	10 (37%)
	Non-medical relatives/friends cannot understand	8 (30%)
	Not wanting to burden one's family	5 (18%)
	Seniority	2 (7%)
	High workload	2 (7%)
Suggestions for better support		
	Mentoring	11 (40%)
	Time-break after complication	10 (37%)
	Counselling services	8 (30%)
	Formal teamwork structures (e.g.	8 (30%)

operating in pairs)	
Structure focused on human aspects of complications	8 (30%)
Open forums for discussion of complications	7 (26%)
Structured debriefing sessions	5 (18%)
Peer support groups	5 (18%)
Complications-related training	4 (15%)
Resources to release surgeons from pressure	3 (12%)

Table 15: Illustrative quotes on support for surgeons in the aftermath of surgical complications

- **Colleagues as main source of support**

“...they [colleagues] can also help you out to make sure that different things around you are dealt with and take some pressure or relief off you and let you concentrate on sorting everything out from that mess that you made...” (2, Consultant)

- **Colleagues adopting blame**

“...quite often the first response of your colleagues is not that of support unless it really is patently clear that you know you’ve been really unlucky, it’s usually that of well ok what did he do wrong, and blame and then what happens is there’s kind of like a sort of whispering culture...” (07, Registrar)

- **Machismo culture as barrier to seeking support**

“...I think you’d find some personalities would feel that it’s weak to discuss your weaknesses...surgery by and large attracts the goody sort of type A people in whom it would be a real weakness to admit that you have a weakness...” (14, Consultant)

- **Importance of good mentoring**

“...The problem with the mentoring system is that a mentor is only really there if you've kind of known each other come up through the ranks and then a mentor is a very natural mentor. And if it's not that way, then you haven't really got a mentor; you've just got somebody else that you should take that complication to and you don't know how they're going to react to it and whether or not they're actually supportive of it or ridicule you slightly for it...” (01, Consultant)

- **Importance of teamwork structures**

“...an ideal system to me would be to have during this time period when a complication has

happened a team approach. I think it's quite important the surgeon is involved to discuss the problems with his colleagues and make sure that it's a collective decision not just for any other political reasons only but it's very important to ensure that the surgeon will be released from some of his stress and also that all the decisions have been made in a clear light...." (04, Consultant)

- **Importance of open forums for discussion of complications**

"...I think if everybody's open about it and there's not whispering campaigns... 'cause I have been participant in the discussion of morbidity for other surgeons elsewhere, and it's discussed unfavourably behind their back but never mentioned..." (19, Consultant)

5.3.2.5 Institutional culture

One third of the participants (30%) described institutions as endorsing a blame and punitive approach to complications: *"...That's how I felt in the past, they [hospital managers] sort of march in to the ward and the immediate implication is that you've done something wrong. So again I don't believe in blameless culture, that is a total fallacy..." (07, Registrar)*. Morbidity and Mortality meetings in particular were commented upon quite negatively. Some interviewees suggested that these meetings are important learning forums. However, almost half of the participants (44%) described them as being dominated by blame, not being supportive (30%) or rigorous (30%), and exacerbating the burden of complications (18%): *"...morbidity and mortality meetings are supposed to be a forum where you can have an open discussion...but if anyone believes that they're only kidding themselves, everybody in that room is very defensive and aggressively pursues an angle that puts them in the best possible light and professional rivalries exist, I don't find them cathartic forums for saying that was just terrible wasn't it..." (07, Registrar)*.

Two interviewees noted that institutional cultures vary between organisations and that they have been lucky to work for institutions with a sensible approach to adverse events and a supportive attitude. For instance: *"...I've worked as a consultant in two places, both of which have seemed to have a*

very sensible approach which is, you know, is it avoidable? Was there anything that should be dealt with? And if not, well, we support you..." (16, Consultant).

5.3.2.6 Comparative analysis between gastro-intestinal and vascular surgeons and consultants and registrars

A comparative analysis between vascular and general surgeons and between junior and senior surgeons did not show any striking differences between the two groups in relation to any of the themes.

5.4 Discussion

This study explored surgeons' experiences of surgical complications in depth, the contextual factors that affect their reactions, and their perceptions of support in the aftermath of serious surgical adverse events.

In summary, surgeons admitted that they are often seriously affected by serious complications and the implications of this impact concern all parties involved: surgeons themselves, their colleagues, patients and the wider organisation. Emotional reactions range from guilt and a crisis of confidence, to anger and worry about one's career. Even though the intense emotional impact progressively fades there are certain cases that surgeons recollect many years later. Serious complications often make surgeons more conservative or risk-averse in the management of patients, which can be detrimental for patient care. Wu et al. (Wu et al. 1991) also reported a similar finding in their early study on house officers' medical mistakes. The authors of that study found that the

participants reported increased use of vigilant behaviours in the aftermath of their mistakes such as paying more attention to detail, personally confirming case-related data and trusting others' judgement less (Wu et al. 1991). We saw in Chapter 3 that use of vigilant behaviours and tendency to become more risk-adverse are often indicative of post-traumatic stress (Yehuda 2002). The finding therefore that a significant percentage of the interviewees reported that they tend to become more risk-adverse in the aftermath of surgical complications may imply that certain cases have a traumatic impact on surgeons. The prevalence of post-traumatic stress in surgeons who experience serious patient complications needs further investigation.

The study also revealed a range of factors that determine how seriously surgeons are affected by complications. "Knowing that you've caused something by your own hand" was reported as a particularly painful experience. Surgeons' sense of direct responsibility over the care that they provide possibly makes the experience of surgical mistakes more personal than in other medical specialties. For instance, Shanafelt et al., in their study of burnout and medical errors in surgeons, found that over 70% of the participants attributed errors to individual rather than system level factors (Shanafelt 2010). This heightened sense of personal responsibility may place surgeons at risk for severe distress after their involvement in surgical complications, as self-criticism is a significant predictor of depression in clinicians (Brewin and Firth-Cozens 1997; Vaglum and Falkum 1999; Tyssen and Vaglum 2002). Moreover, the findings suggest that surgeons' appraisals of complications as preventable contribute to stronger emotional reactions in line with evidence that the individuals' perceived locus of causality and controllability of stressful life events are significant predictors of their wellbeing (Weiner 1986).

Surgeons are typically regarded as more tough-minded than other healthcare professionals and there is indeed some evidence that this is the case (Borges and Savickas 2002). The interviewees however reported that there is a considerable variation in both the nature and severity of reactions to complications, with some people being more affected than others. This was

explained in part, but by no means completely, by seniority and experience. Personality was also reported by many to play a role, but the development and active use of coping strategies might well be the critical factors, as suggested by the literature on coping with stressful life events (Lazarus and Folkman 1984; Lazarus and Folkman 1987). Experienced surgeons may react less strongly to complications in the first place but importantly may also have more effective ways of dealing with those reactions. A variety of different coping strategies were discussed with some being reported more commonly than others (e.g. discussing with peers, evaluating one's skills, rationalising) which confirms the important role that one's coping strategies play when surgical complications occur and the potential value in supporting surgeons to develop constructive ways of dealing with their stress after such incidents. This is particularly critical for junior surgeons who feel less confident clinically after complications and also more worried about the implications of the incidents for their career, but also for more senior surgeons who might also struggle with the effects of complications on their lives due to feeling more accountable for mishaps that happen in their practice.

Another common theme was that institutions often endorse a blame culture and a punitive approach to complications, both within the wider organisation and seemingly from professional colleagues. Criticism was particularly directed at Morbidity and Mortality meetings, which were said to be dominated by a blame, cover-up culture, the effects of which might expand on how surgeons deal with complications on a professional and an emotional level. As Orlander et al. point out in their overview of Morbidity and Mortality meetings: *"if the style of the conference is unduly blunt and criticism is directed towards individual persons rather than towards procedures and patterns of decision making, then participants may fear public humiliation and the result may be aversive conditioning rather than the forthright evaluation of poor medical practices and outcomes"* (Orlander et al. 2002). Lack of institutional support and negative reactions from one's colleagues have featured in most recent studies on healthcare professionals' reactions to medical errors as important barriers of effective coping with their aftermath (Sirriyeh et al. 2010).

Finally, surgeons, like other healthcare professionals (Kaldjian 2008; Schwappach and Boluarte 2009; Sirriyeh et al. 2010), regard support from their peers as critical and informal relationships and networks are very important sources of advice and support. This study also suggests that surgeons see value in more formal arrangements aimed both at supporting them in the aftermath of serious complications and training people to manage these events. Common suggestions included more effective mentorship for young surgeons, open forums for the discussion of complications and formal teamwork approaches in the management of complicated cases (e.g. operating in pairs). When serious complications occur, breaks from operating and structured debriefing were also suggested by many.

5.4.1 Limitations

There are certain limitations that need to be considered in the interpretation of our findings. First, very junior surgeons were excluded from the sample, which has restricted our ability to extract the experiences of this group. Surgeons are often affected by major complications that happen early in their careers, and interviews with very junior trainees would be informative in that respect. Moreover, the participants were recruited from two large UK NHS trusts. Surgeons, who work in smaller hospitals, or different healthcare systems, may report different experiences. Finally, the lack of a control group is restricting our ability to examine the extent to which surgeons' experiences are different from those of different groups of healthcare professionals. Nevertheless, published literature on healthcare professionals' experiences of adverse events has allowed us to cross-check our findings against existing research data.

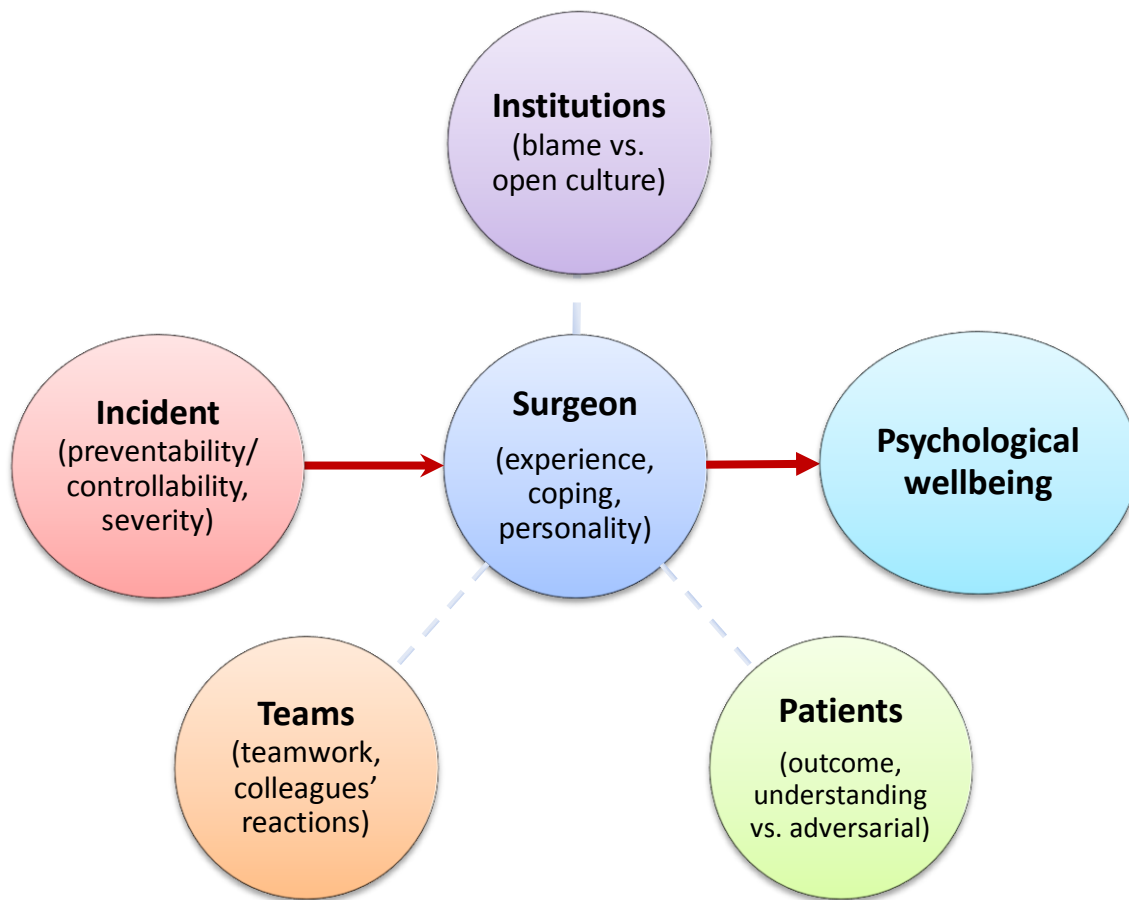
5.4.2 Strengths of the study

Despite any limitations, this is the first study to my knowledge that explored surgeons' experiences of a topic that is so integral to their professional wellbeing and that is seldom openly discussed, using in-depth qualitative methods. Moreover, this study investigated the wider factors that contribute to the severity of surgeons' reactions in the aftermath of surgical complications thus adding to the very limited data on the factors that affect healthcare professionals' emotional reactions to adverse events.

5.5 Conclusions

In summary, this study concluded that surgeons experience a range of emotions after serious complications and that emotional distress often affects their practice, not always in the best interest of patients (e.g. they tend to become more vigilant and more risk-averse, which may indicate symptoms of post-traumatic stress). The extent and severity of this emotional impact as well as its potential implications for the quality and safety of surgical care warrant further investigation. Secondly, the study identified various contextual factors that determine how seriously surgeons are affected by surgical complications. These factors are schematically presented in Figure 3. Lastly, this study suggests that surgeons at any stage would benefit from structures aimed at facilitating coping with serious complications. Further assessment of the most appropriate methods is obviously needed within the surgical community. However, based on findings from this study and previous literature and given the potential impact on surgeons as well as on patients, additional support should be seriously considered by the surgical community and by those involved in the management of surgical services.

Figure 3: Emerging factors of surgical complications' impact on surgeons



Chapter 6: A survey study on surgeons' psychological wellbeing after their most recent major complication

This chapter presents a cross-sectional survey study on surgeons' psychological wellbeing after the most recent major complication of their practice. This study aims to identify how major complications are associated with surgeons' psychological wellbeing (i.e. traumatic stress, anxiety, depression, burnout) and also to statistically examine the contribution of factors that emerged in the interviews as important determinants of surgeons' psychological reactions (i.e. appraisals of complications, institutional response, coping strategies and perceptions of support). The findings are discussed in the context of relevant literature while the chapter closes with an overview of the methodological strengths and limitations of this piece of work.

6.1 Introduction

The surgeons of the interview study in Chapter 5 described a range of emotional reactions in the aftermath of serious surgical complications such as guilt, anger, rumination, loss of concentration and an inability to relax, some of which resemble those that are encountered in the aftermath of well-studied traumatic incidents (Clohessy and Ehlers 1999; Yehuda 2002; Brewin et al. 2003). The majority of the participants reported that they tend to become vigilant and risk-averse in the aftermath of serious surgical complications, a reaction that is also commonly encountered among sufferers of PTSD (Yehuda 2002; Brewin et al. 2003). Low mood, worrying and anxiety were also common effects of serious surgical complications on surgeons. The interviews also highlighted a number of individual, incident and institution related factors that contribute to the severity of surgeons' reactions to complications such as their coping strategies, their perceptions of the causes

that lead to each incident, their perceptions of support and the institutional culture around adverse events.

The extent to which the above emotional reactions develop to psychological distress is not clear. Recent empirical data suggest that surgeons' involvement in a medical error in the previous 3 months is associated with higher levels of burnout and depression (Shanafelt 2010). However, evidence on the prevalence of other relevant psychological outcomes such as post-traumatic stress and anxiety do not exist in relation to surgeons' (or other healthcare professionals') involvement in serious patient safety incidents. An empirical investigation of the relationships between factors such as those that emerged in the interview study and healthcare professionals' wellbeing in the aftermath of serious adverse events is also lacking in the literature.

This study therefore builds on the interview study on surgeons' experiences of surgical complications as well as on existing literature on the aftermath of adverse events and psychological reactions to extreme stress and aims:

- To describe surgeons' wellbeing in the aftermath of major complications and
- To identify the relationships between surgeons' wellbeing and factors that emerged as potential predictors of these outcomes in the interviews

More specifically, this study set out to explore the following hypotheses (informed by the interview findings and relevant literature):

H1: Surgeons' involvement in major surgical complications negatively affects their wellbeing

H2: The ways in which surgeons cope with the stress of major surgical complications are associated with their wellbeing.

H3: Surgeons' causal attributions of major complications are associated with their wellbeing

H4: Surgeons' perceptions of support in the aftermath of a major surgical complication are associated with their wellbeing

H5: Surgeons' perceptions of their institution's response to surgical complications are associated with their wellbeing

6.2 Methods

6.2.1 Study design

This was a cross-sectional survey study with purposive sampling.

6.2.2 Setting and participants

6.2.2.1 Sampling

The eligibility criteria for participation in the study were the following: a) being a surgeon (consultant or trainee), b) specialising in gastro-intestinal or in vascular surgery and c) reporting experience of at least one major surgical complication in one's practice. Gastro-intestinal and vascular surgery were chosen due to their high risks of serious surgical complications in agreement with the sampling rationale that was used in Chapter 5.

6.2.2.2 Participant recruitment

The author attended a series of gastro-intestinal and vascular surgical audit meetings in three NHS trusts. At the end of each meeting surgeons were provided with verbal and written information on the study and were given a hard copy of the survey. They were also sent an online version of the survey by email as a supplementary way of increasing the response rate. Reminder emails were sent twice in order to increase response rates. The completion of the survey was kept anonymous due to the sensitive nature of the topic. Data collection took place between the 2nd of August 2011 and 26th of June 2012. A total of 73 eligible surgeons were asked to participate in the study, and 47 of those completed the survey (a response rate of 64.4%). Ethical approval for the study was granted by the North West London REC 1 ethics committee.

6.2.3 Survey

6.2.3.1 Piloting

The survey was first piloted with 2 consultant surgeons (one gastro-intestinal and one vascular surgeon) and 3 surgical trainees. The piloting was pertinent to the comprehensibility, readability and relevance of the scales and not their psychometric properties due to the fact that the majority of the scales were existing tools with excellent psychometric characteristics. One scale that was developed for the purposes of this study (i.e. surgeons' perceived usefulness of various support structures) was refined based on the pilot participants' feedback.

6.2.3.2 Survey content

The survey included four thematic sections (see also Appendix 15). Section A assessed the participants' characteristics including their age, gender, NHS trust, nationality, relationship status, whether they had children, surgical specialty, clinical position, hours of clinical work per week and whether they held an academic position.

Section B assessed the characteristics of the reported complication. The participants were first asked whether they ever had a major surgical complication in their practice. A major complication was defined as per Dindo et al.'s definition of surgical complications (*i.e. any major deviation from the normal postoperative course e.g. anastomotic leakage after bowel surgery, heart failure after cardiac surgery*). Participants who responded affirmatively (n=47) were asked to complete the rest of the survey in relation to their most recent major complication. The reason for asking them to think of their most recent major complication was in order to control for biases that would operate if participants were allowed to choose any incident. Other items in this section included the timeframe over which the complication occurred, the severity (based on the outcome for the patient) and whether they had been involved in any legal proceedings as a result of this complication. Single items on the internality and controllability of the perceived causes of the complication were used in order to assess the participants' causal attributions [continuous scales from 1 (all to do with you/completely controllable by you) to 7 (all to do with others or external factors/completely uncontrollable by you)]. These scales were adapted from Firth and Brewin (Firth and Brewin 1982).

Section C assessed the participants' psychological reactions to the complication. First, Horowitz's Impact of Events (IES) scale was used (Horowitz et al. 1979). IES is a 15-item scale assessing intrusion and avoidance in relation to a specified event on a 4-point scale. 7 items assess intrusive thoughts (e.g. *I thought about it when I didn't mean to*) and 8 items assess avoidance behaviours (e.g. *I tried to remove it from memory*). The maximum score for intrusion is 35 and the

maximum score for avoidance is 40. A cut-off point of 19 has been suggested by Horowitz as indicating traumatic stress of clinical concern (Horowitz et al. 1979). The participants were asked to retrospectively rate the extent to which they experienced each of the symptoms during the month after the incident. This timeframe was selected because the interviews suggested that surgeons' reactions to complications are stronger in the immediate period after the incidents. Secondly, surgeons' coping with the stress of the complication was assessed with Brief-COPE (B-COPE) which is an abbreviated version of the COPE Inventory with good psychometric properties (Carver 1997). B-COPE assesses the extent of use of various coping strategies known to be relevant to effective and ineffective coping (e.g. self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support) in relation to a specified event. Each coping strategy is assessed by two items on a 4-point scale. The maximum score for each coping strategy is 8. Surgeons' perceptions of the usefulness of various support sources in the aftermath of the reported complication were assessed with a scale, which was designed based on the interview findings and existing literature. A total of 13 sources of support were listed (e.g. *guidance by senior clinical people, discussing the complication at a Morbidity & Mortality meeting, counselling services*) and participants rated the extent to which each of them helped them deal with the complication on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). Lastly, the institutions' response to complications was assessed with the *punitive response to error* scale which is part of the Hospital Survey on Patient Safety Culture (HSPSC), a patient safety culture survey with sound psychometric properties (Sorra and Nieva 2004). This scale consists of 3 items, (e.g. *staff feel like their mistakes are held against them*) which are assessed on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The items were modified in order to reflect the context of the study (e.g. "staff" was replaced with "surgeons").

The final section assessed the participants' current psychological and professional wellbeing. The respondents were first asked to complete the Hospital Anxiety and Depression Scale (HADS) which includes 7 items on anxiety (e.g. *I feel tense or 'wound up'*) and 7 items on depression (e.g. *I*

still enjoy the things I used to enjoy), all of which are assessed on a 4-point scale (Zigmond 1983). The maximum score for both depression and anxiety is 21. A cut-off point of 8 has been proposed as adequately identifying borderline anxiety disorders and depression (Bjelland et al. 2002). HADS has very good psychometric properties with non-psychiatric hospitalised patients but also with primary care patients and the general population (Bjelland et al. 2002). The participants completed HADS in relation to how they felt at present. Lastly, participants were asked to complete an abbreviated version of the Maslach Burnout Inventory (a-MBI), which also includes a short scale on *satisfaction with medicine* (McManus et al. 2002; McManus et al. 2003). A-MBI assesses the three dimensions of burnout (Maslach et al. 2001) on a 6-point scale: emotional exhaustion, depersonalisation and personal accomplishment. The maximum score for each dimension is 18. Cut-off points for clinical burnout do not exist. Example items for the three dimensions include: *"I feel emotionally drained from my work"*, *"I don't really care what happens to some patients"* and *"I feel exhilarated after working closely with my patients"*. The participants completed a-MBI in relation to how they felt at present.

6.2.4 Statistical analysis

The data were analysed using SPSS for Windows version 20. Descriptive statistics (means, standard deviations, medians and ranges) and frequencies were used to summarise continuous, ordinal and categorical data respectively. Histograms as well as tests of normality (Kolmogorov-Smirnov) and homogeneity of variance (Levene's test) were reviewed in order to check the data for their compliance with the assumptions of parametric tests (Field 2011). Parametric tests were used for continuous data that met the assumptions of normality and homogeneity of variance (t-tests, one-way ANOVAs, Pearson's correlations) while non-parametric tests were employed when continuous data did not meet the above assumptions or when the data were ordinal (Mann-Whitney, Kruskal

Wallis, Spearman's correlations). Chi-square tests were used to assess the levels of one categorical variable against the levels of another categorical variable. Lastly, multiple logistic regression was used to assess which factors predicted traumatic stress of clinical concern among surgeons. Factors that were significantly associated with traumatic stress of clinical concern in univariate analyses qualified for entry in the multivariate model. Multicollinearity diagnostic statistics were checked and showed that the assumption of no multicollinearity was met (Field 2011).

6.3 Results

6.3.1 Participants' characteristics

The majority of the respondents were from Trust A (53%), specialised in gastro-intestinal surgery (60%) and were surgical trainees (60%). The mean number of years in their current clinical position was 6.2 ($SD=5.9$, Range=0-35), while the mean number of hours of clinical work per week was 50 ($SD=17.7$, Range=0-72). The majority of the respondents were male (77%), British (77%) and married (68%). 55% of them had children and their mean age was 38.5 years ($SD=7.7$). See Table 16 for a more detailed overview of the sample's characteristics.

Table 16: Participants' characteristics

		N (%)
Gender	Male	36 (76.6)
	Female	11 (23.4)
Nationality	British	36 (76.6)
	Other	11 (23.4)
Relationship Status	Single	7 (14.9)
	In a relationship	7 (14.9)
	Married	32 (68.1)
	Missing	1 (2.1)

Children	Yes	26 (55.3)
	No	21 (44.7)
Seniority	Consultants	19 (40.4)
	Trainees	28 (59.6)
Surgical specialty	General	28 (59.6)
	Vascular	13 (27.7)
	Missing	6 (12.8)
NHS trust	Trust A	25 (53.2)
	Trust B	9 (19.1)
	Trust C	11 (24.4)
	Missing	2 (4.3)
Academic Position	Yes	23 (48.9)
	No	19 (40.4)
	Missing	5 (10.6)

6.3.2 Complications' characteristics

The majority of the participants' most recent major surgical complications happened in the last 3 months (54%), and in most cases the patient developed morbidity but eventually recovered (41%). 19 participants (40.4%) rated the locus of the causes that led to the complications below the mid-point of the scale indicating that the causes had more to do with them while 19 participants rated the locus above the mid-point of the scale indicating that the causes had more to do with external factors. 18 participants (38.3%) rated the controllability of the causes below the mid-point of the scale indicating that the causes were perceived as controllable while 21 participants (44.7%) rated the controllability of the causes above the mid-point of the scale indicating that the causes were seen as uncontrollable. See Table 17 for an overview of the complications' characteristics.

Table 17: Complications' characteristics

	N (%)
Time-frame	
In the last month	13 (24%)
In the last 3 months	16 (30%)
In the last 6 months	9 (17%)
Over a year ago	9 (17%)
Impact on patient	
Patient died	10 (18.5%)

Morbidity with lasting disability	11 (28%)	
Morbidity with full recovery	22 (41%)	
Causal attributions	M (SD)	Range
Internality	3.90 (1.62)	1-6
Controllability	4.01 (1.80)	1-7

6.3.3 Descriptive statistics of surgeons' coping, support and institutions' response to adverse events

“Acceptance”, “planning”, “active coping”, “seeking instrumental support” and “self-blame” were the most frequently used coping strategies in the aftermath of the surgeons' reported complications (i.e. a mix of problem-focused and emotion-focused coping strategies). “Denial”, “substance use”, “humour”, “religion” and “self-distraction” were the least frequent (i.e. all of them are emotion-focused strategies) (see also Table 18).

Table 18: Descriptive statistics of coping strategies (B-COPE)

Coping strategies	Median (Range)	Mean (SD)
Self-distraction	3.00 (3.00-5.00)	2.93 (1.92)
Active coping	5.00 (2.00-8.00)	4.39 (1.75)
Denial	2.00 (2.00-6.00)	2.20 (0.67)
Substance use	2.00 (2.00-6.00)	2.36 (0.96)
Emotional support	3.00 (2.00-8.00)	3.29 (1.56)
Instrumental support	4.00 (2.00-8.00)	4.29 (1.98)
Behavioural disengagement	2.00 (2.00-5.00)	2.38 (0.61)
Venting	3.00 (2.00-8.00)	3.52 (1.56)
Positing reframing	3.00 (2.00-8.00)	3.53 (1.56)
Planning	5.00 (2.00-8.00)	4.93 (2.00)
Humour	2.00 (2.00-7.00)	2.59 (1.16)
Acceptance	5.50 (2.00-8.00)	5.45 (1.63)
Religion	2.00 (2.00-5.00)	2.30 (0.74)
Self-blame	4.00 (2.00-8.00)	4.56 (1.63)

The most highly appreciated sources of support were related to advice and guidance received from the participants' peers (i.e. discussing the complication with colleagues, guidance by senior clinicians, discussing the complication at a Morbidity & Mortality meeting, discussing the complication with clinical friends outside work). On the other hand the least positively appraised sources of support were pertinent to the human aspects of complications (i.e. chaplaincy support, psychological/counselling services, personal legal advice, and training on communication with patients about adverse events) (see

Table 19). Lastly, 64% of the surgeons highly agreed that the healthcare organisation where the complication occurred had a punitive approach to complications.

Table 19: Descriptive statistics of perceived usefulness of different sources of support

Support structures	Median (Range)	Mean (SD)
Break from clinical duties	2.00 (1.00-5.00)	2.30 (1.18)
Receiving information about the processes that are followed in the investigation of serious adverse events	3.00 (1.00-5.00)	2.86 (1.27)
Personal legal advice	2.00 (1.00-5.00)	2.00 (1.14)
Guidance by senior clinical people	4.00 (1.00-5.00)	3.71 (1.21)
Discussing the complication with non-clinical friends outside work	2.00 (1.00-4.00)	2.36 (1.17)
Discussing the complication with partner	4.00 (1.00-5.00)	3.13 (1.29)
Discussing the complication with colleagues	4.00 (1.00-5.00)	4.09 (.86)
Discussing the complication at a Morbidity & Mortality meeting	4.00 (1.00-5.00)	3.35 (1.11)
Discussing the complication with clinical friends outside work	4.00 (1.00-5.00)	3.25 (1.27)
Counselling, psychological or psychiatric services	1.50 (1.00-3.00)	1.64 (.73)
Chaplaincy support	1.00 (1.00-3.00)	1.48 (.65)
Training on communicating with patients & families after adverse events	2.00 (1.00-4.00)	2.03 (.93)
Debriefing	3.00 (1.00-5.00)	3.03 (1.38)

6.3.4 Descriptive statistics of wellbeing outcomes

A total of 17 respondents (36.2%) scored above the cut-off point of 19, which indicates traumatic stress of clinical concern (Horowitz et al. 1979). 11 respondents (23.4%) scored above the cut-off point for borderline anxiety and 4 participants (7.4%) scored above the cut-off point for depression (Bjelland et al. 2002). The mean score for burnout's personal accomplishment was 11.88, 5.02 for emotional exhaustion and 2.56 for depersonalisation. Although the mean scores indicate low burnout levels in the total sample, the ranges suggest that there were some individuals who scored quite high on the burnout dimensions (see Table 20). The mean score for satisfaction with surgery was 4.11, which indicates relatively high career satisfaction among the participants (patient satisfaction items were reverse scored).

Table 20: Descriptive statistics of surgeons' wellbeing outcomes

Psychological outcomes	Mean (<i>SD</i>)	Range	N (%)
IES			
Intrusion	7.75 (6.67)	0-28	
Avoidance	9.47 (7.74)	0-27	
Total score (traumatic stress)	17.44 (12.17)	0-55	
Above 19 ²⁰			17 (36.2)
Below 19			26 (55.3)
Missing			4 (8.5)
HADS			
Anxiety	4.98 (3.56)	0-14	
Above 8 ²¹			11 (23.4)
Below 8			32 (68.1)
Missing			4 (8.5)
Depression	3.25 (3.07)	0-13	
Above 8 ²²			4 (8.5)
Below 8			39 (83)
Missing			4 (8.5)
Burnout			
Emotional exhaustion	5.02 (3.18)	0-13	
Depersonalisation	2.56 (2.99)	0-14	
Personal accomplishment	11.88 (3.61)	5-18	
Satisfaction with surgery	4.11 (2.05)	0-11	

²⁰ Cut-off point for traumatic stress of clinical concern

²¹ Cut-off point for borderline anxiety

²² Cut-off point for borderline depression

6.3.5 Hypothesis I: Major complications affect surgeons' wellbeing negatively

One third of the participants scored above the cut-off point of 19 that is suggested to indicate traumatic stress of clinical concern (Horowitz et al. 1979). High levels of traumatic stress during the first month after the complication were also significantly associated with higher anxiety ($r_s=0.33$, $p<.05$) and higher (burnout's) emotional exhaustion ($r_s=0.40$, $p<.01$) at present. These data confirm that *surgeons' involvement in major surgical complications is negatively associated with surgeons' wellbeing.*

6.3.6 Hypothesis II: The ways in which surgeons cope with the stress of complications are associated with their post-incident wellbeing

Due to the large number of coping strategies that were correlated with each psychological outcome, only highly significant relationships (i.e. $p<.01$) were considered for the second hypothesis in order to control for family-wise error. Firstly, higher traumatic stress and higher anxiety were significantly correlated with more frequent use of self-distraction ($r_s=.481$, $p=.002$ and $r_s=.445$, $p<.001$). Higher anxiety was also significantly correlated with more frequent use of active coping ($r_s=.423$, $p=.007$), seeking instrumental support ($r_s=.449$, $p=.003$), planning ($r_s=.406$, $p=.008$) and self-blame ($r_s=.431$, $p=.004$). Depression was significantly correlated with more frequent use of humour ($r_s=.444$, $p=.003$). Finally, higher satisfaction with surgery was significantly correlated with less frequent use of instrumental support ($r_s=.398$, $p=.008$) (see Appendix 16). Highly significant relationships were not found between surgeons' coping strategies and any of the burnout dimensions.

More importantly, Mann-Whitney tests showed that respondents with traumatic stress of clinical concern reported significantly more frequent use of self-distraction ($U=278.5$, $p=.006$). Participants with borderline anxiety reported significantly more frequent use of venting ($U=241$, $p=.008$) and self-blame ($U=252$, $p=.005$) and participants with borderline depression reported significantly more frequent use of humour ($U=142.5$, $p<.001$) (see also Appendix 17 and Appendix 19). The above findings confirm that *surgeons' coping strategies in the aftermath of major complications are associated with their post-incident wellbeing*.

6.3.7 Hypothesis III: Surgeons' causal attributions of complications are associated with their wellbeing

A higher external locus of the causes that led to the complication was marginally correlated with higher (burnout's) personal accomplishment ($r_s=0.30$, $p=.05$). No other significant relationships were found between the perceived locus or the controllability of the causes that led to the complication and wellbeing outcomes. Therefore, the data partly support the hypothesis that *surgeons' causal attributions of major complications are associated with their wellbeing* (Appendix 20).

6.3.8 Hypothesis IV: Surgeons' perceived support in the aftermath of complications is associated with their wellbeing

Due to the large number of support sources that were correlated with each wellbeing outcome only highly significant relationships were considered for this hypothesis ($p<.01$). There was only one highly significant relationship between higher perceived usefulness of psychological support services

in the aftermath of the reported complication and higher anxiety at present (see Appendix 18). The data therefore only partly confirm that *surgeons' perceptions of support in the aftermath of their reported complications are associated with their wellbeing*.

6.3.9 Hypothesis V: Institutional approach to complications is associated with surgeons' wellbeing

Higher perceptions of a punitive institutional response to complications was significantly correlated with higher traumatic stress ($r_s=.309$, $p=.047$) (see Appendix 20). The data therefore partly support that *the institutions' approach to complications is associated with surgeons' wellbeing*.

6.3.10 Other significant correlations with wellbeing outcomes

Significant relationships were not found between surgeons' wellbeing and the complications' characteristics (i.e. severity and recency). Traumatic stress was also analysed against the participants' characteristics and the only significant finding was that there were more gastrointestinal surgeons with traumatic stress of clinical concern (52%) than vascular surgeons (8.3%) [$\chi^2(2, N=39)=6.57$, $p=.013$].

6.3.11 Predictors of traumatic stress of clinical concern

The factors that were significantly associated with traumatic stress of clinical concern in univariate analysis (i.e. surgical specialty, use of self-distraction and punitive institutional response to complications) were entered in a multiple logistic regression analysis in order to assess their independent contribution to the occurrence of traumatic stress of clinical concern. The model showed that being a gastro-intestinal surgeon ($b=3.10$, $SE=1.38$, $OR=22.3$, $CI=1.48-346.6$, $p=.025$) and using self-distraction in the aftermath of a major complication ($b=1.53$, $SE=0.65$, $OR=4.64$, $CI=1.3-16.58$, $p=.018$) were associated with higher odds of scoring above the cut-off point for traumatic stress of clinical concern. Institutions' punitive response to complications did not significantly predict traumatic stress of clinical concern in the multivariate analysis ($b=0.80$, $SE=0.5$, $OR=1.08$, $CI=0.40-2.87$, $p=.872$).

6.4 Discussion

This study investigated the extent to which surgeons' involvement in major surgical complications is negatively associated with their psychological and professional wellbeing and explored the psychosocial correlates of this association. The findings suggest that major surgical complications are often associated with clinical levels of traumatic stress one month after the incident, and traumatic stress is associated with current levels of anxiety and burnout. Moreover, surgeons' coping strategies, causal attributions and the institutions' response to surgical adverse events emerged as significant correlates of the distress that surgeons experience in the aftermath of major surgical complications.

One third of the participants reported traumatic stress of clinical concern one month after the incident. Even though the Impact of Events Scale was rated retrospectively and caution should be taken in the interpretation of this finding, this percentage is suggestive of the high emotional burden

that major complications cause on surgeons. More importantly, traumatic stress was significantly correlated with higher current levels of anxiety and burnout which implies that traumatic stress experienced in the aftermath of surgical complications may contribute to long-term psychological distress. The relationship between traumatic stress and burnout's emotional exhaustion in particular, seen through the lens of the *"Job Demand-Resources"* model (Demerouti et al. 2001), may mean that certain serious complications represent highly demanding work-related stressors that under certain conditions (e.g. lack of adequate support) contribute to emotional exhaustion.

This study also sought to explore how surgeons' coping with the stress of major complications is associated with their psychological and professional wellbeing. First, self-distraction was more frequently used by participants who experienced traumatic stress and anxiety of clinical concern and was an independent predictor of traumatic stress of clinical concern in multivariate analysis. This is not surprising, as suppression of thoughts related to a traumatic incident is known to be associated with higher PTSD symptoms or slower recovery from PTSD (Clohessy and Ehlers 1999; Ehlers and Clark 2000; Brewin 2003). Surgeons with borderline anxiety also blamed themselves more often for the occurrence of the complication than those with normal anxiety scores. This finding suggests that surgeons who are highly critical of themselves in the aftermath of serious complications may be at higher risk of psychological distress, in line with existing data on the association of attributing negative events to one's self and higher psychopathology (Joseph et al. 1991; Joseph et al. 1993; Brewin and Firth-Cozens 1997; Vaglum and Falkum 1999). Higher anxiety was also associated with more frequent use of active coping, planning and seeking instrumental support. Moderating variables such as the perceived controllability of complications may explain these relationships. For example, active coping with uncontrollable stressors is associated with higher distress (Forsythe and Compas 1987). Less intuitive was the significantly more frequent use of humour by surgeons with borderline depression. This could be partly explained by the idea that a coping strategy is adaptive or maladaptive depending on the context within which it is used (Lazarus and Folkman 1984; Lazarus and Folkman 1987). This is something that warrants further investigation.

A punitive response to complications was also significantly associated with the experience of traumatic stress in univariate analysis. More than two thirds of the participants of this study reported that their institutions adopt a punitive approach to complications. The existence of strong blame cultures and the lack of adequate institutional support for staff in the aftermath of adverse events is a common finding (Schwappach and Boluarte 2009; Sirriyeh et al. 2010). However, to my knowledge no study has tested the statistical relationship of institutional blame with healthcare professionals' distress in the aftermath of serious adverse events. This study provides some evidence on the existence of a negative relationship between existence of institutional blame and surgeons' wellbeing in the aftermath of serious complications. The lack of a significant contribution of this factor in multivariate analysis indicates that this relationship warrants further investigation. Lastly, perceptions of an external locus of causality were significantly associated with higher personal accomplishment suggesting that surgeons' attributions of complications to external factors may protect them from feelings of incompetence while attributions to internal factors may lead to feelings of failure and guilt (Weiner 1986).

A highly significant relationship was found between higher anxiety and higher perceived usefulness of psychological support services which possibly implies that those surgeons who struggle more in the aftermath of serious complications are more likely to see value in structures of psychological support. Lastly and very interestingly, being a gastro-intestinal surgeon was predictive of higher odds of experiencing traumatic stress of clinical concern both in univariate and in multivariate analysis. A possible explanation for this intriguing finding is that gastro-intestinal surgeons are less accustomed to the occurrence of serious complications due to the usually lower risks of serious complications in gastro-intestinal procedures compared to vascular ones. This finding highlights the importance of contextual variables such as surgeons' expectations of the surgical outcome in explaining their reactions to complications and raises questions on which surgical specialties are at higher risk for emotional distress after major complications.

6.4.1 Strengths of the study

Despite the fact that there is a significant amount of literature showing that healthcare professionals are emotionally affected in the aftermath of adverse events (Schwappach and Boluarte 2009; Sirriyeh et al. 2010), to my knowledge this is the first study that assessed the prevalence of traumatic stress in the aftermath of serious adverse events. Moreover, this is the first study that statistically tested the associations of evidence-based psychosocial factors of psychological reactions to stress with surgeons' wellbeing in the aftermath of major complications. Finally, an important strength of this study is the use of well validated and widely used scales for the assessment of the various independent and dependent variables.

6.4.2 Limitations

A few methodological limitations need to be taken into consideration. First, the study's design is cross-sectional which does not allow causal inferences about the observed relationships. Secondly, the small sample size reduced the statistical power of the multivariate regression analysis and did not allow a more comprehensive use of this type of statistical analysis that is more appropriate for the investigation of moderating and mediating variables. The small sample size may have also masked important significant relationships between variables of interest (e.g. causal attributions and wellbeing outcomes). Another limitation of the study was that an abbreviated version of MBI was used for the assessment of burnout, which has not been validated as extensively and caution should be taken when comparing the findings of this study with empirical data on the original MBI. Another limitation of the study is the use of a self-devised scale for the assessment of participants'

perceptions of the usefulness of various support structures. This scale has not been validated and caution should be taken when interpreting the relevant findings.

6.5 Conclusions

This study suggests that a significant proportion of surgeons experience traumatic stress in the immediate aftermath of major complications and that acute traumatic stress is associated with surgeons' long-term anxiety and burnout. Surgeons' coping strategies, appraisals of the locus of causality and perceptions of the institutions' response to complications were significant correlates of their wellbeing. The above findings demonstrate that surgeons may experience severe psychological distress in the aftermath of serious complications and imply that the extent to which their wellbeing will be affected is dependent on their own appraisals of the complications, their ways of coping with stress but also to the wider organisational culture. As previously argued, institutions need to start thinking how best to support their staff when serious patient safety incidents occur and how to eliminate cultures dominated by blame and non-constructive criticism. Future studies with bigger samples, longitudinal designs and use of multivariate techniques are needed in order to better understand the prevalence of psychopathology in the aftermath of serious patient safety incidents and the role of psychosocial variables in predicting healthcare professionals' emotional reactions to adverse events.

Chapter 7: An interview study on patients' experiences of postoperative complications after major surgery

This chapter returns to investigate the implications of surgical complications for patients' wellbeing. It presents an exploration of the experiences of patients who suffered complications after major gastro-intestinal or vascular surgery using in-depth semi-structured interviews at two time-points (i.e. before discharge and two months post-discharge). The overarching themes that emerged from the analysis were pertinent to patients' pre-operative expectations of their surgery, their physical and emotional recovery from their complicated surgery and the different factors that determined the psychological impact of complications on them. The findings are discussed in relation to relevant existing literature and the limitations and strengths of the study.

7.1 Introduction

The systematic review in Chapter 4 found that patients who suffer complications after major surgery report lower physical and mental quality of life and higher levels of depression and anxiety than patients who do not experience complications, often for a significant amount of time post-surgery. It also suggested that it is not only serious life-threatening or disabling complications that are associated with worse patient wellbeing but also minor events such as wound infections and atrial fibrillation. It concluded that an understanding of patients' experiences of surgical complications and the factors that affect patients' psychological reactions to a complicated surgical recovery is required in order to identify how best to support patients in the aftermath of surgical complications.

The following two chapters therefore build on the systematic review findings and existing literature on the aftermath of adverse events and patients' wellbeing in the context of ill health and medical treatment in order to shed light on how surgical complications affect patient's psychological wellbeing. Given the lack of psychological literature on the challenges that patients who suffer surgical adverse events face, an in-depth investigation of surgical patients' experiences after complicated surgery is the first step that is required. The study presented in this chapter aims to explore the experiences of patients who suffer surgical complications by adopting an in-depth qualitative design methodology and comparing patients with a range of recovery trajectories. The aims of this study are two-fold:

- To explore how surgical patients are affected by surgical complications over time and
- To explore the factors that affect patients' reactions to surgical complications and their post-operative wellbeing in the aftermath of complicated surgery.

7.2 Methods

7.2.1 Design

A longitudinal design, using in-depth, semi-structured, individual interviews, was selected. Patients were interviewed at two time-points: before discharge and two months after discharge. A two time-points design was selected in order to investigate how patients' experiences of surgical complications change over time.

7.2.2 Setting and participants

A purposive sampling technique was used in accordance with guidelines on qualitative research methodology which suggest that the researcher should select the most productive sample to answer the research question (Marshall 1996; Coyne 1997). Patients were therefore eligible to participate if:

- (a) they had major gastro-intestinal or vascular surgery. These two specialties were selected due to their high association with surgical complications (in accordance with the previous chapters on surgeons' experiences of complications).
- (b) they experienced complications after their surgery. A balanced design was chosen so that patients who suffered a range of complications ranging from minor to more serious were represented. Also, a small number of patients with an uncomplicated recovery were interviewed in order to investigate whether the experiences of patients who suffered complications were different from the experiences of patients who did not suffer complications.

Participants were recruited from one acute teaching hospital in London, UK, which provides for a large number of patients undergoing general or vascular surgery.

7.2.3 Procedure and materials

7.2.3.1 Participant recruitment

The participants were identified through two consultant surgeons who practised in the hospital that patients were recruited from, one in vascular surgery and one in gastro-intestinal surgery. Patients with various postoperative trajectories in terms of their experience of surgical complications were invited to take part in the study. All patients who were invited agreed to participate. Patients were given an information sheet by the researcher (AP), who was also available to answer any questions that the participants had. The participants' consent to the study was confirmed in writing. Participants were reassured that any data would be reported anonymously and confidentially.

Ethical approval for the study was given by the London REC Committee 1/Dulwich.

7.2.3.2 Interviews

The interviews were semi-structured. A standard topic guide was used which was developed based on literature that was summarised in Chapters 1-3 and through consultation with surgeons, psychologists and academics in patient safety. The guide was piloted with one patient representative and one nurse for comprehensibility and relevance of the questions and included general topics of investigation and relevant prompts. The general topics were:

- Life before surgery
- Recovery during hospital stay
- Life after surgery (2 month follow-up interviews)

A detailed overview of the interview questions and prompts under each general thematic area is presented in Appendix 21.

The first time-point interviews were conducted on the wards, face to face, before patients were discharged from the hospital. If the participants were mobile, the interviews were conducted in the family room, provided it was available. However, in most cases the interviews took place at the patients' bedside with closed curtains to allow for more privacy. The follow-up interviews took place two months after the patients' discharge and were conducted on the phone. The interviews were conducted by a researcher with a background in psychology and patient safety research (AP), lasted 30-75mins (both time-points combined), were audio-recorded and professionally transcribed verbatim for analysis. The interviews took place between February 2012 and July 2012.

7.2.3.2.1 Analysis

The interview transcripts were analysed in QSR NVIVO qualitative analysis software (version 8) using Interpretative Phenomenological Analysis (IPA). IPA is a model of qualitative analysis where the aim is to explore in detail how participants are making sense of their personal and social world with a strong emphasis on the meanings particular experiences, events or states hold for participants (Smith and Osborn 2003). This paradigm of qualitative analysis was chosen due to its phenomenological approach (i.e. detailed exploration of personal perceptions and meanings), which is the most appropriate for the aims of this study, which are pertinent to understanding the meanings of surgical complications for patients' lives.

An idiographic iterative approach was followed starting from coding the detail of each transcript and slowly working up to more general categorisations and statements (Smith and Osborn 2003). The text was initially divided into small units of meaning, which were assigned a code describing the particular excerpt. As the analysis of the various transcripts progressed, emerging higher-level themes were noted reflecting more general psychological entities (e.g. coping,

emotional reactions). The emergent themes were assessed for connections, which led to organising emerging themes in a hierarchical tree of super-ordinate and sub-ordinate themes. The emerging tree was used as a guide in the analysis of the remaining transcripts with a continuous assessment and incorporation of convergent and divergent data. A final list of super-ordinate themes was produced where themes were reduced to key overarching thematic areas based on the prevalence of the themes but also the richness of the included passages in terms of highlighting aspects of the research questions. Transcripts were first coded by the researcher who conducted the interviews (AP) who subsequently received input from one other researcher with a nursing background who was not involved in the interviews (MB), to ensure multiple perspectives and consistency in coding as recommended by qualitative research experts (Glaser and Strauss 1967; Strauss and Corbin 2007; Yardley 2013).

The participants' personal data were de-identified to ensure anonymity and confidentiality.

7.3 Results

7.3.1 Participants

A total of 17 surgical patients were interviewed at discharge and 12 of these patients were also available for a follow-up telephone interview two months later. One patient was represented in the interviews by his family, as he felt too weak to participate himself. Participant recruitment stopped when it was felt that new themes were not emerging, therefore saturation had been achieved.

The majority of the participants were male (59%), white-British (76.5%), retired (53%) and married (47%). Their age ranged from 26 to 91 years. 10 (59%) patients had major gastro-intestinal

surgery (e.g. bowel resections) and 7 (41%) had major vascular surgery (e.g. aneurysm repairs). 5 patients did not experience any complications, 5 patients suffered minor complications (e.g. infections, diarrhoea, nausea) while 7 patients suffered major postoperative events (e.g. anastomotic leaks, incisional hernias, respiratory distress, ischaemia) during their hospital stay. Five out of the seven patients who suffered major complications had a reoperation aimed at fixing the complications. All of the patients who were available to follow-up (except one) had experienced surgical complications during their hospital stay. An overview of the participants' characteristics is presented in Table 21. The exact operation and the complications that each participant suffered are not presented in order to protect patients' anonymity.

Table 21: Participants' characteristics

Patient ID	Age	Employment status	Ethnicity	Relationship status	Gender	Children	Surgery	Complications	Minor vs. Major complications
01	91	Retired	White-British	Married	Male	Yes	Vascular	No	Not Applicable
02	37	Missing	White-British	Missing	Male	No	GI	No	Not Applicable
03	70	Retired	White-British	Divorced	Male	Yes	Vascular	Yes	Major
04	26	Missing	White-British	In a relationship	Female	No	GI	No	Minor
05	61	Retired	White-British	Single	Female	Yes	Vascular	Yes	Minor
06	31	Unemployed	Non white-British	Single	Male	Yes	GI	Yes	Minor
07	Missing	Employed	Non white-British	Married	Female	Yes	GI	Yes	Minor
08	29	Missing	White-British	Missing	Male	No	GI	Yes	Minor
09	Missing	Employed	White-British	Married	Male	Missing	Vascular	No	Not Applicable
10	79	Retired	White-British	Married	Female	Yes	GI	Yes	Major
11	72	Retired	White-British	Married	Male	Yes	Vascular	No	Not Applicable
12	46	Employed	Non white-British	Married	Female	Yes	GI	Yes	Major
13	62	Employed	Other	Married	Male	Yes	GI	Yes	Major
14	64	Retired	White-British	Divorced	Female	Yes	Vascular	Yes	Major

15	73	Retired	White-British	Divorced	Male	Yes	Vascular	Yes	Major
16	66	Retired	White-British	Divorced	Female	Yes	GI	Yes	Major
17	79	Retired	White-British	Married	Male	Yes	GI	Yes	Major

7.3.2 Themes

The emerging themes were organised in three key thematic areas that reflect patients' pre-operative and postoperative course. These are: (a) patients' preoperative expectations of surgery, (b) patients' recovery from surgery and the associated complications and (c) factors affecting the psychological impact of complications on patients. Each of the overarching themes is described below with illustrative quotes. Emphasis is given to the experiences of the patients who suffered complications.

7.3.2.1 Pre-operative expectations of surgery

Four patients described surgery as the only solution to a "life or death" situation (e.g. aneurysms). Six patients proceeded to surgery after considering the risks and benefits and with the hope that surgery would improve their quality of life (e.g. eradicate cancer, control pain etc.). Five patients had a detailed pre-operative consultation with their surgeon about the associated risks whereas many patients (n=7) reported that the risks were not emphasised in their consultation because serious complications were not expected. A patient who later suffered a major complication reports: *"Well to be honest they didn't talk me through everything because when they went in to do the operation I think the expectation was that it was going to be a couple of hours until it got complicated..."* (Patient 15). Most of the patients had positive expectations for their surgery. Six patients felt excitement about their operation as they were looking forward to

returning to a better quality of life. Half of the patients felt relaxed about the operation while the other half felt apprehensive and worried. For instance: *"I had my doubts 'cause my surgery wasn't supposed to be booked till 8th of 11th on Friday...he [the surgeon] said how about we do it on Monday, I thought this Monday? I've got children, you know, I was all over the place. And I thought to myself you know what, you're never going to be mentally ready...having children you're never mentally ready. So I said if you think I'm physically ready then let's go with it."* (Patient 07)

7.3.2.2 Recovery from surgery and the complications

Patients' experiences of the postoperative period varied. A total of 12 patients experienced surgical complications, which ranged from relatively minor morbidity such as infections or nausea to quite major events such as anastomotic leaks, severe breathlessness or limb ischaemia. Five patients who did not experience any complications were not concerned about their recovery and maintained a positive attitude throughout their post-operative experience. One patient who did not experience complications during his hospital stay and was available to follow-up also reported a very positive mood and very high satisfaction with his surgical outcome two months after his discharge. This patient described: *"...they've done a marvellous job on my gut. I won't ever forget them for giving me back my life...My friends have awaited for me, like everyone's been saying, "Get well soon." I feel like crying 'cause I've got my life back. So I'm just happy..."* (Patient 06). Patients who suffered complications on the other hand described a range of physical and emotional effects of these events on their wellbeing both during their hospital stay and two months after their discharge. These are described below.

7.3.2.2.1 Physical impact of complications

Patients who suffered complications after their operation reported various levels of discomfort and disability ranging from minor to severe during their hospital stay. Six patients had a reoperation

aimed at treating the complications. Four patients who suffered major complications recollected feeling very ill after their surgery, sometimes to the extent of worrying that they might die, as per the patient below: *"In the meantime my body was all out of balance and bloated and I felt very, very stressed, physically. Heart rate really fast, atrial fibrillation...They needed to give me the operation. The second one I thought, God, I think I'm going to die."* (Patient 16). The family of a patient who suffered a very serious complication, which led to a second big operation described how unwell their relative looked after the operation. *"...He was uncomfortable. My mum was telling them, "His hands are blue, his lips are blue, his eyes are rolling"."* (Patient 13). Two patients who ended up with a temporary stoma after major complications reported long-lasting discomfort or disability. Most patients with complications stayed in the hospital longer than they had originally expected.

Two months after the patients' discharge the physical effects of complications were still present in the majority of the participants. Most of the interviewees reported that they were still concerned about their recovery. Six of them reported that even though their symptoms had improved there were still certain symptoms such as pain that continued to affect their quality of life. Four patients who suffered serious complications explained that these were still affecting their quality of life significantly. A patient commented about the impact of a serious leg-related complication that he suffered after his operation: *"...my leg, is still not right and, I mean, so much so that it's very difficult for me to walk any distance. And, in fact, I now, any distance at all I now have a wheelchair..."* (Patient 15). The family of a patient who suffered a life-threatening adverse event described how debilitating the complication had been for their relative since he returned home: *"...Obviously day-to-day life, everything has been turned upside down. Before he was going to work, did everything himself, and now his family does everything for him. He needs help completely and has a carer come in to give him a wash in the morning. He can't bend down, he can't do anything like that himself, can't walk for too long because he gets dizzy, he has always got low blood pressure now after his surgery..."* (Family of patient 13). A smaller proportion of the followed-up patients (n=4) were happy with the progress of their recovery despite their experience of in-hospital complications due to the fact that they had started resuming their usual activities and feeling normal, as per below: *"...Well, I'm not passing blood, because that was my main thing that I went to the doctor's about. And I have my temporary stoma and that's working very well, and no trouble at all. I've got to grips with that and I had*

a stoma nurse visit twice, and that's fine. And eating well now;- and I'm beginning to sleep better. And altogether I'm beginning to feel more my old self, which is marvellous..." (Patient 10)

7.3.2.2 Emotional impact of complications

Most of the patients who suffered minor or major complications reported some degree of emotional distress during their hospital stay. Patients commonly expressed feeling anxious about when the complications would be resolved. A patient who suffered severe nausea after her operation reported: *"It's nausea, that's been bothering me. I'm thinking how long is it going to take...When you feel sick you don't realise until you have vomited how much you use those muscles. I think that's what's bothering me. I don't like feeling nauseous."* (Patient 07). Another patient described that he felt very depressed at one point due to a series of adverse events that prolonged his hospitalisation for a very long time: *"When I kept having these knock backs I felt like I was taking one step forward and two back....in one period I was very depressed...there were a couple of times when I was I was really down, that really hit me though. That was the lowest ever I was. Because nothing was going right, you see?"* (Patient 17). A few patients who suffered very serious complications also reported fear for their life and despair.

The family of one of the patients was feeling angry with the clinical team whom they held responsible for the adverse event that their relative suffered. Their anger was aggravated by the clinical team's insensitive behaviour: *"Angry. The nurse was ringing the doctor saying, "You need to come up, there's something seriously wrong with this man." He was, "No, no, he's fine, he's fine." But then my sister got on the phone and she said, "I will scream down the ward if you don't come up". So they came up and realised obviously something is going wrong and then they called up the specialists..."* (Family of patient 13). This patient and his family, as well as a second patient who suffered a life-threatening complication that she attributed to negligence, lost their trust in the healthcare professionals that were responsible for their care. Both patients regretted having the operation: *"I don't know how I feel. Because at the moment now I'm in pain and I feel a bit*

disappointed. I feel as if... umm... I just regret the operation, doing it. But what else could I have done? Because I wasn't expecting this." (Patient 12)

Two months after their discharge some interviewees reported that the complications were still affecting them emotionally by making them anxious, depressed and frustrated that certain physical effects had not disappeared. One patient who suffered a series of minor complications after he returned home explained how the combination of a difficult recovery with wider social and financial difficulties made him feel severely depressed: *"...I haven't got the energy I'm just feeling very depressed, suicidal you might even say ...I haven't got the energy to even go to the shop...So yeah I've had a lot of headaches, so I've just been taking painkillers, painkillers but how many of these painkillers can you take and take and take before they don't do anything for you..."* (Patient 06). The family of the patient who suffered a serious preventable complication was still angry and was considering pursuing legal action: *"...they were all terrible...I don't want to speak to anyone because I'd rather take it the legal way. 'm just waiting for my dad to get better and I'm going to take legal action. At the end of the day, it's nothing to do with just making a complaint. It's what has happened to him they are probably doing it to other people there all the time"* (Family of patient 13). Five patients still recollected vividly how poorly and out of control they felt in the early stages of their recovery. These were patients who suffered complications of various levels of severity. A patient who had suffered a serious post-operative chest infection recollects: *"I don't know what kind of infection I had but that's the week I was very poorly...I was quite bothered, but I wasn't really with it, in a way – I just let things happen to me. I went into a slump. I kind of gave up..."* (Patient 05)

A minority of patients reported that they were not affected by their complications emotionally (n=4). These were either patients who suffered minor complications (n=2) or patients whose complications, despite being quite serious, were managed in time and did not affect their physical wellbeing significantly (n=2): *"They've done their very best in the circumstances. I feel I have been looked after well in spite of difficulties, the hurdles we've had to go over and the little unexpected setbacks"* (Patient 10).

7.3.2.3 Factors of emotional impact of complications

This theme consists of four groups of factors that emerged as determinants of the impact of complications on patients' emotional wellbeing: (a) causal attributions of complications, (b) pre-operative expectations of surgical experience, (c) coping with stress of recovery and (d) perceptions of support.

7.3.2.3.1 Causal attributions

Some patients tried to explain why the complications occurred. One patient blamed himself for being a chronic smoker: *"...I'm not sure whether it was an oversight or what, there's no way in which I'm blaming anybody for the condition I'm in. The only person I blame for the condition I'm in is me because I'd been a chain smoker all those years ago, that's what started it all. And everybody else since then in the National Health has tried their best to alleviate the fact that I was giving myself a slow death...there's no one to blame on this but myself..."* (Patient 15). Two patients attributed their complications to unfortunate circumstances, while three patients suspected that their complications resulted from a medical oversight. The latter three suffered major postoperative events that required reoperation. One patient who believed that her complication resulted from a mistake by the junior surgeon who was involved in her operation was very understanding because her complication was managed promptly. The second patient who had indications from other clinicians that her complication occurred due to a medical mistake reported feeling very drained and disappointed by her surgical experience. The third patient and his family held the aftercare team responsible for not identifying the complication in time and for dismissing their concerns that there was something wrong with their relative. This reinforced their belief that the complications resulted from negligence and aggravated their fury: *"Wife: Not the surgeon's fault. Daughter:- it's an aftercare thing. Wife: The doctor who looked after him. Even the nurses...She never look at him for two*

days, she never look to see what's wrong with him. And I came to the hospital, I called the doctor. He came, he said, "He's fine, he's fine". I said, "No, he's not fine. Look, his colour's not right, his eyes are black and he doesn't look... his fingers are blue" (Family of patient 13).

7.3.2.2.2 Preoperative expectations of surgical experience

Patients' pre-operative expectations of the surgical outcome featured as a factor of how patients felt about their complications. Five patients expected a quicker and smoother recovery. The occurrence of complications that they had not prepared themselves for made them upset and anxious. The family of one patient emphasised that the risks were downplayed in their preoperative consultation with the surgeon: *"...if he was ever to go to surgery again, we wouldn't just go ahead and do it. Before the first surgery, on the day that he went in it was, like, 'Oh, it's so easy. You'll be in and out... Yes, there is a risk of leakage, that's one of the main risks, but let's not talk about that'. So if you knew that's one of the big main risks, why was that not spotted when the tell tale signs were there?" (Family of patient 13).* However, when complications were managed promptly unexpected complications were less of an issue: *"...I think they did a grand job; it was just unfortunate that there was a little hernia in the small bowel and I had to go back. I hadn't realised it was going to be quite as major, because I've already had an ovarian cyst removed and a hysterectomy and I was quite chirpy after five days of that and recovered very quickly from it..." (Patient 10)*

7.3.2.2.3 Coping with stress

The participants described how their ways of dealing with stress helped them overcome the challenges of their complications. The most commonly quoted coping strategy both during the participants' hospital stay and two months later was actively managing their recovery by gradually resuming activities such as walking, getting on with their life by caring for their dependents or by

going back to college, and generally doing anything that was required in order to speed up their recovery: *"...just try and keep moving. And when I'm resting, keep my feet up to help with the swelling, which has gone down considerably...So I might have a little walk out beside the canal. If it's not raining. Take my rubbish out..."* (Patient 05). Seeking support from family and friends was also a very common approach to dealing with the overwhelming stress of their complicated recovery: *"...one of the things that keeps you going is your family support...My children, my husband, my mum and my cousins...and their presence makes a big difference – the one time it doesn't make you think about your condition too much when you're going through that process. Especially in hospital – because if you can imagine if you've gone through a major surgery and you don't have anyone visiting, that's the most depressing thing ever..."* (Patient 07) Patients who suffered major complications also tended to rationalise and accept the difficulties that they were encountering during their recovery: *"... I'm a fairly philosophical person with regard to such things. I would rather feel better than I do, I mean, at the moment especially since I've got this heavy cough, but as there's no one to blame, as it were, everybody has done the best they can..."* (Patient 15).

Other ways of dealing with stress included believing in one's ability to recover, faith in God, faith in surgeons' expertise, seeking health-related information and maintaining a generally positive attitude to life, as per below: *"...I've decided the positive approach to life, which is what I've always had, and you come through difficult times but you survive better than if you are very negative about everything and the sort that is always full of moans and groans..."* (Patient 10).

7.3.2.2.4 Perceptions of support

The discussions of support were extensive and related to three different aspects: importance of support received from loved ones, importance of support received from healthcare professionals and suggestions for improving patient support after complicated surgery.

7.3.2.2.4.1 Support from loved ones

Family and friends were the most important source of emotional and practical support for patients. In the case of one patient who suffered a major complication, family also played a key role in identifying problems with the patient's recovery: *"I feel sorry for anyone that has to go in that has no family and my dad's lucky he's got family looking after him. If he didn't have anyone that day he would've gone and we would have got a phone call going, "Oh sorry, he passed away. We don't know why"...He was lucky we were here" (Family of Patient 13).* Only one patient who was seriously depressed at the follow-up interview was negative about the support that he received from his personal networks: *"..certain friends I've pushed them out and it's because I just can't take no one on. Like people will come to you and say, "Oh why don't you do this, why don't you not ..." I know everything I have to do by now and everything is the tap of a button in the Internet you know. This is common sense but I hate that anyone I see or even a stranger or these organisations, "Why don't you do this, why don't you do that?"..." (Patient 06)*

7.3.2.2.4.2 Support from healthcare professionals

Patients emphasised the importance of feeling supported by the healthcare professionals who looked after them. A few patients highlighted how the emotional support that they received from their surgeons and the nurses during their hospital stay helped them deal with the challenges of their complicated recovery. One patient who suffered a series of complications described how vital the support that he had from his surgeon and the nursing staff was when he was feeling helpless: *"...I did reach this low point, and the two nurses who were on duty at the time, they were trying their very best to comfort me as much as possible. So in that respect I was getting a lot of support, because they knew how down I was. I was basically in tears, I was just fed up to the teeth. But they came along and tried to placate me, then eventually the consultant came..." (Patient 17)*

On the other hand, patients who were not treated with empathy by the clinical staff during their hospital stay were evidently distraught. Two patients who suffered serious preventable

complications described a lack of compassion and infrequent visits on the part of the nursing staff which aggravated their frustration and anger: *"...some of the nurses are quite competent, they're quite good, but then some of them are absolutely not...because I work with young people, and pregnant women and the homeless, I'm used to giving support so I can see the lack of support that I am getting, things that they should be doing which they're not. And they don't see the urgency of it because it's not the ones who are feeling the pain. So there's a lack of empathy..."* (Patient 12) These patients were also disappointed with the lack of clear and honest communication regarding their complications as well as with the staff's reluctance to take responsibility and apologise: *"...the more senior doctors, they wouldn't dare say; they're very careful, you know, they use a choice of words. But you can tell underneath that's what they done, that is their fault why this has happened...but none of them is actually giving me the full explanation...."* (Patient 12)

The support provided by healthcare professionals was also important after patients' discharge from the hospital. The help that patients received at home from district nurses, physiotherapists or dieticians was often highly appreciated. One third of the followed-up patients pointed out that the existing arrangements for the long-term support of patients who undergo major complicated surgery are insufficient. For example, one patient commented on the limited range of help that carers offer in the postoperative period: *"...these days you have surgery and you're out as soon as they can get you out...And I know from experience of friends who have had care in the community it's a very limited care: someone may come in and help you with a wash and a dress but that's about it, there's no like the old home-help service, which was available when I was nursing, you had someone who actually did a few domestic duties for you like shopping and cleaning. They don't do that anymore...it's all so rigid...you just have to do it yourself really..."* (Patient 10)

7.3.2.2.4.3 Ideas for improving support for patients after complicated surgery

A few patients made suggestions on how to improve support for patients who have complicated surgery. Two patients suggested that a visit by a mental health specialist during their hospital stay would have helped them deal with their severe anxiety which resulted from their serious post-operative complications: *"...I know that the services are limited, but I think when I have this real anxiety and panic, I*

need not a pill or a tablet but someone who can allow me to think it through...techniques of coping with panic....I think the sort of counselling thing, a lot of people might say, "God, you think I'm mad, go away." A lot of people are very wary of it. But you know, personally I think it's a wonderful thing..." (Patient 16) One patient suggested that convalescence arrangements should be available on the NHS as she had a very positive experience with a private convalescence scheme, which helped her overcome the physical and emotional hurdles of her complicated surgery. A patient struggling with various aspects of his life talked about the importance of state support with housing and financial difficulties, as social stability is a prerequisite for recovery from ill health. The majority of the patients made the point that better support services are mostly needed for patients who suffer surgical complications and do not have family or friends to stand by them, as per below: *"...there was one lady they asked if she wanted to go home and she said no. I spoke to her afterwards and she said to me as I was leaving, "Good luck to you. But the reason why I don't want to go home is..." Because she's going to stay with some friends afterwards. She just had this fear that she may become a burden on her friends...I think most people who don't have the family network or family support – that's the ones, in particular, that may need it [more support]..." (Patient 07)*

7.4 Discussion

This study investigated the experiences of patients who suffer surgical complications after major high-risk surgery, using in-depth semi-structured interviews, a two time-points design and a phenomenological approach for the analysis of the interviews. The findings support that surgical adverse events affect patients' psychosocial wellbeing above and beyond the effects of surgery alone and highlight a range of factors that may moderate the impact of complications on patients.

Patients who had an uncomplicated surgical experience or patients who suffered complications that were managed in time and did not have a lasting impact on their physical recovery were not emotionally distressed. They had a positive attitude to their recovery and, even if

they experienced disability or discomfort during their hospital stay, they did not describe any serious concerns. Patients on the other hand who suffered surgical complications (minor or major) that were not managed promptly or took some time to be resolved reported a range of effects on their physical and emotional wellbeing.

Some patients vividly recollected feeling scared for their lives during their in-hospital recovery. Whether the existence of long-term memories indicates the presence of post-traumatic stress is not clear from this study as the interviews did not investigate the experience of PTSD symptoms. However, intrusive memories of extreme stressors are one of the diagnostic criteria for PTSD (Yehuda 2002; Brewin et al. 2009) and the finding that a few patients had strong recollections of how terrified they were during their hospital stay may indicate a traumatic impact of complications on patients. Other emotional effects of complications that were often still present at the follow-up interviews included feelings of anxiety, frustration and depressed mood, in agreement with the results of the systematic review which found that patients who suffer surgical complications report significantly higher anxiety and depression levels often for a long time after their surgery.

Patients' feelings in the aftermath of their complications were very much dependent on psychological factors such as their preoperative perceptions of their surgery and their attributions of the complications. Two patients who attributed their complications to negligence were angry and disappointed. On the other hand patients who did not attribute their complications to preventable factors or who perceived their consequences as controllable did not experience severe distress, in line with the causal attribution theory which proposes that individuals' perceptions of the locus of causality and controllability of stressors predict their wellbeing (Weiner 1986). Moreover, patients who expected that their operation would be quick and straightforward were more upset by the occurrence of complications. Patients' pre-operative expectations are an important determinant of their post-operative wellbeing (Wheelock et al. 1998; McCarthy et al. 2003) and therefore patients

who are not mentally prepared for a complicated surgical recovery are likely to be at higher risk of psychological distress.

Patients' ways of dealing with the stress of their surgery were also an important factor of how effectively they dealt with the challenges imposed by their complications. Actively managing one's recovery, seeking support from family and friends and accepting the limitations of one's health protected patients from overwhelming stress. Helping patients adopt constructive ways of dealing with their stress may be an effective way of supporting patients in the aftermath of complicated surgery, especially since coping is a key predictor of postoperative wellbeing (Ai et al. 2006; Walker et al. 2006; Boehmer et al. 2007).

Lastly, the support that was available to patients from their family, friends and healthcare professionals was crucial for allowing them to maintain their optimism and overcome the challenges of their recovery, in agreement with the stress-buffering effect of social support (Kulik and Mahler 1989; Schröder et al. 1998; Schwarzer et al. 2004; Boehmer et al. 2007). Patients who experienced major complications that were not dealt with in an honest and compassionate way by the clinical staff experienced severe distress, lost their trust in their healthcare professionals and in one case were considering legal action in agreement with early findings (Vincent et al. 1993; Vincent and Coulter 2002). Considering that patients expect transparency and compassion when things go wrong in their care (Hobgood et al. 2002; Gallagher et al. 2003), failure to communicate in an honest and compassionate way with patients and their families regarding surgical complications may seriously compromise patients' post-operative wellbeing and patients' relationship with healthcare professionals.

7.4.1 Strengths of the study

This study contributes to the existing literature on surgical complications, which is restricted to clinical studies on the medical aspects of complications and lacks evidence on their psychological consequences. By using an in-depth qualitative design this study allowed the emergence of important psychological factors that help us understand the psychological effects of surgical complications on patients such as patients' coping mechanisms, their causal attributions, their pre-operative expectations and their perceptions of support. Finally, this study contributes to the mostly non-theoretical and non-empirical literature on the psychological impact of adverse events on patients by providing evidence on the psychological implications of surgical complications for patients' wellbeing

7.4.2 Limitations

Certain methodological limitations should be considered in the interpretation of the study findings. First, this is a one-site study which limits the generalisability of the findings as organisational factors that are specific to this site may have affected patients' experiences of complications (i.e. especially in relation to the availability of support and the open communication of adverse events). Another limitation is pertinent to the fact that patients were recruited from only two high-risk surgical specialties, which does not allow us to be confident that the same experiences would be reported by patients undergoing surgery in other specialties. However, most studies with surgical patients are limited to one type of surgery and the fact that the participants of this study underwent a range of different procedures from two different high-risk specialties makes the findings relevant beyond these two specialties.

7.5 Conclusions

This study investigated the experiences of patients who suffered surgical complications of various severity levels after major surgery in two high-risk specialties. In summary, the data showed that patients who experience complications after major surgery are indeed affected not only physically but also emotionally. This is the case both after minor and major complications that have a long-lasting impact on patients' recovery. Patients' pre-operative expectations of their recovery, their causal attributions of the complications, the duration of the complications' effects on their lives, their coping strategies and their perceptions of support from family, friends and healthcare professionals featured as important determinants of patients' emotional wellbeing in the aftermath of their surgery. These findings confirm the importance of a holistic approach to the aftercare of patients who suffer complications by attending both to their physical and their psychological needs. Moreover, they highlight the importance of compassionate, clear and honest communication about complications and prove that when patients feel that there is deliberate concealment of information and lack of empathy in their interactions with the clinical staff they experience significant distress, anger and loss of trust in their healthcare professionals. Finally, the findings emphasise the importance of psychosocial factors for understanding patients' reactions to surgical complications (and potentially other types of medical harm). The contribution of the emerging factors to patients' psychological wellbeing after complicated surgery will be further explored in a longitudinal cohort study that is presented in the following chapter.

Chapter 8: A prospective cohort study on the association of surgical complications with patients' psychological wellbeing and the contribution of psychosocial factors.

This chapter presents a prospective cohort study on the association of surgical complications after major gastro-intestinal, vascular or cardio-thoracic surgery with patients' psychological wellbeing. Patients who experienced complications secondary to their surgery are compared against patients who had uncomplicated recovery on various indices of psychological wellbeing (i.e. anxiety, depression and QoL). This study also explores the independent contribution of psychosocial factors that emerged in the previously reported interview study as important determinants of patients' emotional reactions to surgical complications (i.e. pre-operative expectations of surgery, social support and ways of coping with the stress of surgery). The findings are discussed in relation to existing literature on the aftermath of healthcare-related adverse events and in relation to psychological literature on coping with stress. The chapter concludes with a summary of the limitations and strengths of the study.

8.1 Introduction

Both the systematic review and the patient interviews suggested that surgical complications are a significant source of stress for patients above and beyond the stress of surgery alone and compromise their psychosocial wellbeing for a long time after surgery. The interviews also suggested that the severity of patients' emotional reactions is dependent on factors such as patients' pre-operative expectations, their perceptions of what caused the complications, how successfully they

were controlled, their coping strategies and their perceptions of support from their loved ones and their healthcare professionals, all of which are well-known predictors of psychological wellbeing after health threats (Lazarus and Folkman 1984; Leventhal et al. 1984; Weiner 1986; Schwarzer and Leppin 1991; Orbell et al. 1998; McNally and Newman 1999; Penley 2002).

To my knowledge no study to date has attempted to apply these psychological factors in the investigation of the association of surgical complications (or other adverse events) with patients' wellbeing. This study therefore builds on findings from the systematic review, the patient interviews and psychological literature on psychological reactions to stress and aims:

- To explore the contribution of surgical complications to patients' psychological wellbeing after major high-risk surgery.
- To explore the contribution of psychosocial factors in the association between surgical complications and patients' wellbeing after major high-risk surgery.

The following research hypotheses were developed based on the systematic review and the interview findings:

H1: Patients who experience surgical complications will report worse post-operative psychological wellbeing than patients with uncomplicated recovery after controlling for their baseline wellbeing.

H2: The ways in which patients cope with the stress of their surgery will significantly moderate the association of surgical complications with patients' wellbeing over time.

H3: Patients' perceptions of support from their loved ones and healthcare professionals will significantly moderate the association of surgical complications with patients' wellbeing over time.

H4: Patients' pre-operative expectations of their surgery will significantly moderate the association of surgical complications with patients' wellbeing over time.

H5: Appraisals of the causation and controllability of the complications will significantly moderate the association of surgical complications with patients' wellbeing over time.

8.2 Methods

8.2.1 Study design and patient recruitment

This was a prospective, longitudinal, cohort study. Consecutive patients undergoing major gastro-intestinal, cardio-thoracic or vascular surgery in one London teaching NHS trust were recruited in the study. Patients were eligible to participate if they met each of the following eligibility criteria:

- Patients undergoing major gastro-intestinal, vascular or cardio-thoracic surgery. Major surgery was defined based on the BUPA schedule of operations (BUPA 2012) as any surgical procedure that is classified as Major+ and above under the hospital category.
- Patients undergoing elective or urgent operations
- Patients over 18 years old
- Patients able and willing to give informed consent
- Patients that speak and understand English

Patients were excluded from the study if they were undergoing reoperations aimed at fixing the complications of a recent operation for the same problem.

Patient recruitment took place between the 27th of March 2012 and the 30th of November 2012. A total of 243 patients met the eligibility criteria for inclusion in the study during that period.

108 patients agreed to take part in the study (i.e. 44.4% response rate). Reasons for non-participation included: (a) the patient was not interested (n=55), (b) the patient was unable to complete the questionnaire due to concurrent medical procedures or lack of time (e.g. patient was having dialysis at the time of recruitment) (n=31) and (c) the researcher was not available (n=49).

The patients were approached on their admission to the hospital, were informed about the aims and procedures of the study and were asked whether they were interested in participating. Patients' consent was recorded in writing. The baseline questionnaire (t1) was completed when patients were admitted to the hospital and within 24 hours before their operation. The second questionnaire (t2) was completed within 24 hours before patients' discharge from the hospital. The third (t3) questionnaire was posted to the participants two months after their discharge from the hospital. Patients who failed to return their t3 questionnaire in the specified time were kindly reminded on the phone to complete and return it. Ethical approval was granted by the London REC Committee 1-Dulwich.

8.2.2 Measures

The questionnaire took 15-20 minutes to complete with pilot participants and included well-validated measures of psychological wellbeing and of psychosocial factors. The same questionnaire was used at all time-points, including or excluding certain scales, as appropriate. The pre-operative questionnaire, which was the basis for the follow-up questionnaires, is presented in Appendix 22.

The following demographic and clinical data were collected at baseline: gender, age, education, relationship status, whether the participants had children, job status, ethnicity, condition for which they needed surgery and surgical procedure. The following psychological constructs were also assessed:

- **Anxiety and Depression:** Anxiety and depression were assessed with the Hospital Anxiety and Depression Scale (Zigmond 1983). For a more detailed description of HADS see Chapter 6. Anxiety and depression were assessed at all three time-points.
- **Quality of life:** Quality of life (QoL) was measured with the Short Form 12, version 2, Health Survey (SF-12) (Ware et al. 1996) which is an abbreviated version of the widely used SF-36 (Ware and Sherbourne 1992). SF-12 is a generic measure of QOL that has been validated extensively and has high reliability, validity and sensitivity (Ware et al. 1996; Ware Jr et al. 1998; Ware et al. 2002). SF-12 yields one score for physical health status (PCS) and one for mental health status (MCS) which are computed using norm-based methods based on the US general population (2009) (Maruish 2012). Each component score has the same mean (50) and the same standard deviation (10). Mean scores below 47 are interpreted as being below the average range for the general population. QoL was not assessed at discharge. This is because a few of the SF-12 items assess patients' ability to perform day-to-day activities which patients cannot assess while they are in the hospital.
- **Illness Perceptions:** Patients' illness perceptions were assessed with the Brief Illness Perceptions Questionnaire (Brief-IPQ). The Brief IPQ is a nine-item questionnaire with good psychometric properties which assesses patients' representations of their illness (Broadbent et al. 2006). It assesses five cognitive illness representations (i.e. consequences, timeline, personal control, treatment control and identity) in agreement with the *Common Sense Model* (Leventhal et al. 1984), two emotional representations (i.e. concern and emotions), illness comprehensibility and causal attributions of one's illness. Each representation (except for the causal attributions) is assessed with a single item on a 10-point scale. The representation that was of interest to the study was treatment control, which was used for the assessment of patients' preoperative expectations of the benefits of surgery. Patients' illness representations were only assessed pre-operatively.

- **Coping:** Patient's coping with the stress of their surgery was assessed with the Brief-COPE (B-COPE) (Carver 1997) which has been described in detail in Chapter 6. Patients' coping strategies were only assessed pre-operatively.
- **Social support:** Patients' perceptions of social support were assessed with the Multi-dimensional Support Scale, which is a self-report measure of the adequacy and frequency of social support from various sources (i.e. confidants, peers and experts) with good psychometric properties (Winefield et al. 1992; Winefield et al. 2003). Only the adequacy of social support from confidants and healthcare professionals were assessed in this study. MDSS assesses emotional, practical and informational support. Six items were used for the adequacy of support from confidants (e.g. *How often did you feel that they were really trying to understand you?*), and five for the adequacy of support from experts (e.g. *How often did they really listen to you when you talked about your problems or worries about surgery?*). Each item was assessed on a 3-point scale: 1=not enough, 2=too often, 3=it was just right. Social support was only assessed pre-operatively.
- Patients' attributions of their complications were not assessed because of ethical and practical difficulties in probing patients to make judgements about their complications as it proved that patients were not always aware that they had suffered surgical complications.

8.2.3 Recording of complications

Patients' in-hospital surgical complications were recorded based on Dindo et al.'s definition of surgical complications as "*any deviation from the ideal postoperative course*" (Dindo et al. 2004; Dindo and Clavien 2008). Sequelae that are inherent to the procedure (e.g. inability to walk after an amputation of the leg) are not considered complications. For the purposes of the study, patient

records, electronic discharge summaries, clinical and laboratory tests were reviewed by members of the clinical team (i.e. nurses and consultant surgeons) in order to identify any postoperative surgical complications that the participants experienced during their hospital stay. Their severity was rated according to Dindo et al.'s framework (Dindo et al. 2004). See Appendix 23 for a detailed description of the grading framework. Post-discharge complications were not recorded. Complications were recorded on a standardised log (see Appendix 24).

8.2.4 Data analysis

8.2.4.1 Cross-sectional univariate analysis

The data were analysed using SPSS for Windows version 20. They were first summarised using descriptive statistics (i.e. frequencies and percentages for categorical data/mean, standard deviation for continuous data and median, range for ordinal or non-normal data) and were explored for normality of distribution and homogeneity of variance using histograms, stem-and-leaf plots and statistical tests (i.e. Kolmogorov-Smirnoff test for normality and Levene's test for homogeneity of variance). Patients who completed the questionnaire were compared against those who were lost to follow-up on their demographic and clinical characteristics using chi-square tests for categorical data, t-tests for continuous data or Mann-Whitney tests for data that did not meet the assumptions of parametric tests. Any significant differences were controlled for in the longitudinal multivariate analyses.

The data were first analysed cross-sectionally. Patients with complications were compared to patients without complications on their post-operative psychological outcomes (i.e. anxiety, depression, physical and mental quality of life) using t-tests or Mann-Whitney tests when the data

did not meet the assumptions of parametric tests. Patients' post-operative psychological outcomes were also correlated with the pre-operative psychosocial factors using Spearman's correlations (i.e. pre-operative expectations of the benefits of surgery, coping and social support).

8.2.4.2 Longitudinal multivariate analysis: Multilevel linear mixed models

The data were then analysed longitudinally using Multilevel Linear Mixed Models Analysis with random coefficients (unstructured covariance and intercept as random in order to account for individual variability in change of psychological outcome over time). This approach is highly recommended for longitudinal data because it takes into consideration that data from the same individuals at different time-points are correlated (Krueger and Tian 2004; Fitzmaurice et al. 2011). Also it performs more accurately with unbalanced designs (i.e. unequal sample sizes at different time-points or between groups), unequally spaced time-points and missing data, all of which apply to this study. A separate linear mixed model analysis was performed for each psychological outcome. A two-stage approach was followed with two consecutive models being fitted on each outcome, one simpler and one more complex (Field 2011).

The first (simple) model investigated the contribution of time, the occurrence of complications and any demographic or clinical characteristics that were significantly different between those who completed the questionnaires and those who were lost to follow-up. Time was entered in the models in two different formats simultaneously: time-points 1-4 and number of days since baseline. The number of days since baseline was entered in order to control for the participants' length of stay, which varied considerably between individuals. The second model was identical to the first except that it also assessed the contribution of psychosocial factors (i.e. pre-operative expectations of the benefits of surgery, coping, social support). Rules of thumb for a

sample size and power calculation for multilevel modelling do not exist due to the complexity of this statistical method. The general approach is that models with a large number of parameters need more data (Field 2011). Therefore, in order to narrow down the number of the parameters that were entered in the second model, psychosocial factors were entered in the second model only if they were significantly correlated with the postoperative psychological outcomes in the cross-sectional analysis. For the same reason only the main effects of the above factors were assessed. No interactions were assessed except between the occurrence of surgical complications and time, as this was the main hypothesis of the study. The same sequence of models was also repeated in relation to the occurrence of major complications (i.e. above grade III on Dindo's grading framework).

Only the final models (with the psychosocial factors) are presented in the results section, as they were always an improved version of the first simpler models (without the psychosocial factors). The first models are presented in Appendix 25, Appendix 27, Appendix 29 and Appendix 31. The first models were compared to the second models with the -2 Log Likelihood criterion (i.e. smaller values indicate a better model) and a graphic representation of the observed values of each outcome against the values that were predicted by each model. The residuals of each model were assessed and were found to comply with the assumptions of normality and homogeneity of variance.

8.3 Results

8.3.1 Participants' characteristics

A total of 108 consecutive surgical patients completed the baseline questionnaire. The majority were male (72%), married (52%), white-British (72%) and retired (58%). Their mean age was 65.15 years

(24-86). 44% were admitted for vascular surgery, 38% for gastro-intestinal surgery and 19% for cardio-thoracic surgery. 52% of the participants suffered surgical complications of any severity while 19% experienced major complications (i.e. above grade III which indicates complications that require medical/surgical intervention and/or HDU/ITU management). The only significant difference between patients with complications and patients without complications was that patients with surgical complications had a significantly higher length of stay (i.e. number of days in the hospital since the day of their surgery) ($Mdn=10.50$ vs. $Mdn=6.00$) ($U=377$, $p<.001$) and also a significantly higher proportion of patients who were admitted for gastro-intestinal surgery (52% vs. 23%) [$\chi^2(2, N=106) = 9.61$, $p=.008$].

A total of 73% of the patients completed the t2 (discharge) questionnaire and 47% completed the t3 questionnaire (2 months post-discharge). The most common reason for participants' loss to follow-up was that patients did not return their questionnaires. Four patients withdrew their consent during the conduct of the study, two patients passed away, two patients were discharged to other hospitals which made it difficult to track them down and one patient suffered serious neuro-cognitive complications which restricted his cognitive ability for completing the follow-up questionnaires. The only significant difference between those who completed the follow-up questionnaires and those who did not was that there was a significantly higher representation of patients undergoing cardio-thoracic surgery among completers (24%) than among those who were lost to follow-up (3%) [$\chi^2(2, N=108)=6.09$, $p=0.048$] (see Table 22 for a detailed overview of the participants' characteristics).

Table 22: Patients' demographic and clinical characteristics

	Baseline (t1)	Discharge (t2)	2 months (t3)
Patient characteristics	N (%)	N (%)	N (%)
Total sample	108 (100)	79 (100)	51(100)
Demographics			
Gender			
Male	72 (66.7)	53 (67.1)	35 (68.6)
Female	36 (33.3)	26 (32.9)	16 (31.45)
Children			
Yes	84 (77.8)	59 (78.7)	40 (78.4)
No	20 (18.5)	16 (20.3)	10 (19.6)
Missing	4 (3.7)	4 (5.1)	1 (2.0)
Relationship status			
Single	12 (11.1)	9 (11.4)	8 (15.7)
In a relationship	9 (8.3)	5 (6.3)	2 (3.9)
Married	56 (51.9)	43 (54.4)	27 (52.9)
Divorced	12 (11.1)	9 (11.4)	4 (7.8)
Widowed	18 (16.7)	12 (15.2)	10 (19.6)
Missing	1 (0.9)	1 (1.3)	0 (0)
Ethnicity			
White-British	78 (72.2)	59 (74.7)	41 (80.4)
White-Other	16 (14.8)	11 (13.9)	5 (9.8)
Asian-British (Indian)	4 (3.7)	3 (3.8)	3 (5.9)
Asian-British (all other)	2 (1.9)	2 (2.5)	1 (2.0)
Black-British (Caribbean)	3 (2.8)	0 (0)	0 (0)
Other	3 (2.8)	2 (2.5)	0 (0)
Missing	2 (1.9)	2 (2.5)	1 (2.0)
Job status			
Employed	29 (26.9)	22 (27.8)	14 (27.5)
Unemployed	6 (5.6)	4 (5.1)	4 (7.8)

Retired	63 (58.3)		47 (59.5)		28 (54.9)	
Other	2 (1.9)		1 (1.3)		1 (2.0)	
Missing	8 (7.4)		5 (6.3)		4 (7.8)	
Education						
GCSEs	21 (19.4)		13 (16.5)		9 (17.6)	
A levels	10 (9.3)		6 (7.6)		5 (9.8)	
Undergraduate degree	11 (10.2)		11 (13.9)		6 (11.8)	
Postgraduate degree	9 (8.3)		8 (10.1)		6 (11.8)	
Professional Qualification	19 (17.6)		16 (20.3)		7 (13.7)	
No qualifications	29 (26.9)		21 (26.6)		15 (29.4)	
Missing	9 (8.3)		4 (5.1)		3 (5.9)	
	Mean (SD)	Min-Max	Mean (SD)	Min-Max	Mean (SD)	Min-Max
Age	65.15 (13.24)	24-86	64.72 (13.11)	24-86	63.95 (14.18)	24-86
Clinical characteristics						
Type of surgery						
General GI	40 (37.7)		28 (35.4)		19 (37.3)	
Vascular	48 (44.4)		32 (40.5)		21 (41.2)	
Cardio-thoracic	20 (18.5)		19 (24.1)*		11 (21.6)	
Any surgical complications						
Yes	50 (46.3)		37 (46.8)		25 (49)	
No	56 (51.9)		41 (51.9)		25 (49)	
Missing	2 (1.9)		1 (1.3)		1 (2)	
Major surgical complications						
Yes	20 (18.5)		13 (16.5)		9 (17.6)	
No	83 (76.9)		64 (81)		40 (78.4)	
Missing	4 (3.7)		2 (2.5)		2 (3.9)	
	Mean (SD)	Min-Max	Mean (SD)	Min-Max	Mean (SD)	Min-Max
Length of stay	11.94 (12.64)	2-70	10.27 (9.07)	2-70	9.13 (5.61)	2-28

* $p<0.05$

8.3.2 Comparisons of patients with complications vs. patients without complications on post-operative psychological outcomes

8.3.2.1 Anxiety and depression

Significant differences were not observed between patients who suffered complications of any severity and patients who did not suffer complications on their post-operative anxiety levels (Table 23). Anxiety decreased post-operatively in both groups. Depression on the other hand was significantly higher at discharge in patients who suffered complications ($U=530$, $p=.046$).

8.3.2.2 Quality of life

Two months post-discharge physical quality of life (PCS) was significantly better in patients who did not suffer complications [$t(48) = -2.10$, $p=.041$]. Significant differences were not found on mental quality of life (MCS) between the two groups (see Table 23).

Table 23: Psychological outcomes

Psychological outcomes	Total sample		Any complications		No complications		Test of difference
	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)	Median (Range)	
Anxiety t2	5.55 (3.47)	5 (0-16)	5.23 (2.26)	6 (0-13)	5.58 (3.80)	5 (0-15)	$U=734.5$, $p=.95$
Anxiety t3	4.75 (4.19)	5 (0-16)	4.04 (3.07)	4 (0-11)	5.00 (4.60)	3 (0-13)	$U=347.5$, $p=.67$

Depression t2	6.55 (3.98)	6 (0-15)	7.35 (4.00)	7 (0-15)	5.58 (3.62)	4 (1-15)	$U=530.5$, $p=.046^*$
Depression t3	4.78 (3.74)	4.5 (0-14)	5.00 (3.57)	5 (0-13)	4.23 (3.55)	3 (0-12)	$U=281$, $p=.41$
Physical QOL t3	43.26 (9.66)		39.78 (9.56)		45.65 (10.12)		$t(48)=-$ 2.10 , $p=.04^*$
Mental QOL t3	49.72 (9.02)		48.70 (10.15)		49.66 (8.81)		$t(48)=-.36$, $p=.72$

8.3.3 Correlations of pre-operative expectations of surgery, coping and social support with post-operative psychological outcomes

A number of significant Spearman's correlations were identified between the post-operative psychological outcomes and the baseline psychosocial factors (i.e. preoperative expectations of the surgery's benefits, coping and adequacy of support from loved ones and healthcare professionals) (see Table 24). Correlations were considered significant at $p<.01$ in order to control for family wise error due to the big number of correlations with each psychological outcome.

Higher preoperative expectations of the benefits of surgery were highly significantly correlated with lower anxiety 2 months post-discharge ($p<.01$). No other highly significant relationships were identified between pre-operative expectations of surgery and post-operative wellbeing outcomes.

From the coping strategies, higher use of self-distraction was associated with worse postoperative wellbeing (i.e. higher anxiety and depression and lower mental quality of life) ($p<.01$). Other highly significant correlations included more frequent use of instrumental support with higher anxiety ($p<.01$), more frequent use of venting with higher anxiety ($p<.01$) and lower mental quality of life ($p<.01$), more frequent use of religion with lower physical quality of life ($p<.01$) and more frequent use of planning and self-blame with lower mental quality of life ($p<.01$). Most of the above coping strategies (except for planning and use of instrumental support) are directed towards managing the emotional consequences of surgery-related stress.

Lastly, lower perceived adequacy of support from one's loved ones was highly significantly correlated with higher depression two months post-discharge ($p<.01$). No other highly significant relationships were found between perceived adequacy of support from confidants or healthcare professionals and postoperative psychological outcomes.

Table 24: Spearman's correlations of post-operative psychological outcomes with baseline psychosocial factors

		Anxiety_t2	Anxiety_t3	Depression_t2	Depression_t3	PCS_t3	MCS_t3
Illness perceptions	Expected benefits of surgery (treatment control of Brief-IPQ)	-.011	-.366**	-.091	-.337*	.340*	.296*
Coping	Self-distraction	.368**	.525**	.184	.376**	-.308*	-.401**
	Active coping	.159	.235	.023	.195	-.117	-.303*
	Denial	.145	.152	.142	.067	.033	-.125
	Substance use	.318**	.264	.367**	.306*	-.186	-.281
	Emotional support	.265*	.316*	.086	.214	-.281	-.260
	Instrumental support	.352**	.465**	.278*	.331*	-.152	-.355*
	Behavioural Disengagement	.096	.124	.130	.325*	-.118	-.153
	Venting	.411**	.292*	.187	.145	-.024	-.403**
	Positive reframing	.129	.294*	-.110	.101	-.025	-.129
	Planning	.221	.358*	.089	.337*	-.299*	-.395**
	Humour	.132	-.011	-.060	-.084	-.001	-.081
	Acceptance	.204	.192	.152	.087	.016	-.006
	Religion	-.013	.219	.067	.234	-.390**	-.280
	Self-blame	.194	.328*	.085	.221	-.073	-.587**
Adequacy of support	From loved ones	-.192	-.232	-.209	-.422**	.104	.155
	From healthcare professionals	-.181	-.157	-.130	-.297*	.095	.186

*p<0.05

*p<0.01

8.3.4 Longitudinal Multilevel Linear Mixed Models Analysis

As it was explained under the data analysis section (see page 182) a multilevel linear mixed models analysis approach was chosen in order to examine the longitudinal associations of surgical complications with patients' post-operative wellbeing. Multilevel modelling was constructed in two phases for each outcome. Phase one included only the essential variables of interest (i.e. time, occurrence of complications, interaction between time and occurrence of complications, and surgical specialty). Surgical specialty was included in order to control for the fact that there were significantly more cardio-thoracic patients among those who completed the follow-up questionnaires than among those who were lost to follow-up. Phase two also included those baseline psychosocial factors that were significantly associated with the outcome of interest in the univariate cross-sectional analysis. The results of the multilevel model analysis are presented more analytically below for each psychological outcome. The significant parameters of each model are summarised with their beta values (b), standard errors (SE) and 95% confidence intervals (CI). First are presented the models that examined the effects of the occurrence of complications of *any* severity on patients' wellbeing, followed by a short section on the models that investigated the effects of the occurrence of *major* complications.

8.3.4.1 Complications of any severity

8.3.4.1.1 Anxiety

The final model on anxiety is summarised in Table 25. In summary, anxiety reduced significantly after surgery in all patients ($p < .01$) and patients who suffered complications reported lower anxiety over

time ($p<.05$). Moreover, vascular and cardio-thoracic patients reported higher anxiety than gastrointestinal patients over time ($p<.05$). Finally, higher use of emotion-focused coping strategies [i.e. self-distraction ($p<.001$), venting ($p<.001$) and substance use ($p<.05$)] significantly predicted higher anxiety over time. Patients' preoperative expectations of surgery did not independently predict their anxiety over time.

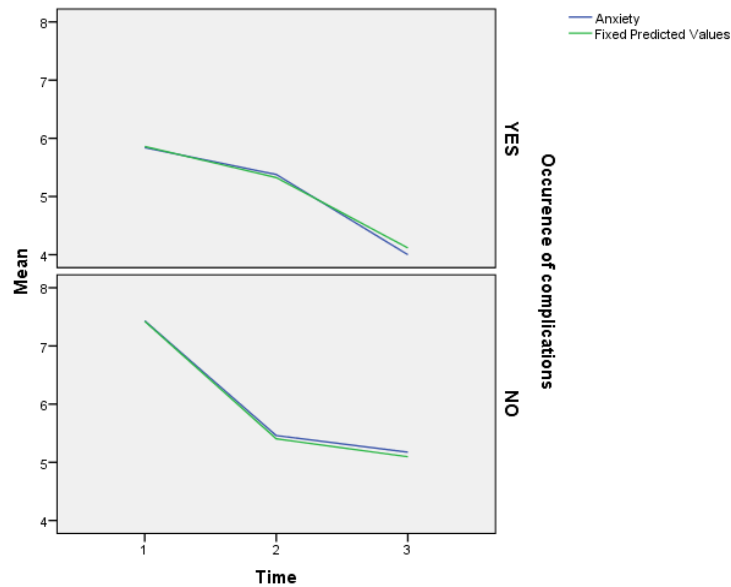
Table 25: Final model on anxiety

Parameters			Anxiety		
		<i>p</i>	<i>b</i>	SE	95% CI
Basic parameters	Time (time-points)	$p<.01$	-2.42	0.70	-3.82, -1.01
	Time (days from baseline)	$p>.05$			
	Occurrence of complications	$p<.05$	-3.08	1.52	-6.08, -0.07
	Time-points*Complications	$p>.05$			
	Days from baseline*Complications	$p>.05$			
Psychosocial factors²³	Surgical specialty: Vascular/Cardiothoracic vs. GI	$p<.05$	1.52	0.60	0.31, 2.72
	Preoperative expectations of the benefits of surgery	$p>.05$			
	Self-distraction	$p<.01$	0.49	0.15	0.17, 0.80
	Seeking instrumental support	$p>.05$			
	Venting	$p<.001$	0.80	0.19	0.40, 1.19
	Substance Use	$p<.05$	0.36	0.17	0.01, 0.71

A graphic representation of anxiety over time by the occurrence of complications is presented in Figure 4. This graph shows that even though patients who suffered complications of any severity generally had lower anxiety than patients who did not suffer complications at all time-points, patients who did not suffer complications had a steeper decrease in their anxiety levels at discharge compared to patients who suffered complications.

²³ Preoperative psychosocial factors that were significantly correlated with postoperative psychological outcome in cross-sectional analysis

Figure 4: Mixed linear model on anxiety (with psychosocial factors)



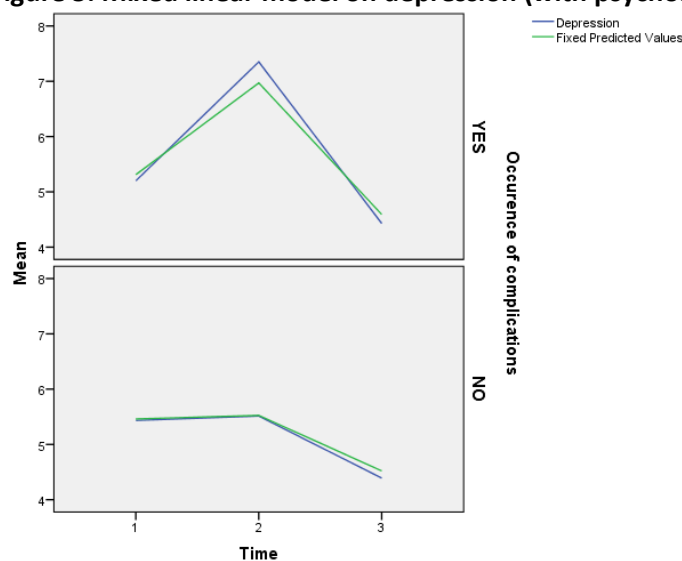
8.3.4.1.2 Depression

The final model on depression is summarised in Table 26. Firstly, there was a significant interaction between the occurrence of complications and time ($p < .05$). An examination of the estimated marginal means (Appendix 28) shows that after controlling for baseline depression, complications contributed to significantly higher depression at discharge ($p < .05$). Secondly, there was a significant main effect of surgical specialty with patients who had cardio-thoracic or vascular surgery reporting higher depression than patients who had gastro-intestinal surgery ($p < .01$). Moreover, more frequent use of self-distraction ($p < .01$) and lower perceived adequacy of support from one's loved ones ($p < .01$) predicted higher depression over time.

Table 26: Final model on depression

Parameters		Depression			
		<i>p</i>	<i>b</i>	SE	95% CI
Basic parameters	Time (time-points)	<i>p</i> >.05	-2.42	0.70	-3.82, -1.01
	Time (days from baseline)	<i>p</i> <.05	-0.00	0.02	-0.40, 0.03
	Occurrence of complications	<i>p</i> <.05	-3.08	1.52	-6.08, -0.07
	Time-points*Complications	<i>p</i> <.05	2.59	1.21	0.19, 4.98
	Days from baseline*Complications	<i>p</i> <.05	-0.6	0.31	-0.12, -0.00
	Surgical specialty: Vascular/Cardiothoracic vs. GI	<i>p</i> <.01	2.07	0.64	0.80, 3.35
Psychosocial factors²⁴	Self-distraction	<i>p</i> <.01	0.37	0.14	0.09,0.67
	Adequacy of support from family/friends	<i>p</i> <.01	-1.06	0.61	-2.84, -0.40

A graphic representation of the observed values of depression over time by the occurrence of complications is shown in Figure 5. The graph clearly shows that patients who suffered complications had a much steeper increase in their depression levels at discharge compared to patients who did not suffer complications. This graph and the -2 Log Likelihood criterion (see Appendix 28) suggest that this model is more accurate than the simpler model in the prediction of depression than the first simpler model (see Appendix 27) confirming the importance of psychosocial factors in predicting patients' postoperative depression.

Figure 5: Mixed linear model on depression (with psychosocial factors)

²⁴ Preoperative psychosocial factors that were significantly correlated with postoperative psychological outcome in cross-sectional analysis

8.3.4.1.3 Physical quality of life

The final model on physical QoL (PCS) is summarised in Table 27. The only significant effect was of surgical specialty, with patients having vascular or cardiothoracic surgery scoring lower on physical QoL than patients having gastro-intestinal surgery ($p<.05$). No other significant effects were identified (see also Appendix 30).

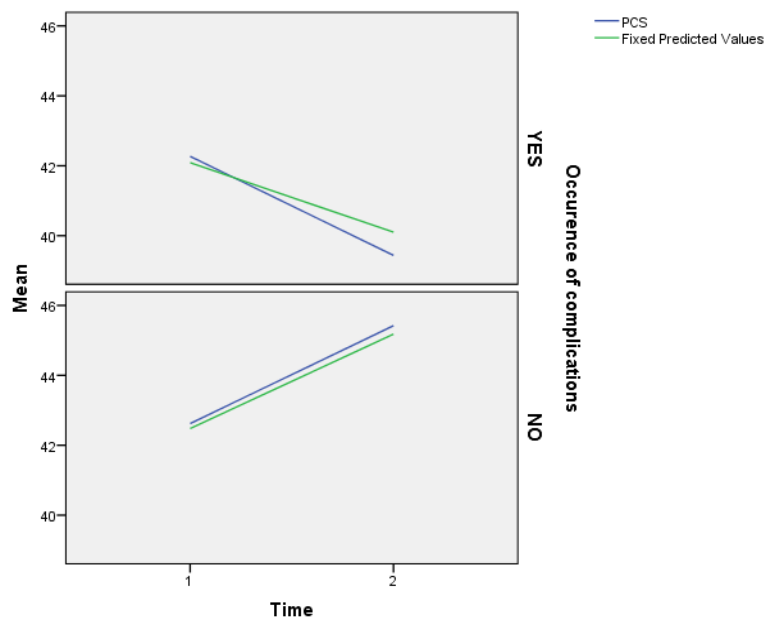
Table 27: Final model on physical QoL

Parameters		Depression			
		<i>P</i>	<i>b</i>	SE	95% CI
Basic parameters	Time (time-points)	$p > .05$	-7.80	2.52	-12.54, -2.75
	Time (days from baseline)	$p > .05$			
	Occurrence of complications	$p > .05$			
	Time-points*Complications	$p > .05$			
	Days from baseline*Complications	$p > .05$			
	Surgical specialty: Vascular/Cardiothoracic vs. GI	$p < .05$	2.07	0.64	0.80, 3.35
Psychosocial factors²⁵	Religion	$p > .05$			

A graphic representation of physical QoL by the occurrence of complications over time is shown in Figure 6. The graph suggests that even though both groups started with similar levels of physical QoL before surgery, patients who suffered complications reported a decline two months post-discharge whereas patients without complications reported an improvement. However, this trend did not reach statistical significance in the multilevel analysis.

²⁵ Preoperative psychosocial factors that were significantly correlated with postoperative psychological outcome in cross-sectional analysis

Figure 6: Mixed linear model on physical QoL (with psychosocial factors)



8.3.4.1.4 Mental quality of life

The final model on mental QoL (MCS) is summarised in Table 28. There were no significant effects or interactions on patients' mental QoL after their surgery.

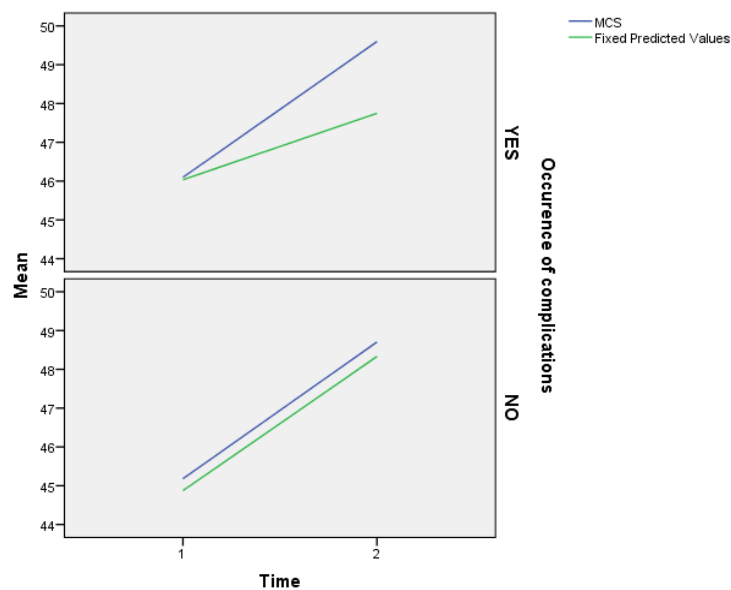
Table 28: Final model on mental QoL

Parameters		Depression			
		<i>P</i>	<i>b</i>	SE	95% CI
Basic parameters	Time (time-points)	<i>p</i> >.05			
	Time (days from baseline)	<i>p</i> >.05			
	Occurrence of complications	<i>p</i> >.05			
	Time-points*Complications	<i>p</i> >.05			
	Days from baseline*Complications	<i>p</i> >.05			
	Surgical specialty: Vascular/Cardiothoracic vs. GI	<i>p</i> >.05			
Psychosocial factors²⁶	Venting	<i>p</i> >.05			
	Planning	<i>p</i> >.05			
	Self-blame	<i>p</i> >.05			
	Self-distraction	<i>p</i> >.05			

²⁶ Preoperative psychosocial factors that were significantly correlated with postoperative psychological outcome in cross-sectional analysis

A graphic representation of patients' mental QoL by the occurrence of complications over time is presented in Figure 7. The graph suggests that in both groups their mental QoL showed an improvement trend from baseline to two months post-discharge.

Figure 7: Mixed linear model on mental QoL (with psychosocial factors)



8.3.4.2 Major complications

The same models were repeated for the analysis of the contribution of the occurrence of major complications on psychological outcomes (i.e. above grade III on Dindo's complications grading system). Differences were found only in relation to anxiety. The final model on anxiety by the occurrence of major complications is presented in Table 29. The main difference with the model presented on pages 191-192 was that this time there was a significant interaction of the occurrence of major complications with time ($p < .05$) which based on the Estimated Marginal Means (see

Appendix 33) suggests that patients who suffered major complications had significantly higher post-operative anxiety at discharge than patients who did not experience major complications.

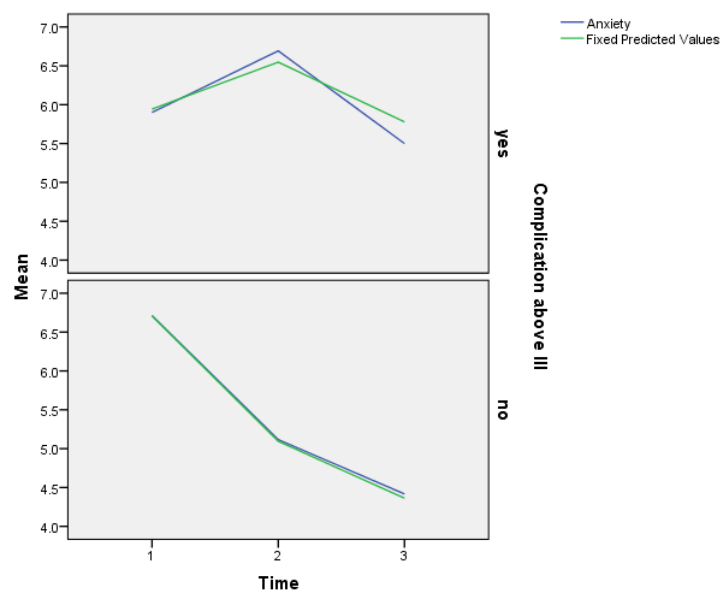
Table 29: Final model on anxiety by occurrence of major complications

Parameters		Anxiety			
		<i>p</i>	<i>B</i>	SE	95% CI
Basic parameters	Time (time-points)	<i>p</i> >.05			
	Time (days from baseline)	<i>p</i> >.05			
	Occurrence of complications	<i>p</i> <.05	-4.37	2.00	-8.33, -0.41
	Time-points*Complications	<i>p</i> <.05	2.99	1.49	0.04, 5.93
	Days from baseline*Complications	<i>p</i> >.05			
	Surgical specialty: Vascular/Cardiothoracic vs. GI	<i>p</i> <.05	1.76	0.57	0.01, 2.87
Psychosocial factors²⁷	Preoperative expectations of the benefits of surgery	<i>p</i> >.05			
	Self-distraction	<i>p</i> <.01	0.54	0.15	0.22, 0.85
	Seeking instrumental support	<i>p</i> >.05			
	Venting	<i>p</i> <.001	0.79	0.20	0.38, 1.20
	Substance Use	<i>p</i> >.05			

Figure 8 shows that the anxiety levels of patients who suffered major complications increased at discharge whereas anxiety decreased in patients who did not suffer major complications. Two months post-discharge both groups' anxiety levels decreased but they remained higher for patients who suffered major complications even though this difference was not statistically significant. Higher use of self-distraction (*p*<.05) and higher use of venting (*p*<.001) were again significant predictors of higher levels of anxiety over time as was having cardio-thoracic or vascular surgery as opposed to gastro-intestinal surgery.

²⁷ Preoperative psychosocial factors that were significantly correlated with postoperative psychological outcome in cross-sectional analysis

Figure 8: Mixed linear model on anxiety (with psychosocial factors)



8.4 Discussion

This was a longitudinal cohort study, which investigated the association of surgical complications with patients' wellbeing after major surgery and tested the contribution of psychosocial factors in this association. In summary, multilevel longitudinal analysis with mixed linear models showed that patients who suffer complications of any severity report significantly higher levels of depression at discharge than patients with uncomplicated recovery. Moreover, patients who suffer major complications (i.e. requiring medical/surgical intervention and ITU treatment) have significantly higher levels of anxiety at discharge than patients who do not suffer major complications. Most importantly, patients' coping and adequacy of support from their loved ones were significant independent predictors of anxiety and depression over time even after controlling for the occurrence of complications.

The finding that patients who suffer complications of any severity report higher levels of post-operative depression than patients who recover without complications supports the central

hypothesis of this study which states that surgical complications affect patients' psychological wellbeing above and beyond the effects of surgery. Moreover, it validates the findings of the systematic review in Chapter 4 and the interview study in Chapter 7, which found that a few patients who suffered complications reported feelings of depressed mood during their post-operative recovery.

Anxiety on the other hand reduced significantly in the post-operative period and this was the case both for patients who suffered complications of any severity and for those who did not. This finding possibly reflects the time at which baseline anxiety was measured (i.e. within 24 hours before surgery when patients are expected to feel nervous due to the anticipation of surgery) (Spielberger et al. 1973; Mark 2003). However, multilevel longitudinal analysis by the occurrence of only major complications showed that after controlling for baseline anxiety the anxiety levels of patients who suffered serious complications increased at discharge, whereas patients who did not experience serious complications were significantly less anxious at the same time. Therefore, it is patients who suffer complications that require further medical/surgical interventions or ITU/HDU management that are at higher risk of severe anxiety during their hospital stay.

As for patients' QoL, cross-sectional analysis suggested that the physical quality of life of patients who suffered complications was significantly worse two months post-discharge than in patients who did not suffer complications, although this finding was not confirmed with multilevel longitudinal analysis. Postoperative mental quality of life was not statistically worse in patients who suffered complications than in patients who did not neither in cross-sectional nor in longitudinal analysis. These findings contradict the systematic review, which concluded that the adverse psychosocial impact of complications on patients' quality of life often lasted for more than one year post-surgery. A possible explanation for the lack of significant effects of complications on patients' wellbeing two months post-discharge is that the analyses were underpowered for the detection of

significant effects at that time-point due to the small number of participants with complications two months post-discharge.

The second major aim of the study was to test the contribution of psychosocial factors in the impact of surgical complications on patient's psychological wellbeing. We found that after controlling for the occurrence of surgical complications and baseline levels of patients' wellbeing, use of emotion-focused coping strategies and perceived adequacy of support from one's loved ones significantly predicted worse psychological wellbeing in longitudinal multi-level analysis. Post-operative anxiety was significantly predicted by the use of self-distraction in agreement with literature which suggests that avoidance is associated with worse psychological wellbeing (Ehlers and Clark 2000; Roesch and Weiner 2001; Brewin 2003). Anxiety was also significantly predicted by more frequent use of venting and substance use in line with evidence which suggests that emotion-focused coping is often negatively associated with psychological outcomes (Penley 2002). Depression on the other hand was significantly predicted by the perceived adequacy of support from loved ones which highlights the importance of the quality of one's social relationships as a significant buffer to the stress that is associated with surgical complications (Kulik and Mahler 1989; Schröder et al. 1998; Boehmer et al. 2007). Overall, the above findings strongly suggest the importance of psychosocial factors in explaining how seriously patients are affected by surgical complications and highlight the importance of considering patients' broader psychological profiles when trying to identify those patients who are most at risk for severe psychological distress in the aftermath of serious surgical complications.

It is worth noting that patients' preoperative expectations of the surgical outcome did not significantly predict patients' postoperative psychological wellbeing above and beyond the effects of surgical complications as it was hypothesised. This is in disagreement with the patient interviews, which suggested that patients' preoperative expectations of the surgical outcome were an important determinant of how patients felt about surgical complications. Patients who were

expecting a positive outcome and a smooth recovery were more distraught when serious complications occurred. The lack of significant effects may be explained by the fact that patients' expectations of the benefits of surgery may matter more for patients who suffer complications rather than the total population of surgical patients. It is the dissonance between high preoperative expectations from surgery and experience of harm that is expected to lead to lower postoperative wellbeing. Unfortunately, the interactions of psychosocial factors with the occurrence of surgical complications were not assessed due to the lack of adequate statistical power thus it was not possible to examine this moderating effect.

8.4.1 Limitations

Certain methodological limitations need to be taken into consideration in the interpretation of the findings. First, the sample size of the study has been a significant barrier for the exploration of the various interactions between psychosocial factors and the occurrence of surgical complications. An analysis of these interactions would have allowed a more accurate investigation of the hypotheses that this study set out to explore. The small number of participants with complications at the second follow-up may also be responsible for the fact that we did not find any significant effects of the occurrence of surgical complications on psychological outcomes two months post-discharge. The small sample size was also the reason that only the psychosocial factors that were significantly correlated with outcomes in the cross-sectional analysis were entered in the mixed linear models. Secondly, the recording of complications was conducted by a different healthcare professional for each surgical specialty, which may have introduced biases pertinent to each coder's subjective interpretation of complications. In order to control for these biases, a structured complications log was constructed after consultation with consultant surgeons and a standardised grading system for the severity of complications was followed. However, the potential of in-coder variability biases

should be considered in the interpretation of the above findings. Another limitation is that post-discharge complications were not recorded. Although this was outside the scope of the study, it may have limited the study's ability to detect the extent of the complications' impact on patients' lives. Moreover, the study is single-site and restricted to major high-risk surgery, which potentially limits the generalisability of the findings to the wider population of surgical patients. Lastly, as it was explained in the methods, it was not possible to assess patients' appraisals of the causation and controllability of their complications due to the sensitive nature of the topic. This restricted the ability of the study to assess the contribution of patients' appraisals of their complications on their post-operative wellbeing.

8.4.2 Strengths of the study

This is the first study to my knowledge which attempted to use evidence-based psychosocial predictors of psychological wellbeing in order to examine the psychological impact of surgical complications on patients. Moreover, this study investigated the psychological impact of surgical complications across different surgical specialties using a prospective longitudinal design in order to control for baseline levels of psychological wellbeing, consecutive patients and sophisticated statistical methods for the analysis of longitudinal data.

8.5 Conclusions

This study found that the occurrence of complications of any severity significantly predicts higher levels of depression at patients' discharge while the occurrence of major complications significantly

predicts higher levels of postoperative anxiety. Cross-sectional analysis also suggested worse physical quality of life for patients who suffered complications two months post-discharge, but this was not confirmed with the longitudinal analyses. Overall, the findings confirm that surgical complications impact negatively on patients' postoperative psychological wellbeing even when they are not life-threatening and reaffirm the importance of psychological support for patients who suffer adverse events after surgery. More importantly, this study confirms the importance of psychological mechanisms such as patients' coping and social support as moderators of the impact of complicated surgery on patients' postoperative wellbeing. These factors could be used as screening criteria for identifying patients who are at risk for severe psychological distress in the aftermath of complicated surgery. Patients who do not feel that they receive adequate support from their loved ones or patients who deal with the challenges of their recovery through avoidance, venting and substance use may be at risk for the development of depression and anxiety after complicated surgery.

Chapter 9: Supporting patients and staff in the aftermath of serious patient safety incidents in the NHS: An online survey study²⁸

This chapter presents an online survey study on the current NHS practices in relation to supporting patients and staff in the aftermath of serious adverse events. Patient safety managers of English NHS trusts were asked about the frequency of being open with patients and families after patient safety incidents of three different levels of severity, the typical content and structure of discussions with patients and families and the general availability of support for patients, families and healthcare staff in the aftermath of serious patient safety incidents. The findings are discussed in relation to existing literature on the aftermath of adverse events and the methodological limitations and strengths of the study are explained.

9.1 Introduction

As discussed in Chapter 1 and confirmed by the patient interviews in Chapter 7, patients and families may suffer in two ways after serious incidents; firstly from the incident itself and secondly from the way it is handled (Vincent 2003; Vincent 2010). It is now well established that when patients are harmed, they and their families need an explanation, an apology, an assurance that action will be taken to prevent recurrence and, in many cases, additional treatment and support of various kinds (Witman et al. 1996; Hobgood et al. 2002; Gallagher et al. 2003; Mazor et al. 2004; Cleopas et al. 2006; Hobgood et al. 2006; Lopez et al. 2009). Concealment, evasion and lack of prompt action to

²⁸ This study was published by the British Medical Journal of Quality and Safety: Pinto, A., Faiz, O. and Vincent, C. (2012). Managing the after effects of serious patient safety incidents in the NHS: an online survey study. *BMJ Quality & Safety* **21**(12): 1001-1008.

ameliorate both physical and psychological damage can cause immense distress and anger and lead to a breakdown of trust between family and staff (Vincent et al. 1994; Vincent 2010).

In June 2010, a public enquiry was announced in the UK into Mid Staffordshire NHS Foundation Trust, following reports by an independent regulator on severe failings in emergency care and patient concerns about the care they or a relative received at the trust. One of the most striking findings from the review was not only the poor care given to some patients but the lack of openness after patients were harmed. The chair of the enquiry, Robert Francis, commented that ‘I heard of too many cases in which patients had experienced some traumatic event ...after which the next of kin only discovered what had happened on arriving to visit. Common humanity requires the close family to be told as soon as possible of distressing events so that they can offer comfort and support’ (Francis 2010).

Healthcare staff may also suffer psychologically when they are involved in adverse events, particularly if a patient is harmed and even more so if they are seen as primarily responsible for the outcome (Christensen et al. 1992; Schwartz and Sprangers 1999; Wu 2000; Aasland and Forde 2005; Engel et al. 2006; Waterman et al. 2007; Scott et al. 2009; Sirriyeh et al. 2010; Vincent 2010). The chapters on surgeons’ experiences of surgical complications suggest that the emotional burden of these incidents is often severe with wider implications for their personal and professional wellbeing.

Considerable progress has been made in the development of policies to encourage and support organisations in providing effective support for patients, families and also for staff. An overview of existing principles and guidelines in the UK around supporting patients and staff in the aftermath of healthcare-related adverse events was given in Table 1 on page 29. The most popular guidance is the National Patient Safety Agency (NPSA) on ‘Being Open’ which is a best practice framework on how to create an open and honest environment where (a) patients, their families and carers receive the information they need to understand what went wrong, and the reassurance that everything possible will be done to prevent recurrence and (b) all involved, patients, families and

healthcare professionals, feel supported. Currently the extent to which NHS organisations have endorsed such guidelines and put them into practice is unknown.

9.1.1 Study aims

This study aimed to investigate the current state of practice in English NHS trusts in relation to the communication of serious patient safety incidents to patients and families and the provision of support for patients, families and staff in their aftermath. Serious patient safety incidents were defined as incidents that result in unexpected or avoidable patient death, permanent, long-lasting harm, outcome that requires major life-saving intervention, prolonged pain or psychological harm, as per the NPSA's 2010 national framework for reporting and learning from serious incidents requiring investigation. Such incidents are the result of treatment or care rather than the result of a patient's illness or underlying condition (National Patient Safety Agency 2010).

9.2 Methods

9.2.1 Study design

A cross-sectional quantitative design using online surveys and purposive sampling was used.

9.2.2 Setting and participants

In collaboration with the NHS Litigation Authority (National Health Service Litigation Authority 2010) a principal risk or patient safety manager was identified in each NHS trust in England. These managers would have responsibility for the implementation of the 'Being Open' policy and also be involved in the management and follow-up of patients involved in serious incidents. They were therefore best placed to give an accurate overview of the organisational policies, procedures and actions after serious incidents based on their personal impressions of how such policies are implemented at their trusts. The respondents have a variety of formal titles but here they are referred to as 'patient safety managers'.

9.2.2.2 Procedure and materials

9.2.2.2.1 Participant recruitment

An invitation email for participation to the study was sent to the relevant patient safety manager in each English NHS trust (n=386). The email included a description of the study and the link to the online survey. Reminder emails were sent to the participants every three weeks. Data collection took place between November 2010 and February 2011.

9.2.2.2.2 Online survey

A questionnaire was developed through a comprehensive review of relevant literature (see Chapter 1) and consultation with risk and patient safety managers, clinicians and experts in patient safety and quality improvement. The questionnaire included questions on hospital policies and practices relating to the management of the aftermath of serious patient safety incidents. Specific scales were developed to explore the following areas:

- (a) Availability of local policies on being open, frequency of being open and change of frequency of being open over the last two years
- (b) Structure (i.e. parties involved in being open discussions, timeframe and regularity of being open discussions) and content of discussions with patients and their families
- (c) Barriers to being open with patients and families (see Figure 9 for specific items)
- (d) Availability of different forms of support for patients and families (see Table 33 for specific items)
- (e) Importance and availability of different forms of support for staff (see Table 34 for specific items)

The content of discussions with patients and families and the availability of support for patients and families in the aftermath of serious incidents were assessed in relation to three different levels of incident severity: incidents leading to patient death, injuries leading to severe harm and lastly incidents from which the patient is likely to make a full recovery. An open-ended question at the end of the survey prompted participants to provide general comments about being open in the aftermath of serious patient safety incidents.

The questionnaire was delivered using the 'Survey Monkey' online survey tool and was piloted with 10 patient safety managers who provided feedback on the relevance of the questionnaire items, their comprehensibility, readability and length (see the questionnaire in Appendix 34).

9.2.3 Data analysis

The data were analysed using SPSS for Windows version 20. Descriptive statistics (i.e. means, standard deviations, medians and ranges) were used to summarise the participants' ratings of patient and staff support policies and practices. Frequencies and percentages were calculated for categorical data. Due to the fact that most of the data were ordinal, non-parametric tests were used for the investigation of significant differences. Non-parametric Mann-Whitney tests were employed to investigate differences in the uptake of being open policies between acute and non-acute trusts. Related samples Friedman's tests were used to investigate the differences in the compliance of trusts with openness and other patient support practices by incident severity. Cases with missing data were omitted from the corresponding analyses. In order to control for family-wise error (i.e. the probability of finding false significant relationships due to multiple comparisons) differences were considered significant at the .01 level ($p < .01$).

9.3 Results

9.3.1 Patient safety managers' characteristics

We received partially or wholly completed surveys from 209 respondents, corresponding to a 54% response rate. A total of 153 participants (40%) completed the survey in its entirety. Table 30 shows the participants' characteristics (n=209).

Table 30: Participants' characteristics

Characteristics	N (209)	%
Trust type		
Acute Trusts	100	47.8
Ambulance Trusts	8	3.8
Mental Health & Learning Disabilities Trusts	29	13.9
Primary Care Trusts	58	27.8
Other	14	6.7
Foundation status		
Yes	76	36.4
No	133	63.6
Years of experience in current position		
0-11 months	22	10.5
1-2 years	42	20.1
3-5 years	76	36.4
6-9 years	46	22.0
10-20 years	22	10.5
21 or more years	1	0.5
Professional background		
Nursing	86	41.1
Medicine	2	1.0
Law	4	1.9
Management	66	31.6
Other	51	24.4
Years of experience in healthcare		
0-11 months	3	1.4
1-2 years	2	1.0
3-5 years	10	4.8
6-9 years	22	10.5
10-20 years	54	25.8
21 or more years	118	56.5

9.3.2 Awareness of “being open” and related policies

Almost all the participants (98%) reported that they are familiar with the “Being open” guidance issued by the NPSA and 91% of the trusts had a board approved policy in place. Six years after the

first release of the guidance therefore, 9% of trusts do not have a board policy on open disclosure. Less than half the managers (44%) reported that the guidance is followed all the time, with 38% (n=80) saying that it was followed more than half the time, and 18% less than half the time. 22% (n=46) of the respondents thought that the number of open discussions has not changed over the last two years in their trusts, 38% (n=80) that it has increased slightly while 38% (n=79) reported a substantial increase. Significant differences were not found between acute trusts and community trusts on the extent of the guidance followed [(*Mdn*=4 vs. *Mdn*=4, *U*=5871, *p*=.271] or on the change in use of the guidance over time (*Mdn* =4 vs. *Mdn* =4, *U*=4815, *p*=.121].

9.3.3 Frequency of open discussions with patients/families by incident severity

A Friedman's test revealed that incidents were much more likely to be discussed openly with patients and families when they were of a serious nature [$\chi^2(2)= 46.22$, *p*<.001]. Pair-wise comparisons with Wilcoxon signed-rank tests confirmed that incidents that are followed by full recovery (*Mdn*=4) are discussed openly significantly less often than incidents that lead to death (*Mdn*=5, *z*=.402, *p*<.001) or incidents that lead to severe long-lasting disability (*Mdn*=5, *z*=.363, *p*<.01).

9.3.4 Structure of "being open" meetings with patients/families

When open disclosure meetings do take place executives and managers are more strongly represented than clinicians, though the lead clinician on an investigation is often present. Table 31 shows the percentages at which various people have been reported as being routinely involved in

discussions with patients and families, the timeframe at which such discussions usually happen and their regularity. About a third of open disclosure meetings take place within 3 weeks, but two thirds take place 3 to 6 months after the investigation.

Table 31: Structure of “being open” meetings

	N (158)	%
Parties involved		
Executive director(s)	125	79.1
Clinical person involved in investigation	97	61.4
Clinical person involved in incident	45	28.5
Non-clinical person involved in investigation	113	71.5
Risk manager(s)	103	65.2
Timeframe		
Within 24 hours	25	16.3
Within 1-3 weeks	23	15.0
Straight after the investigation	1	0.7
3-6 months after the investigation	95	62.1
Other	9	5.9
Regularity		
One-off meeting	22	10.5
2-3 meetings	42	20.1
> 3 meetings	76	36.4
As many as the patient/family wish	46	22.0
Other	22	10.5

9.3.5 Content of discussions with patients and families by incident severity

Table 32 shows the relative frequency of a range of elements of open disclosure meetings. ‘Sharing investigation findings’ was reported as the most frequent component of such discussions whilst ‘taking responsibility for harm’ was the least frequent. Friedman’s tests showed that all of the listed elements are significantly less likely to occur for less serious incidents with most elements being followed significantly lower for incidents from which patients recover fully than for incidents that lead to death or severe long-lasting disability ($p<.001$).

Table 32: Frequency of different elements in discussions with patients and families²⁹

		Deaths	Severe long-lasting disability	Full recovery		
	N	Median (Range)	Median (Range)	Median (Range)	Friedman's Test (df)	P
Acknowledge harm	153	5 (1-5)	5 (1-5)	4 (1-5)	25.33 (2)	$p<.001$
Apologise	153	5 (1-5)	5 (1-5)	5 (1-5)	29.71 (2)	$p<.001$
Ask patients/families their fears & concerns	153	5 (1-5)	5 (1-5)	5 (1-5)	14.43 (2)	$p<.001$
Check how patients/families are	153	5 (1-5)	5 (1-5)	5 (1-5)	17.62 (2)	$p<.001$
Promise a system improvement	153	5 (1-5)	4 (1-5)	4 (1-5)	27.90 (2)	$p<.001$
Promise to share investigation results	153	4 (1-5)	4 (1-5)	4 (1-5)	33.07 (2)	$p<.001$
Provide an explanation	153	5 (1-5)	5 (1-5)	5 (1-5)	38.25 (2)	$p<.001$
Share findings from investigations	153	5 (1-5)	5 (1-5)	5 (1-5)	28.72 (2)	$p<.001$
Take responsibility for harm	153	4 (1-5)	4 (1-5)	4 (1-5)	9.96 (2)	$p<.001$

9.3.6 Frequency of different support practices for patients and families by incident severity

Table 33 shows the frequency at which a range of support practices were reported to take place after discussions of serious patient safety incidents with patients and families. ‘Provision of details of a person of contact’ was the only common practice and this did not always occur. Friedman’s tests confirmed that all of the listed practices (except provision of ex gratia payments) are followed less frequently for less serious incidents than for those that result in severe long lasting disability or death ($p<.001$).

²⁹ The response scale was a five point Likert scale ranging from 1 (never) to 5 (all the time).

Table 33: Frequency of different types of support for patients and families³⁰

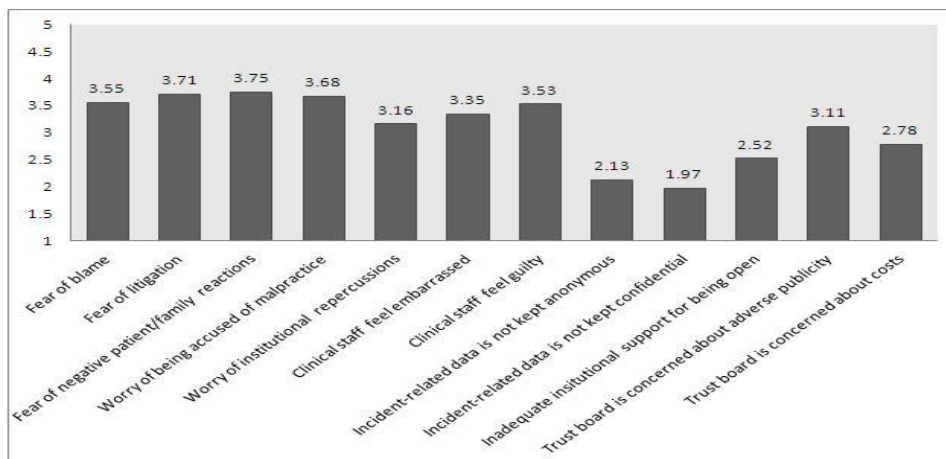
		Deaths	Severe long-lasting disability	Full recovery		
	N	Median (Range)	Median (Range)	Median (Range)	Friedman's Test (df)	p
Additional treatment	153	N/A	4(1-5)	4(1-5)	23.71 (2)	p<.001
Provide details of a person of contact	153	5(1-5)	5(1-5)	5(1-5)	21.30 (2)	p<.001
Provide details of support groups	153	4 (1-5)	4 (1-5)	3 (1-5)	37.54 (2)	p<.001
Provide details of regulatory agencies	153	3 (1-5)	2 (1-5)	2 (1-5)	25.79 (2)	p<.001
Provide information about lawyers	153	1 (1-5)	1 (1-5)	1 (1-5)	10.85 (2)	p=.004
Provide ex gratia payments	153	1 (1-5)	1 (1-5)	1 (1-5)	2.000 (2)	p=.368
Follow-up patients/families in the long term	153	2 (1-5)	4 (1-5)	2 (1-5)	19.71 (2)	p<.001

9.3.7 Barriers to being open with patients and families

The most highly rated barriers to being open were a fear of negative patient and family reactions, fear of litigation and managers' concerns about clinicians' response to being accused of malpractice. Managers had fewer anxieties about confidentiality or anonymity and did not fear a lack of institutional support for being open (see Figure 9). Patient safety managers' comments at the end of the survey highlighted a number of important barriers to them being as open as they would like, suggesting overall that while the policies may have been adopted in the majority of NHS organisations much more needs to be done to make their use a daily reality (See Appendix 35).

³⁰ The response scale was a five point Likert scale ranging from 1 (never) to 5 (all the time).

Figure 9: Barriers of being open



9.3.8 Importance and availability of support for staff

Patient safety managers considered that highly important (i.e. mean score above 4) forms of support for staff were: guidance by clinical supervisors, prompt debriefing, information about processes after serious patient safety incidents, peer support groups, occupational health and psychological services, exemption from clinical duties after serious incidents and training on being open; the least highly rated (mean score lower than 4) were chaplaincy support, stress management services and personal legal advice. In terms of availability, certain forms of support that were rated as highly important were not rated as always available. (i.e. guidance by clinical supervisors, prompt debriefing, exemption from duties after serious incidents, peer support groups and training on being open) (see Table 34).

Table 34: Frequency of different types of support for staff³¹

Staff support	Availability		Importance	
	n	Median (Range)	Median (Range)	
Chaplaincy support	153	5 (1-5)	3 (1-5)	
Psychological services	153	5 (1-5)	4.5 (1-5)	
Exemption from clinical duties following incidents	153	4 (1-5)	4 (1-5)	
Information about processes after incidents	153	5 (1-5)	5 (1-5)	
Occupational health services	153	5 (1-5)	4 (1-5)	
Peer support groups	153	4 (1-5)	4 (1-5)	
Personal legal advice	153	3 (1-5)	4 (1-5)	
Prompt debriefing	153	4 (1-5)	5 (1-5)	
Stress management services	153	2 (1-5)	4 (1-5)	
Guidance/mentoring by senior clinical people	153	4 (1-5)	5 (1-5)	
Training on being open	153	3 (1-5)	4 (1-5)	

9.4 Discussion

The study findings showed that almost all patient safety managers who completed the survey are familiar with the Being Open guidance (National Patient Safety Agency 2009). Nevertheless, six years after the initial release of the guidance, 9% of trusts do not have a policy in place and 18% of trusts openly discuss incidents with patients and families half, or less than half, of the time. Disclosure policies seem to be implemented less frequently for less serious incidents, that is, those that do not lead to serious harm or death. A potential explanation for this could be that organisations are more likely to be open when there are higher expectations of a patient complaint. For instance, Bismark et al., in New Zealand found that the propensity of injured patients to complain increased significantly with incident severity: odds of complaint were 11 times greater after serious permanent injuries than after temporary injuries, and 18 times greater after deaths (Bismark and Paterson 2005). Mazor et al., in a study of patients' attitudes to hypothetical scenarios of medical errors, found that

³¹ The response scales were five point Likert scales ranging from 1 (never) to 5 (all the time) for availability and from 1(unimportant) to 5 (very important) for importance.

patients' intention to seek legal advice was significantly higher for non-disclosure in the case of the life-threatening outcome than in the case of the less serious outcome (Mazor et al. 2006). Most patient safety managers reported that the frequency of such discussions is increasing, which potentially reflects the emphasis that being open has received recently at policy level.

Being open with patients in the aftermath of patient safety incidents poses considerable challenges for the organisation and for the clinical staff involved. A host of different barriers have been suggested by empirical studies, such as discomfort and clinical staff's lack of training on how to disclose, a fear of litigation, a culture of infallibility among health professionals and inadequate systems for analysis, discussion and learning from mistakes (Manser and Staender 2005; Kaldjian et al. 2006). Patient safety managers in this study considered that the most important barriers to open discussions with patients and families concern clinical staff's understandable fear of litigation, blame and the reaction of the patient and family. They tended to view institutional barriers as less problematic, in contrast to findings from other studies focusing on clinicians' views (Gallagher et al. 2003; Garbutt et al. 2007; Kaldjian et al. 2007; Kaldjian 2008). Patient safety managers, with a more institutional perspective, perhaps see greater clinical barriers to disclosure whereas clinicians perceive more managerial and organisational barriers. The range of factors that this and previous studies have suggested as potential barriers to being open constitute the context within which guidelines such as the NPSA's Being Open framework are being implemented, therefore it would be valuable in future studies to understand the contextual factors that impede or facilitate openness from the different perspectives of those involved.

Informing patients about what happened and how is of huge importance in maintaining trust, as studies on patients' and the public's attitudes to medical incident disclosure also highlight (Hobgood et al. 2002; Duclos et al. 2005; Cleopas et al. 2006; Iedema et al. 2008; Iedema et al. 2011). When meetings do occur there are signs that organisations do commonly share findings, provide explanations and apologies but less frequently take responsibility for the harm caused. The

causes of the incidents are no doubt complex and may not be due to poor care, so organisations would not necessarily wish to shoulder responsibility and are probably also influenced by fear of potential litigation (Gallagher et al. 2003; Kaldjian et al. 2006). However, accepting responsibility for harm has been associated with higher patient satisfaction (Wu et al. 2009) and the finding of this study that this is followed less than half the time could be damaging for effective discussions with patients and families. A particularly worrying finding is that a high proportion of patient safety managers reported that the first open meeting with patients and families takes place 3 to 6 months after the investigation, which itself may have lasted some months. This implies that many patients and families are waiting up to a year before any clear explanation of serious incidents is given, which is clearly extremely stressful in many cases. Patients are in favour of prompt provision of information about things that go wrong in their care (Hobgood et al. 2002; Duclos et al. 2005; Cleopas et al. 2006; Iedema et al. 2008) and this delay in itself is likely to exacerbate the distress already caused, erode trust and may also increase the likelihood of further complaints and litigation. This is confirmed by the patient interviews of Chapter 7 where two patients who felt that there was deliberate concealment of information regarding their complications were evidently distraught and angry. The survey of patient safety managers also suggests that there is limited representation of clinical staff in comparison to managers at open disclosure meetings, despite evidence suggesting that patients attach great importance to clinical staff who are involved in patient safety incidents being also involved in the communication of the incidents to the patients (Witman et al. 1996).

The provision of support to patients and families appears to be much less well established than open disclosure. Provision of details of a contact person was commonly, but not always, offered to patients whereas other forms of support were offered on a “half the time or less than half the time” basis. A qualitative study investigating patients’ experiences of actual disclosures highlighted that while the initial disclosure and explanation is critical, a host of other issues may weigh heavily in patients’ minds in the aftermath of adverse events. Patients and families, for instance, want financial and other support, changes in practice or an opportunity for patients to meet with staff originally

involved in the adverse event (Iedema et al. 2008). More recently, patients and family members who were involved in high severity incidents in Australia confirmed that open disclosure still falls short of patient and family member expectations, such as their need for more follow-up support (Iedema et al. 2011). The patient studies of this thesis strongly suggest that patients who suffer surgical complications may experience significant emotional distress for very long periods of time after their discharge from the hospital which further emphasises the importance of healthcare organisations investing more effort on following up patients who experience medical harm in the long-run.

Finally, support for staff was clearly recognised to be important in the aftermath of serious incidents but, equally clearly, did not seem to be available to the degree that it was thought to be important. Training on being open, especially, was recognised by our participants as an important structure for staff but was reported as available less than half the time. Provision of guidance for staff on open disclosure and support for staff is almost certainly needed on a wide scale, given that only a small proportion of incidents come to the attention of patient safety managers. Findings from the surgeons' studies in Chapters 5 and 6 in conjunction with existing literature (Engel et al. 2006; Schwappach and Boluarte 2009) suggest that clinicians' ability to cope with the emotional impact of adverse events is very much dependent on available reassurance and opportunities for learning.

9.4.1 Strengths and limitations

This is the first study to my knowledge that examined in detail the current state of practice in English NHS trusts in relation to being open and supporting patients and healthcare professionals in the aftermath of serious patient safety incidents. Moreover, this study is important in that it sheds light on the progress of NHS trusts in meeting the needs of those affected by the occurrence of serious healthcare-related adverse events.

However, the above findings need to be interpreted in the light of certain limitations. First, the participants hold management roles in their organisations and it is likely that their perceptions differ from those of frontline staff. The views of patient safety managers are important in reflecting institutional policy and intentions but they may differ considerably from the experiences of patients and staff involved in serious incidents. For example, following the policy and guidance may not always equal delivering open disclosure, as patients must actually feel that they have had an open and honest discussion and that they have been genuinely supported after the incident. Nevertheless, patient safety managers, as key informants of patient safety policies, are well placed to provide an authoritative view on organisational policy implementation. Another limitation of the study is the fact that the survey was distributed to only one person per organisation. However, the participants were those nominated by their trusts as the most relevant for the provision of information on patient and staff support practices after serious patient safety incidents.

9.5 Conclusions

The findings suggest that there is high awareness amongst patient safety managers of the importance of being more open with patients, but that progress is slow and that some trusts have simply failed to recognise the importance of adequately supporting patients and staff in the aftermath of serious patient safety incidents. The findings of this study in conjunction with the findings of the previous chapters highlight the need for NHS trusts to look closer into the ways in which they manage the aftermath of patient safety incidents and to ensure that sensitive support mechanisms are in place for patients, families and staff.

Chapter 10: Discussion of thesis findings and conclusions

This thesis set out to explore the psychological impact of surgical complications on patients and surgeons and also to identify the psychosocial factors that contribute to it. In this chapter I discuss the key findings of the presented work in relation to each of the aims that the thesis set out to explore (see page 63). I conclude this chapter with a discussion of the methodological limitations of the presented studies, directions for future research and the wider implications of the findings for supporting patients and surgeons in the aftermath of serious surgical complications.

10.1 Summary of key findings by thesis aims

10.1.1 Aim 1: To explore the psychological impact of surgical complications on patients

The systematic review found that there is a substantial amount of surgical literature on the association of complications with health-related quality of life, and more rarely with anxiety and depression. Even though this association was usually part of a general evaluation of different types of surgery, three very interesting findings emerged. Firstly, patients who suffered surgical complications reported significantly lower psychosocial wellbeing than patients without complications in most of the studies. A meta-analysis of studies with available data confirmed that the overall effect sizes of the association of complications with different domains of quality of life including mental and social aspects were significant and clinically important. Secondly, the review concluded that there is a long-lasting psychological impact of complications on patients. A large

number of studies found that patients who suffered complications reported worse quality of life or higher anxiety and depression than patients with uncomplicated recovery for months, sometimes years, after surgery. Lastly, it was not only major complications that were associated with worse psychological wellbeing but also less serious events such as wound infections. The systematic review therefore confirmed that surgical complications of major or minor severity compromise patients' psychological wellbeing above and beyond the effects of surgery and highlighted the need to investigate the psychological mechanisms that may moderate these adverse effects.

Two empirical studies were designed in order to explore the psychological impact of surgical complications on patients and its psychosocial predictors. The patient interview study confirmed that patients who underwent major gastro-intestinal or vascular surgery and had experienced complications were indeed affected not only physically but also emotionally. This was the case both for minor and major complications that had a long-lasting impact on patients' recovery. Feelings of anxiety, depression, frustration and anger were reported by the participants and were often still present two months after their discharge.

A longitudinal cohort study on the association of surgical complications with patients' psychological wellbeing found that patients who had experienced complications of any severity reported significantly higher levels of depression at discharge compared to patients who did not suffer complications. More importantly, the anxiety levels of patients who experienced major complications (i.e. requiring intervention or HDU/ITU management) increased significantly after their surgery unlike patients who did not experience serious complications whose anxiety decreased post-operatively as it is commonly expected (Spielberger et al. 1973; Mark 2003). Two months post-discharge these effects were not significant but this is possibly due to the small sample size at that time-point and the very small percentage of patients with complications. The lack of statistical power two months post-discharge possibly also explains the fact that significant differences were

not found between patients who suffered complications and those who did not on their physical and mental quality of life.

The above data reveal that the psychological impact of surgical complications on patients is significant and that, even though the impact is more prevalent in the short-term, complications often affect patients' psychological welfare for a very long time after their surgery. More importantly, all three studies highlight that in addition to serious complications minor complications may also affect patients emotionally in significant degrees.

10.1.2 Aim 2: To identify the psychosocial factors that moderate the psychological impact of surgical complications on patients

A number of important factors of the psychological effects of complications on patients emerged from the patient interviews. Firstly, the interview study highlighted the importance of healthcare professionals offering compassionate and honest communication when patients experience adverse events in their care. Patients who felt that the complications were explained to them clearly and compassionately were more positive about their experiences. Patients who felt that there was deliberate concealment of information and lack of empathy reported emotional distress, anger, loss of trust in healthcare professionals and even an intention to pursue legal action. These findings are in agreement with literature on the significant relationship between doctors' communication behaviours and patient satisfaction (Clever et al. 2008). More importantly, they support early findings which show that failure of healthcare professionals to communicate adverse events in an honest and compassionate way is detrimental not just for patients' emotional wellbeing but also for patient trust and patients' relationship with their healthcare providers (Vincent 2003; Mazor et al. 2005).

Patients' appraisals of what caused their complications and of how effectively the complications were managed were also important determinants of their feelings. Complications that were perceived as controllable were less burdensome whereas complications that were not managed in time and that were attributed to negligence caused stronger emotional reactions. This finding emphasises the importance of the attributions that patients make in the aftermath of complicated surgery as a significant factor of how seriously they are affected psychologically, in line with literature on the perceived locus of causality and controllability of stressors as predictors of psychological wellbeing (Weiner 1986). Patients' preoperative expectations of the surgical outcome were also an important factor of their reactions. Patients who expected a smooth recovery were more distressed, which highlights the importance of patients' preoperative expectations when complications occur for their post-operative psychosocial functioning (Wheelock et al. 1998; McCarthy et al. 2003). Another factor was the duration of the effects of complications. Patients whose complications had a lasting impact on their day-to-day life reported low mood two months after their discharge even if the complications were not classified as clinically major. Finally, patients who felt adequately supported by their family, friends and healthcare professionals were less bitter which shows that the support that patients receive from their personal networks and the clinical staff are essential factors of their psychological wellbeing in the aftermath of complicated surgery.

The longitudinal cohort study tested the contribution of the majority of the above-emerging factors in the association of patients' post-operative psychological wellbeing with surgical complications. The study found that after controlling for the effects of surgical complications and for patients' baseline wellbeing, more frequent use of emotion-focused coping strategies and lower satisfaction with adequacy of support from confidants were significant predictors of higher anxiety and depression at patients' discharge. These findings highlight that coping and social support, both of which are well known predictors of psychological outcomes in other contexts (Lazarus and Folkman 1984; Schwarzer and Leppin 1991), are significant moderating variables of the extent to

which complications adversely affect patients' psychological wellbeing. The implications of these findings for supporting patients in the aftermath of surgical complications are discussed later.

10.1.3 Aim 3: To explore the psychological impact of surgical complications on surgeons

The third major aim of this thesis was to understand surgeons' experiences of surgical complications. The interviews revealed that surgeons are affected by surgical complications on an emotional, cognitive, behavioural, social and professional level. The participants reported that they often experience intense emotional reactions in the aftermath of serious complications such as guilt, anxiety, anger, a crisis of confidence, worry about their reputation, and worry about the patient. Some surgeons described a period of rumination and difficulty in maintaining concentration, while memories of major complications often lasted for years. Many interviewees also stated that serious complications have an adverse impact on their clinical practice as they tend to become more risk-averse in the management of their patients, which may indicate the presence of traumatic stress (Yehuda 2002). Other effects included not being able to relax and enjoy one's social life and physical reactions (e.g. feeling sick), which are indicative of high levels of anxiety.

Further to the interview study, a cross-sectional survey study on surgeons' wellbeing after their most recent major complication showed that a significant percentage of the participants scored above the cut-off point for traumatic stress of clinical concern during the first month after the incident. Post-traumatic stress was significantly correlated with current levels of anxiety and burnout's emotional exhaustion, which suggests that those surgeons who were seriously affected shortly after their most recent major complication were also more distressed at the present time.

The above data suggest that the stakes of serious surgical complications for surgeons' psychological wellbeing are high and that surgical adverse events hold significant implications not only for surgeons' mental health but also for their professional lives and the quality of their surgical practice.

10.1.4 Aim 4: To identify the psychosocial factors that moderate the psychological impact of surgical complications on surgeons

The interviewees discussed five different groups of factors: case-, surgeon-, patient/family-, team- and institution-related factors. Unexpected and preventable complications had a greater personal impact, in a similar way to complications that happen in elective surgery where the expectations of adverse events are low. Personality and surgical experience were also discussed as important determinants of surgeons' psychological reactions with most of the interviewees suggesting that different surgeons cope differently with stress and also that senior surgeons are affected less due to their higher confidence and a better record of outcomes to rely on. Other quoted factors of surgeons' reactions included the outcome of the complications, with complications that lead to severe disability or death having the strongest emotional impact, then patients' and families' reactions, colleagues' support and institutional culture. The existence of strong blame cultures was often discussed as an additional source of stress that further affects surgeons' wellbeing in the aftermath of complications. Institutions were generally described as not adequately supporting staff in the aftermath of surgical events and certain structures such as the morbidity and mortality meetings were seen as dominated by blame and professional rivalries.

The above factors were subsequently tested in a cross-sectional survey study on surgeons' wellbeing in relation to their most recent major complication. This study found that surgeons'

coping strategies in the aftermath of the complication were consistently and significantly correlated with post-traumatic stress, anxiety and depression. Use of self-distraction in particular, which is associated with higher PTSD symptoms and slower recovery from PTSD, (Clohessy and Ehlers 1999; Ehlers and Clark 2000; Brewin 2003) was highly significantly and positively correlated with most of the psychological outcomes. Moreover it was a significant predictor of traumatic stress of clinical concern in multivariate analysis. Self-blame, active coping, planning and seeking instrumental support were also significantly correlated with worse psychological outcomes. Significant relationships were also found between acute traumatic stress and institutions' punitive response to complications in univariate analysis, in agreement with literature on PTSD which suggests that social environments characterised by blame and negative criticism are an important factor for PTSD development (Holeva et al. 2001). Surgeons' appraisals of the controllability and internality of the causes that led to their most recent major complication were not significantly correlated with surgeons' psychological wellbeing. The only exception was a marginally significant association of an internal locus of causality with lower personal accomplishment. The latter may be explained by Weiner's cognitive theory of emotions which suggests that attributing negative outcomes to internal and controllable factors is related to feelings of guilt which exacerbate negative emotions (Weiner 1986). The lack of further significant relationships with causal attributions may imply that major surgical complications affect surgeons emotionally despite their perceptions of how the complications occurred, even though this explanation does not correspond with the interview findings. A more likely explanation is the insufficient statistical power due to the small sample size of the study and the use of single items for the measurement of surgeons' causal attributions. Lastly, practising gastro-intestinal surgery was predictive of higher odds of scoring above the cut-off point for traumatic stress of clinical concern, which may be explained by the lower expectations of serious surgical complications in gastro-intestinal as opposed to vascular surgery.

Surgeons' emotional reactions to major surgical complications should therefore be interpreted in the context of the coping strategies that surgeons use in order to deal with the stress

of these incidents, their expectations of complications and the institutions' approach to adverse events. The implications of the above findings for supporting surgeons in the aftermath of serious surgical complications will be discussed later.

10.2 Methodological limitations of studies

The above findings should be interpreted in the context of certain methodological limitations of the work presented in this thesis. These are discussed below.

10.2.1 Sampling criteria

Complications were examined only in relation to specific surgical specialties, which limits the generalisability of the findings to the entire population of surgeons and surgical patients. Surgeons or indeed patients who experience complications after different surgical procedures may report different experiences from the populations that were examined in this thesis. Similarly, the patient studies were interested in complications experienced after major surgical procedures, which may question the generalisability of their findings after minor surgery. However, the fact that complications after high-risk surgery negatively affected patients' psychological wellbeing implies that a similar if not bigger impact should also be expected after less complex surgical procedures where the expectations of adverse events are lower.

10.2.2 Sample sizes

The small sample size of the survey study on surgeons' most recent major complication may have been responsible for the lack of significant associations between surgeons' wellbeing and variables of empirical and theoretical relevance (e.g. surgeons' appraisals of the locus of causality and the controllability of the complication). Therefore, the findings of this study should be interpreted with caution.

Secondly, the longitudinal study on the association of surgical complications with patients' psychological wellbeing suffered a significant loss of participants to follow-up. The high attrition rate two months after patients' discharge is probably responsible for the lack of significant effects of the occurrence of complications on patients' wellbeing at that time-point. Also the lack of adequate statistical power did not allow for testing the interactions between psychosocial factors and the occurrence of complications over time. The analysis of these interactions would have offered a more accurate picture of the moderating effects of psychosocial factors in the psychological impact of surgical complications on patients.

10.2.3 Single-site studies

A few studies were either single- or double-site, which may limit the generalisability of the findings to the wider population of surgical patients and surgeons. Organisational issues that are specific to each hospital or to each NHS trust may have affected the participants' reports. The surgeons' studies showed that the institutional culture on adverse events is an important determinant of how surgeons feel in the aftermath of surgical complications. Both sites from which the surgeons of the interview study in Chapter 5 were recruited were large London teaching hospitals and it is likely that

surgeons who work for general district hospitals or hospitals in rural areas have different experiences especially with regard to the availability of support and the existence of blame. This may also apply to the patient studies as both the interviews and the longitudinal study were conducted with patients who were operated in one large London teaching NHS trust. Organisational issues specific to this trust may have had an impact on patients' experiences of the aftermath of surgical complications.

10.2.4 Sensitivity of the topic under investigation

A final overarching limitation of the presented work was pertinent to the sensitive nature of the topic under investigation and the implications of this. As it emerged from the surgeons' interviews, fear of reputation is common when serious complications occur in a surgeon's practice and blame is still prevalent in the NHS. Complications often become terrain for professional rivalries and blame between different surgeons. This aspect of surgical complications may have affected the validity of the findings. For instance, the surgeons who agreed to be interviewed or to complete the survey are likely to be those who felt more comfortable talking about complications. The non-participation of surgeons who potentially felt awkward or defensive about complications may have resulted in sampling bias. Similarly, patients were screened and referred for participation to the interview study by two consultant surgeons. Despite the fact that the sampling criteria were well defined and a purposeful sampling strategy was employed, it is likely that patients who experienced certain complications were excluded from the study due to concerns about confidentiality of sensitive data. Moreover, patients' perceptions of what caused their complications were difficult to explore due to ethical difficulties with probing patients to make judgements in relation to complications that they were not always consciously aware of.

10.3 Directions for future research

Interesting directions for future research have emerged from this thesis. These will be discussed separately for each population.

10.3.1 Patients

The relationship of major surgical complications with post-traumatic stress is a question that needs further investigation. The psychology of trauma and post-traumatic stress was discussed in Chapter 3 as highly relevant for the investigation of the psychological impact of serious patient safety incidents on patients. Even though this thesis did not set out to examine the occurrence of PTSD after surgical complications, patients' interviews suggested that in some cases patients who suffer serious complications vividly recollect their complicated recovery two months after their discharge from the hospital. The longitudinal study also suggested that patients who suffer serious complications report an increase in their anxiety levels at discharge. Given that PTSD falls in the spectrum of anxiety-related disorders (American Psychiatric Association 2000), this data points to a potential link of serious complications with the occurrence of post-traumatic stress and highlight the importance of future research on this association.

Future studies should also extend the investigation of the psychological impact of surgical complications with bigger sample sizes, more follow-up assessments and multiple sites. Large sample sizes with small attrition rates will allow the use of advanced statistical techniques for the accurate analysis of longitudinal data. The mixed linear models that were used in Chapter 9 are an example of a suitable statistical approach for longitudinal data analysis but they were underpowered for the investigation of interactions. Multi-site studies with patients from different surgical

specialties will also help us understand the contextual factors that may moderate the association of complications with patients' wellbeing and will increase the generalisability of the findings to the wider population of surgical patients.

Moreover, patients' appraisals of the causes that led to their complications have not been fully tested in the longitudinal study due to the sensitivity of this topic. However, due to the theoretical importance of causal attributions in explaining psychological reactions to stressful life events (Weiner 1986) as well as due to evidence from the patient interviews which suggested that patients' perceptions of who or what was responsible for their complications affected their feelings, future studies should try to overcome this barrier.

A further step in the investigation of the aftermath of surgical complications would be the design and evaluation of support interventions targeted at the psychological needs of patients who suffer serious complications. This thesis has provided data that could serve as the basis for interventional work in this area.

Finally, the aims of this thesis were specific to the experience of surgical adverse events and the extent to which the findings are relevant to patient safety incidents that occur in different healthcare contexts is unknown. Therefore, future studies should aim to extend our knowledge of the psychological impact of patient safety incidents on patients and its determinants beyond the context of surgery.

It is worth noting that some of the above issues (e.g. the association of surgical complications with PTSD and the use of multiple sites) are currently being addressed in a replication of the longitudinal study that was presented in Chapter 8 with surgical patients from 25 NHS sites (and a sample size of more than 1,000 patients). This study also includes a long-term follow-up assessment (i.e. one year post-surgery), which will track the psychological impact of complications over a longer period of time.

10.3.2 Surgeons

Directions for future research also emerged with regard to surgeons' experiences of surgical complications. The survey study in Chapter 6 found that one third of the surgeons scored above the cut-off point for traumatic stress of clinical concern. The interview data suggested that sometimes surgeons become more vigilant and suffer from loss of concentration and rumination in the aftermath of serious complications, symptoms that are suggestive of post-traumatic stress disorder (American Psychiatric Association 2000; Yehuda 2002). Therefore, surgeons may also be at risk for chronic PTSD after major complications, especially since symptoms of acute traumatic stress are strongly associated with the development of chronic PTSD (Yehuda 2002; Brewin et al. 2003). Future studies should investigate the extent to which surgical complications are associated with chronic PTSD in surgeons and other groups of healthcare professionals.

Longitudinal designs with bigger sample sizes are also needed in order to establish the direction of the relationships between surgeons' social support, appraisals and coping after the occurrence of surgical complications with their psychological wellbeing and to accurately identify mediating and moderating variables. Moreover, further evaluation research is needed on the effectiveness of existing or new support programmes in meeting the needs of the small number of surgeons (and of course of other clinicians) who are affected to the point that personal life and clinical practice deteriorate. Finally, a similar investigation of the psychosocial predictors of the psychological impact of serious patient safety incidents on staff is warranted with healthcare professionals who work in different roles and/or in different medical settings.

10.4 Implications of findings

The findings of this thesis hold wider implications for supporting patients and surgeons in the aftermath of (serious) surgical complications. These are discussed below.

10.4.1 Supporting patients

Distress experienced due to surgical complications could jeopardise patients' physical recovery as stress is associated with slower recovery from surgery (e.g. slow wound healing etc.) (Herbert and Cohen 1993; Kiecolt-Glaser et al. 1998; Kiecolt-Glaser et al. 2002). Supporting patients to cope more effectively with the stress of their complicated recovery could therefore be beneficial both for their psychological wellbeing and their physical recovery. Different types of support of potential value to patients are discussed below.

10.4.1.1 Psychological support

As a first step healthcare organisations should have arrangements in place for psychological support. Patients who are distraught due to the experience of serious surgical complications may welcome the support offered by a mental health professional, as suggested by some interviewees in Chapter 7. Psychological support should not be offered on a prescriptive basis as not every patient would benefit from it, however it is important that mental health specialists are available in hospitals and that patients can easily access them when they need help in order to cope with overwhelming stress.

10.4.1.2 Provision of clear and honest information

The interview study also suggested that when patients perceive that there is concealment of information with regard to their complications they are likely to experience anger, serious distress and may consider legal action, in agreement with early findings (Vincent et al. 1993; Vincent et al. 1994). The survey study with patient safety managers highlighted the NHS's lack of progress in the provision of prompt and forward information in the aftermath of serious patient safety incidents. Provision of timely information was not reported as routine with two thirds of the discussions taking place 3 to 6 months after the investigation of serious incidents. Therefore, healthcare organisations must increase their efforts to establish an open and supportive approach with patients who suffer serious surgical complications (or other types of healthcare harm) and must ensure that injured patients and their families receive honest, clear and timely information.

10.4.1.3 Follow-up support

Healthcare organisations should also improve their arrangements for the follow-up of injured patients. The patient safety managers' study highlighted the infrequent provision of follow-up support for patients who suffer serious patient safety incidents. Considering one of the main findings of this thesis that patients' psychological wellbeing is compromised by surgical complications for long periods of time, patients would possibly welcome the provision of long-term support (e.g. a simple phone call about how they are getting on with their recovery or help to access more specialised resources of support).

10.4.1.4 Support from hospital staff

The patient interviews showed that when patients were happy with the quality of nursing care and the support from their surgeons they were less negative about their experience of complications. One patient who suffered a series of complications that prolonged his hospital stay stressed the important role that the nurses and his consultant surgeon played by listening to him and encouraging him when he was feeling depressed and helpless. Therefore, hospital staff who look after patients who suffer surgical complications, be it nurses, surgeons or health-allied professionals, need to be aware of the challenges of complicated surgery for patients' psychological wellbeing and should ensure that their psychological needs are not neglected. Moreover, in light of the importance of clear and honest information about adverse events, those responsible for the care of patients who suffer surgical complications must try to hold truthful, compassionate and clear discussions with patients and their families about these incidents.

10.4.1.5 Support in the community

The findings of the thesis also hold important implications for patient care in the community. The research presented in this thesis showed that when patients who suffer surgical complications return to their home they are often still emotionally distressed. Therefore, it is essential that healthcare professionals who see surgical patients post-operatively (e.g. general practitioners, district nurses or carers) are also aware of the psychological burden that surgical complications impose on patients' lives. As a result, they will be more prepared to support patients in a holistic manner by taking into account their psychological needs and by referring them to specialised support services when they struggle. The finding that psychosocial factors such as patients' coping

and the perceived adequacy of received support are important moderators of the impact of complications on patients' post-operative wellbeing suggests that healthcare professionals should consider patients' wider psychological profiles as a way of identifying those patients who are at highest risk of severe emotional distress.

10.4.2 Supporting surgeons

The findings of this thesis also hold significant implications for supporting surgeons. The finding that one third of the surveyed surgeons scored above the cut-off point for traumatic stress of clinical concern confirms that under certain conditions surgeons are seriously affected emotionally by surgical complications. In the light of a reciprocal cycle of symptoms where distress experienced due to patient adverse events leads staff to further suboptimal care and more errors (Schwappach and Boluarte 2009), the stakes for supporting surgeons in the aftermath of major complications are high. Some options for supporting surgeons to deal effectively with the emotional burden of serious surgical complications are discussed below.

10.4.2.1 Surgical training

Firstly, it may be useful for surgical training to include more aspects on the human facets of surgical complications. Early guidance on the potential personal, institutional and patient/family reactions to surgical complications, as well as on the availability of support, may be particularly helpful for young surgeons and may prevent symptoms of severe psychological distress, which may lead to further suboptimal care. Moreover, resilience training at the start of surgeons' careers could help them

build effective coping strategies for when they are confronted with patient complications that are emotionally demanding. This is very much supported by the finding of the survey study in Chapter 6 where surgeons' coping strategies after their most recent major complication were consistently and significantly associated with their psychological wellbeing. Use of non-adaptive coping mechanisms such as self-distraction were significantly associated with worse wellbeing outcomes such as acute traumatic stress of clinical concern. Also, in light of an earlier study which showed that junior surgeons are uncertain about how to effectively cope with their surgical practice-related stress (Wetzel et al. 2006), teaching junior surgeons adaptive coping strategies would be beneficial for their wellbeing in the aftermath of serious surgical complications.

10.4.2.2 Mentoring

A large proportion of the surgeons who were interviewed in Chapter 5 highlighted the lack of a structured and formalised mentoring system during surgeons' training. The need for a better mentoring system was the most commonly suggested type of support that would be relevant for surgeons in the aftermath of serious complications. Moreover, both of the surgeons' studies and the patient safety managers' study in Chapter 9 suggested that guidance by senior clinical people are among the most valued sources of support for surgeons (and other clinicians) who struggle with the emotional burden of serious adverse events. A mentoring system therefore within which young surgeons will have the opportunity to discuss confidentially the different aspects of complications including their emotional reactions, could be of great value for surgical trainees and junior consultants. The surgical community and those involved in the management of surgical services may therefore need to consider introducing more structured mentoring systems for young surgeons. Further evaluation research on the effectiveness of formal mentoring for surgeons' wellbeing is certainly needed.

10.4.2.3 Improvement of teamwork

Teamwork in surgical teams has recently received much attention in the literature with many studies proving the importance of good quality teamwork on surgical outcomes and patient safety (Catchpole et al. 2008). Aspects of teamwork, such as colleagues' reactions and the value of surgeons getting together to discuss the management of complications, have also been discussed by the interviewees of Chapter 5 as facilitators of, or barriers to surgeons' coping with the emotional burden of surgical complications. For example, a formal teamwork approach in the management of complicated cases such as surgeons operating in pairs was discussed by some among the interviewed surgeons as a structure that would help them cope with complications more constructively and would prevent reactive decision-making. Discussing complications with peers was also the most highly appraised source of support by the participants of Chapter 6. Therefore, the data suggest that surgical teams may benefit from more formal teamwork arrangements for the management of serious surgical complications.

10.4.2.4 Psychological interventions

Structures with a psychological focus may also be of value for surgeons in the aftermath of serious complications. For instance, peer support groups where clinicians of various seniority levels discuss their human reactions to emotionally challenging incidents with the help of a facilitator are well established structures in other countries such as the US and have been implemented with much success (e.g. Schwartz rounds) (Shanafelt et al. 2002). More recently, researchers from the US have developed a toolkit to help healthcare organisations implement support programs for clinicians suffering from the emotional impact of errors and adverse events (Pratt et al. 2012). Interventions of

this kind may also be helpful for surgeons who are seriously affected to the point that personal life and clinical practice deteriorate. In light of the stigma that is attached to the use of psychological services by healthcare professionals, as suggested by some interviewees in Chapter 5, the acceptability and benefits of psychological support structures aimed at surgeons in the aftermath of serious surgical complications need to be further investigated.

10.4.2.5 Blame-free culture

The interview study revealed that many surgeons hold negative views about surgical audit meetings due to the existence of strong blame cultures and a lack of focus on supporting surgeons to improve and learn. More than two thirds of the surveyed surgeons in Chapter 6 agreed that their institutions adopt a punitive approach to surgical complications. More importantly, a punitive approach to complications by healthcare institutions was significantly associated with higher traumatic stress while the existence of strong blame cultures was reported by the interviewees as one of the factors that impact negatively on their emotional wellbeing in the aftermath of serious complications. The change of organisational culture from that of blame towards openness and justness is undoubtedly a difficult task and one that cannot be achieved without a lot of planning and re-organisation (Khatri et al. 2009). However, considering the implications of institutional culture for surgeons' (and other healthcare professionals') wellbeing in the aftermath of serious complications, the data of this thesis strongly suggest that healthcare organisations and clinical leaders need to put more effort into re-establishing surgical audit meetings and other institutional structures as educational forums rather than opportunities for personal rivalries and blame passing.

10.5 Concluding remarks

The work presented in this thesis set out to explore the aftermath of surgical complications by using various methodological designs and a multiple stakeholders approach. Patients, surgeons and patient safety managers were the informants of the research questions that this thesis embarked on.

Firstly, this thesis addressed the lack of evidence in the patient safety literature regarding the psychological outcomes and the psychological factors that are associated with the impact of adverse events on patients. This gap was addressed in the context of surgery by using a systematic literature review, an interview study and a longitudinal cohort survey study. Both short- and long-term psychological effects of surgical complications on patients were identified. A variety of psychosocial factors were found to contribute to the severity of patients' reactions to complications such as their attributions, their coping strategies and their perceptions of support. The implications of these findings for patients' psychological and physical wellbeing were discussed and the need for more integrated and better thought-out support for patients who suffer complications has been emphasised.

This thesis also addressed gaps in our knowledge of surgeons' experiences of surgical complications. The surgeons' studies strongly suggest that surgeons are also affected psychologically by adverse incidents that happen in their patients' care and that factors such as their coping strategies and the existence of a blame culture in healthcare institutions affect the intensity of their emotional reactions. The implications for supporting surgeons in the aftermath of serious surgical incidents have also been highlighted and different options of support have been discussed.

Lastly, an exploratory study on the management of the aftermath of serious patient safety incidents in the NHS has provided data on the current practices of healthcare organisations in

relation to supporting those involved in serious patient safety incidents. This study highlighted important discrepancies between best and actual practice and showed that healthcare organisations need to better attend to injured patients' and healthcare staff's needs when serious adverse events occur. This study re-affirms the importance of the findings presented in this thesis and points to the need for more interventions aimed at supporting patients and surgeons in the aftermath of serious surgical complications.

I would like to conclude this thesis by saying that this work has been a very important journey for me that taught me a lot both as a researcher and as a psychologist. I hope that this work will contribute to further research in the neglected area of the aftermath of medical harm and will help improve patients' and healthcare professionals' experiences when such unfortunate incidents occur.

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Appendix 1: Search strategies of systematic review

Embase Classic+Embase

1. exp mental stress/
2. exp emotion/
3. exp depression/
4. exp ANXIETY/
5. exp posttraumatic stress disorder/
6. exp "quality of life"/
7. exp wellbeing/
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp surgery/
10. exp complication/
11. 9 and 10
12. exp surgery/co [Complication]
13. exp perioperative complication/
14. exp peroperative complication/
15. exp postoperative complication/
16. exp preoperative complication/
17. exp surgical error/
18. exp iatrogenic disease/su [surgery]
19. exp anesthesia complication/
20. exp ANESTHESIA/co [Complication]
21. exp anesthesia/
22. exp complication/
23. 21 and 22
24. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 23
25. exp patient/
26. adult/
27. female/
28. male/
29. 25 or 26 or 27 or 28
30. 8 and 24 and 29
31. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or

wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or awareness or iatrogen* or ((adverse or unfavourable or unfavorable or untoward or undesired) adj (outcome*1 or effect*1 or event*1 or incident*1 or reaction*1))))).ti,ab.

32. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or peri operative or per-operative or peroperative or intra-operative or intraoperative or intra operative or anesth* or anaesth*).ti,ab.

33. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.

34. 31 and 32 and 33

35. 30 or 34

36. limit 35 to (human and english language)

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)

1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or peri operative or peroperative or per-operative or intra-operative or intraoperative or intra operative or anaesth* or anesth*).ti,ab.
3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))))).ti,ab.
5. (((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))))).ti,ab.
6. 2 and 5
7. 2 and 3 and 5
8. exp Stress, Psychological/
9. exp Emotions/
10. exp Depression/
11. exp Anxiety/
12. exp Stress Disorders, Post-Traumatic/
13. exp "Quality of Life"/
14. 8 or 9 or 10 or 11 or 12 or 13
15. exp Medical Errors/
16. exp Postoperative Complications/
17. exp iatrogenic disease/su [surgery]
18. exp Anesthesia/ae, co [Adverse Effects, Complications]
19. 15 or 16 or 17 or 18
20. 14 and 19

- 21. exp Patients/
- 22. exp adult/
- 23. exp women/
- 24. exp men/
- 25. exp research subjects/
- 26. 21 or 22 or 23 or 24 or 25
- 27. 14 and 19 and 26
- 28. 7 or 27
- 29. limit 28 to (english language and humans)

PsychINFO

1. (psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic or post-traumatic or PTSD or QOL or quality of life or well-being or wellbeing).ti,ab.
2. (surg* or post-operative or postoperative or post operative or peri-operative or perioperative or peri operative or peroperative or per-operative or intra-operative or intraoperative or intra operative or anaesth* or anesth*).ti,ab.
3. (patient* or inpatient* or in-patient* or outpatient* or out-patient* or participant* or women or men).ti,ab.
4. (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))).ti,ab.
5. ((psycholog* or psychosocial or psycho-social or psychiatr* or emotion* or feeling* or anxiet* or depressi*2 or posttraumatic stress or post-traumatic stress or PTSD or QOL or quality of life or wellbeing or well-being) adj25 (complication*1 or harm or error*1 or poor outcome or iatrogen* or awareness or ((adverse or unfavourable or unfavorable or untoward or undesired or unanticipated) adj (outcome*1or effect*1 or event*1 or incident*1 or reaction*1))))).ti,ab.
6. 2 and 5
7. 2 and 3 and 5
8. exp Psychological Stress/
9. exp emotions/
10. exp "depression (emotion)"/
11. exp Anxiety/
12. exp posttraumatic stress disorder/
13. exp "Quality of Life"/
14. exp well being/
15. 8 or 9 or 10 or 11 or 12 or 13 or 14
16. exp postsurgical complications/
17. exp patients/
18. exp Human Females/
19. exp human males/
20. 17 or 18 or 19

21. 15 and 16 and 20

22. 7 or 21

23. limit 22 to (human and english language)

Appendix 3: Edited Newcastle-Ottawa scales for quality assessment of systematic review studies

COHORT STUDIES³²

Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average *surgical patients undergoing the examined surgical procedure* in the community *
- b) somewhat representative of the average *surgical patients undergoing the examined surgical procedure* in the community *
- c) selected group of users e.g. nurses, volunteers (*not applicable*)
- d) no description of the derivation of the cohort

2) Selection of the non-exposed cohort

- a) drawn from the same community as the exposed cohort *
- b) drawn from a different source
- c) no description of the derivation of the non-exposed cohort

3) Ascertainment of exposure (*exposure is the presence of surgical complications*)

- a) secure record (e.g. surgical records, scans, blood tests etc.) *
- b) structured clinical examination*
- c) validated self-report measure for assessment of pain, incontinence etc.*
- d) non validated patient self report for assessment of complications
- e) no description

4) Demonstration that outcome of interest was not present at start of study (*Criterion not applicable to the purposes of this systematic review*)

- a) yes *
- b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for *baseline wellbeing outcome (e.g. QOL, anxiety, depression)* *
- b) study controls for any additional factor (*age, sex or any other patient demographic/clinical factor*)*

Outcome

1) Assessment of outcome (*QOL or anxiety or depression or other wellbeing outcome*)

- a) validated self-report measure or formal psychological assessment*

³² A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

- b) non-validated measure
- c) no description

2) Was follow-up long enough for outcomes to occur

- a) yes (more than 3 months after major surgery/more than 1 month after minor surgery) *
- b) no
- c) range of follow-up period during assessment for one time-point too big

3) Adequacy of follow-up of cohorts in longitudinal studies/of response rate in cross-sectional studies

- a) complete follow-up - all subjects accounted for *
- b) subjects lost to follow-up unlikely to introduce bias - small number lost – (*> 70% follow-up, or description provided of those lost*) (for cross-sectional studies: *response rate > 50%, or description provided of non-respondents*) *
- c) follow-up rate < 70% and no description of those lost (for cross-sectional studies: *response rate < 50% and no description provided of non-respondents*)
- d) no statements

CASE-CONTROL STUDIES³³

Selection

1) Is the case definition adequate?

- a) yes, with independent validation (e.g. >1 person/record/time/process to extract information on complications, or reference to primary record source such as x-rays or medical/hospital records)*
- b) yes, with record linkage (e.g. ICD codes in database) or self-report with no reference to primary record
- d) no description

2) Representativeness of the cases

- a) consecutive or obviously representative series of cases *
- b) potential for selection biases or not stated

3) Selection of Controls

- a) hospital controls (i.e. patients without complications) *
- b) community controls
- c) no description

4) Definition of Controls-*Criterion not applicable for the purposes of this systematic review*

- a) no history of disease (endpoint) *
- b) no description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis

- a) study controls for *baseline wellbeing outcome* (e.g. QOL, anxiety, depression) *
- b) study controls for any additional factor (age, gender, ethnicity, comorbidities)*

Exposure

1) Ascertainment of exposure

- a) secure record (e.g. surgical records, scans, blood tests etc.) *
- b) structured clinical examination*
- c) validated self-report measure for assessment of pain, incontinence etc.*
- d) non-validated patient self report for assessment of complications
- e) no description

2) Same method of ascertainment for cases and controls

- a) yes *
- b) no

3) Non-Response rate

- a) same rate for both groups *
- b) non-respondents described
- c) rate different and no designation

³³ A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Appendix 4: Definitions and methods of surgical complications' recording: Gastro-intestinal surgery studies

Citation	Complications (Definitions and/or range)	Method of assessment
1. Bruns	Surgical (e.g. bile leak or biloma, pneumothorax, wound infection, liver abscess, bleeding, and surgical dehiscence) and medical (e.g. pleural effusion, renal failure, hepatic failure, pneumonia, cardiac insufficiency, and cholangitis)	Patient records
2. Liu	-Digestive, skin, genitourinary, surgical, medical, immediate indirect complications -Early complications: those that were first recorded within 30 days of the surgery. Late complications: occurring 31 days after surgery. Only the first occurrence of each complication was counted	Patient computerised data
3. Bloemen	Only severe complications were considered: Grade III or IV complications (according to Dindo's model) were defined as severe, whereas absence of complications or Grade I and II complications were defined as absent or mild complications	Patient records
4. El-Awady	Postoperative complications: seroma, haematoma, 2ry infection, neuralgia and anaesthesia	Patient observations
5. Scarpa	Medical and surgical complications and need of reoperation (2 anastomotic leaks, 3 intestinal obstructions, 2 intestinal bleeding, and a wound infection were recorded and two re-laparotomies)	Not specified
6. Siassi	Postoperative complications (anastomotic leak, wound infection, delayed food intake, fever, and bladder dysfunction)	Not specified
7. Dasgupta	Major complications were defined as those associated with systemic illness requiring transfer to a higher level of care (high-dependency or intensive care unit) or requiring relaparotomy, or complications needing interventional radiology. Bile leakage was classified as major if it persisted for more than 5 days. Wound infection was classified as major if antibiotic treatment for more than 7 days was necessary or if it caused systemic illness or required wound debridement. Derangement in liver function was not considered a major complication, unless associated with persistent hyperbilirubinaemia or encephalopathy.	Not specified
8. Rutegard	Technical surgical complications, including postoperative bleed exceeding 2000 ml or requiring a reoperation, anastomotic insufficiency, necrosis of the substitute, damage to the recurrent nerve, thoracic duct damage or gastric perforation	Prospective scrutiny of medical and histopathological records/operation charts/extensive study protocol with predefined exposure alternatives was completed by researchers ensuring uniformity.
9. Pittman	Ostomy complications: skin problems, leakage, and difficulty with adjustment (i.e. leakage, peristomal irritant dermatitis, pain, bleeding, stomal necrosis, prolapse, stenosis, herniation, retraction, infection, mucotaneous separation, difficulty adjusting)	Patient reports: Participants rated the extent to which each ostomy complication was a problem for them using a scale 0 to 10. Scores of 8 to 10 were categorized as mild, 5 to 7 as moderate, and 0 to 4 as severe
10. Rea	Postoperative complications requiring intervention.	Not specified
11. Sharma	Postoperative complications: wound, urinary tract and chest infections, cardiac and respiratory complications, deep venous thrombosis, pulmonary embolism and complications related to anastomotic breakdown	Not specified
12. Avery	A major complication was defined as reoperation, readmission to the high-dependency or intensive care unit, readmission to the hospital within 30 days of operation, or death within 30 days of operation or later if the patient did not leave the hospital	Not specified
13. Dubernard	Retrospectively listed complications: rectovaginal fistula diagnosed in 6 women (10.3%), rectovaginal fistulae in 4 women requiring both colorectal and vaginal resections, and two occurred in women undergoing a partial necrosis of posterior vaginal cuff probably related to extensive electrocoagulation. A woman underwent a haemoperitoneum diagnosed on postoperative hour 3 related to a vessel injury of the protective colostomy treated by laparoscopic coagulation. Two others complications were observed including an uroperitoneum diagnosed on day 1 requiring a ureteral stent for 6 weeks and an abscess behind colorectal anastomosis diagnosed on postoperative day 6 requiring a laparoscopic drainage.	Patient observations
14. Lim	Anastomotic leaks, clinical & subclinical: Postoperatively, all patients were monitored for symptoms and signs of an anastomotic leak. Symptoms included any of the following: abdominal pain, abdominal distention, or rectal discharge. Signs included any of the following: abdominal tenderness or peritonism, tachycardia and arrhythmias, pyrexia (> 37.5-C), elevated white cell count, or elevated serum C-reactive protein. The presence of any unexplained symptom or sign and failure of the patient to progress postoperatively necessitated exclusion of an anastomotic leak. Leaks that presented in the immediate postoperative period were confirmed with CT scanning and/or WCE and were regarded as clinical leaks (CL). The method of treatment for each patient with a CL was recorded. Patients with a protective ileostomy were required to undergo WCE within three months of their operation for evaluation of the anastomosis before closure of ileostomy. Any previously undetected radiologic leak detected in this manner was regarded as a subclinical leak (SCL.)	Patient observations, CT scans, WCE
15. Mentis	Complications were noted/ To assess the rates of early and prolonged Anal Incontinence (AI) following LIS, the FISI score was calculated preoperatively and at 2 and 12 months postoperatively. The only postoperative complication noted in this series was perianal abscess/fistula, which developed in three cases.	Patient examination/ FISI score (this index incorporates patient and surgeon ratings of severity with and the score ranging from 0 (no incontinence) to a maximum possible score of 61)

16. Viklund	The complications that were deemed to be of clinical relevance were defined by a group of leading Swedish esophageal surgeons prior to the inclusion phase of the study. These complications were grouped into anastomotic leakage (including necrosis of the substitute), infections (intra-abdominal or intrathoracic abscess, sepsis, or wound infection where intervention was needed), respiratory insufficiency (need for re-intubation or severe pneumonia), cardiac complications (myocardial infarction, or arrhythmia with need for intervention), technical complications (postoperative bleeding >2000 ml or need for reoperation, injury to the recurrent laryngeal nerve, or the thoracic duct first identified after surgery), anastomotic strictures, and others (intervention needed to treat embolus, deep venous thrombosis, rupture of the wound, intestinal obstruction, stroke, renal failure, or liver failure)	Patient records
17. Delaney	Complications occurred in the 30-day postoperative period in 19 patients (23%). Major complications occurred in 9 patients (11%), including anastomotic leak (1), intraabdominal abscess (1), bleeding (4), venous thrombosis (1), renal failure (1), and pneumonia (3). Seven patients (9%) were readmitted in the 30-day period for dehydration (1), intraabdominal abscess (1), small bowel obstruction (2), pneumonia (1), anastomotic leak (1), and wound infection (1)	Database review
18. Kalliomaki	Persistent postoperative pain (patients with pain of Grade 3, i.e. pain that could not be ignored but did not interfere with everyday activities, or higher in the IPQ)	Patient reports (Inguinal Pain Questionnaire) & clinical examination
19. Bitzer	Postoperative complaints: Any complaint 33.8% (49), Wound infection 3.8 % (5), Seroma 10.0% (13), Pneumonia 0.8% (1), other complaints 21.5 (28)	Patient reports
20. Hawn	Complications were summarized by 4 categories: (1) hematoma/seroma, (2) orchitis, (3) neuralgia of the leg or groin, and (4) other. Complications classified as "other" included: (1) early postoperative complications (urinary tract infection, urinary retention, and hematuria); (2) life-threatening complications (respiratory insufficiency, myocardial ischemia, cardiac arrhythmia, intraoperative hypotension, and stroke); and (3) long-term complications (4 weeks or more postoperative	-Patient reports for neuralgia & orchitis -Expert consensus for life-threatening complications
21. Anthony	Morbidity was defined as any event that resulted in the need for additional therapy or readmission to the hospital within 30 days of initial discharge. Patients with multiple morbid events were classified according to the most significant complication.	Not specified
22. Champault	Early complications requiring therapy occurred in 10 patients (6.5%): antibiotherapy for pulmonary atelectasis or pneumonia was required for 3 patients. Two of them had a prolonged ileus, 4 minor wounds problems and the last a urinary retention. 17 slippage (11.2%) occurred with a peak incidence during the second postoperative year. Band erosion with penetration into the stomach occurred in 5 cases (3.3%) between 10 and 38 months postoperatively. Access port problems (infection, hematoma, leak, disconnection) occurred in 12 patients (7.8%). 16 bands have been explanted (5%), associated with erosion (n=5), obstruction (n=5), immediate intolerance (n=4), and recurrent tubing break (n=1).	Not specified
23. Chang	Operation related complications, including gastrojejunal anastomotic stricture (12 patients), gastrojejunal anastomotic ulcer (9), upper gastro-intestinal bleeding (1) and GORD (2)	Not specified
24. Douma	Surgery-related complications	Self-reports & medical records
25. Ince	No reference	Not specified
26. Riss	Anastomotic leakage: Defined as grade A (no change in patient's management) in 7 patients (43.7%), grade B (requires active therapeutic intervention but is managed without relaparotomy) in 3 patients (18.8%) and grade C (requires relaparotomy) in 6 patients (37.5%)	Review of the institutional colorectal database and individual chart reviews.
27. Polese	Postoperative complications (in particular anastomotic stenosis) Anastomotic stenosis: After surgery, all patients were regularly assessed in the outpatient clinic and underwent rectoscopies 3 months after surgery and thereafter every 6 months. During the examination the patients were also questioned about their bowel habits, faecal continence, and if they were experiencing abdominal pain. Rectoscopic examinations were utilised to evaluate the distance from the anal verge to the anastomosis, the presence of anastomotic stenosis and signs of recurrence. An anastomotic stenosis was defined as a narrowing of the lumen impeding passage of an 18 mm rectoscope. Patients diagnosed with stenosis were considered symptomatic if they complained of constipation or abdominal pain. Whenever an anastomotic stenosis was found, a flexible endoscope was advanced beyond the stenosis to carry out a full evaluation.	Clinical examination
28. Kement	-Anal incontinence/Patients with WIS 6 1 were classified as being incontinent. Then, a subgroup analysis was conducted on incontinent patients according to their severity of incontinence. -Severity of incontinence was defined as mild or severe when the WIS scores were <=4 or >= 5, respectively. A blinded observer to the severity of the problem in another general surgery department examined the incontinent patients with EUS to assess the thickness of the remaining internal sphincter in the anterior, posterior and contralateral portions, and to evaluate whether or not an injury was present in the external sphincter.	Patient reports: Wexner Incontinence Score system (WIS) ³⁴
29. Targarona	Hernia recurrence: Recurrence was defined as any migration of the cardia to chest level or evidence of a new paraesophageal sac.	A barium swallow was given to all patients to rule out an anatomic recurrence. An independent radiologist evaluated all the explorations.

Appendix 5: Definitions and methods of surgical complications' recording: Cardio-thoracic surgery studies

Citation	Complications (Definitions and/or range)	Method of measurement
1. Gjeilo	Chronic pain (pain arising after surgery and persisting either continuously or intermittently for 3 months or more)	BPI (Brief Pain Inventory)
2. Merkouris	Retrospective list of complications: Atrial fibrillation (N=25, 39.7%), re-exploration for bleeding 3 (5%), low cardiac output syndrome 4 (6%), acute respiratory failure 2 (3%), sternal wound infection 1 (2%), neurological dysfunction 7 (11). After discharge 8 patients reported mild problems related to leg incision healing or swelling, chest incision discomfort and medications	Not specified
3. Peric	The patients were observed for the presence and absence of postoperative complications. There was a low cardiac output (cardiac index lower than 2 L/min/m ²), mechanical ventilation longer than 24 hours, reoperation for bleeding, sternal wound infection, perioperative myocardial infarction (confirmed by ECG, laboratory, and echocardiography), pericardial effusion (with diameter longer than 10 mm), arrhythmic complications (atrial fibrillation, ventricular tachycardia, ventricular fibrillation), abdominal complications, and other complications)	Observations/clinical tests (ECGs, echocardiography, laboratory tests)
4. Le Grande	Post-surgical complications such as cardiac arrhythmias, stroke and infections	Hospital records
5. El Baz	Postoperative events such as use of inotropes, atrial arrhythmias, or ventricular arrhythmias, sternal resuturing, re-exploration for bleeding, and time spent on mechanical ventilation	Registry database, medical notes, outpatient notes and intensive therapy unit charts
6a. Myles	1. Respiratory: postoperative mechanical ventilation for more than 24 h or pneumonia, defined as pulmonary infiltrate with positive microbial cultures; 2. Cardiac: arrhythmia requiring treatment with antiarrhythmic medication or electrical cardioversion reversal; radiologic evidence of pulmonary edema; or myocardial infarction, defined by new Q waves on electrocardiogram or creatine kinase-MB isoenzyme concentration greater than twice normal; 3. Renal: acute renal failure, defined by serum creatinine concentration greater than 200 M; 4. Neurologic: stroke, defined as a new central neurologic deficit; 5. Sepsis: wound infection requiring excision of tissue or antibiotic therapy, or positive microbial culture (other than pneumonia).	Clinical and laboratory tests (microbial cultures, radiologic data, electrocardiograms etc.)
6b. Myles	See 7a	See 6a
7. Jarvinen	Perioperative myocardial infarctions: The criteria of perioperative myocardial infarction (PMI) included significant new electrocardiographic (ECG) Q waves in at least two adjacent leads (greater than 0.04 s in duration with a depth of at least one third of the height of the R wave in the same QRS complex) or creatine phosphokinase isoenzyme MB (CK-MB). 75 IU/l in one of three serial postoperative samples. A cardiologist reviewed 12-lead electrocardiograms routinely on the day before surgery, 4 h postoperatively, on the first 2 postoperative mornings, on the fourth postoperative day and at other times if clinically indicated, and they were reviewed by a cardiologist. Myocardial enzymes were measured postoperatively at 6 and 18 h (or more frequently if clinically indicated). PMI was defined as infarction occurring within 7 days after surgery.	Clinical examination/clinical tests (ECGs, echocardiography, laboratory tests)
8. Martin	Rates were calculated for perioperative myocardial infarction, mediastinitis, superficial wound infection, septicemia, permanent stroke, transient ischemic attack, continuous coma, prolonged intubation, ventilator-associated pneumonia, cardiac tamponade, atrial fibrillation, reoperation for bleeding, renal failure, renal failure which required dialysis, and length of stay. Definitions by the Society of Thoracic Surgeons National Adult Cardiac Surgery Database Registry	Not specified
9. Jideus	SWIs: The clinical diagnosis of SWI was made by the surgeon performing the re-exploration and based on both preoperative signs and symptoms (such as fever, chest pain, purulent or serous secretion from the wound, sternal dehiscence, and bleeding) and intraoperative findings (such as pus, necrotized tissue, and bleeding vessels). This definition of SWI, is a deep infection involving retrosternal tissue and/or the sternal bone.	Clinical examination
10. Deaton	Complications in the postoperative period were recorded as "yes" if any of the following were recorded in the medical record : infection of the leg, thorax, sternum, bloodstream or urinary tract; central neurological deficit (stroke or transient ischemia, coma); pneumonia, pulmonary insufficiency with prolonged ventilation or re-intubation, pulmonary embolism; renal failure; arrhythmias requiring treatment; prolonged inotropic support or use of intra-aortic balloon pump; or reoperation for bleeding or tamponade. Because of the low incidence of any single complication, complications were grouped together	Patient records
11. Hata	Postoperative morbidity (minor stroke, infection, pneumonia, haemodialysis, paraplegia)	Clinical records
12. Landoni	ARF (acute renal failure) requiring RRT (renal replacement therapy)	Administrative database/registry
13. Ferguson	Complications were categorized as pulmonary (pneumonia, prolonged intubation, reintubation, air leak more than 7 days, lobar collapse requiring intervention), cardiovascular (pulmonary embolism, myocardial infarction, new postoperative arrhythmia, need for intravenous inotropic agents), other, and any complication	Administrative database, hospital medical records, office shadow files
14. Rodriguez	Compensatory sweating (CS): Excessive sweating considered abnormal in other parts of the body after TS. Classified as mild (minimal, intermittent), moderate (not interfering with daily life), and severe (systemic, interfering with daily life). Gustatory sweating: Facial sweating after eating foods Excessive dryness: Dryness affecting the hands and requiring hydration	Not specified
15. Tully	New-onset atrial fibrillation (AF)/ confirmed between the patient's day of admission to the intensive care unit and the median day of discharge (day 5) after CABG during the index hospitalization. All patients underwent an ambulatory ECG and transthoracic echocardiograph up to 7 days before the scheduled surgery, and were monitored daily in the hospital ward or intensive care unit after surgery, with a 24-hour Holter monitor for the first 3 postoperative days, and 5 daily ECGs thereafter until discharge. The ECGs were performed by certified technicians, using a 12-lead surface. Both technician reports of the Holter monitor and the ECGs were used to determine incident AF. Patient ECGs were reviewed independent of the original assessors and by reviewers blinded to patients' psychological distress scores. Agreement between technician and blinded-reviewer ECG report was excellent (k % .91).	ECGs, transthoracic echocardiographs reviewed by technicians and reviewers blinded to patients' psychological distress scores
16. Moller	If the patients had any complication, they were classified as Complication: Yes, and otherwise as Complication: No. Complication was defined as any of the following postoperative complications: new onset atrial fibrillation, prolonged air leak (chest tubes in place for more than 5 days), pneumonia, re-intubation, reoperation, or hospital stay of 8 days or more.	Not specified
17. Kinney	Chronic post-thoracotomy pain	Leeds Assessment of Neuropathic Symptoms and Signs/self-reports

Appendix 6: Definitions and methods of surgical complications' recording: Vascular surgery studies

Citation	Complications (Definitions and/or range)	Method of measurement
1. Nguyen, et al.	Wound complications (WC): patients having infection, necrosis, hematoma/haemorrhage, or seroma/ lymphocele at the surgical incision or harvest site within 30 days of the bypass surgery. Inclusion terms for the infection category included infection, cellulitis, and abscess; while inclusion terms for the necrosis category included necrosis, dehiscence, gangrene, delayed healing, and eschar. Ischemic ulcers or foot gangrene present prior to IB were not counted as WC, but were tracked for their relation to the development of WC. A subset analysis was also performed for patients with serious WC (SWC) utilizing the more detailed descriptions of treatment and outcomes available in their serious adverse event (SAE) reports.	Adverse events (SA) clinical trial documentation with reference to source documentation (hospital notes etc.)
2. Nguyen, et al.	Graft-related events (GREs): development of a >70% graft stenosis or having undergone a percutaneous or surgical revision or a major amputation	Clinical tests (angiography, ultrasonography etc.), source documentation (hospital notes, discharge notes, operative and procedural notes etc.)
3. Subramonia, et al.	-Bruising (All areas of bruising were mapped out meticulously by using a standardized approach) -Sensory abnormalities, both subjective and objective, that may indicate cutaneous nerve injury or inflammation were recorded at both follow-up visits. Subjective sensory abnormalities recorded were paresthesia and dysesthesia (paresthesia was defined as "spontaneous abnormal sensation occurring in the absence of sensory stimulation," usually described as "pins and needles" or a "tingling sensation," and dysesthesia was defined as "unpleasant distorted sensation from actual sensory stimulation. The area of the detected sensory abnormality was recorded as involving the anterior, medial, posterior, or lateral aspects of the upper third, middle third, or lower third of the thigh, leg, or foot.	-Bruising: Tracing method -Sensory abnormalities: Patient reports, sensory testing
4. Lohse, et al.	Retrospective list of severe postoperative complications: Postoperative bleeding 8 (6%), Myocardial infarction 6 (4.4%), Stroke 8 (6.0), Pneumonia 8 (6%), Respiratory insufficiency 3 (2.2%) Acute renal dysfunction 3 (2.2%), Sepsis 2 (1.5%), Lung fistula	Not specified

Appendix 7: Quality assessment scores of gastro-intestinal surgery papers

COHORT STUDIES

Citation	Representativeness of exposed cohort (i.e. patients with surgical complications) (1 or 0) (1=truly or somewhat representative of the community)	Selection of non-exposed cohort (i.e. patients without surgical complications) (1 or 0) (1= drawn from same community as the exposed cohort)	Ascertainment of exposure (i.e. method of complications assessment) (1 or 0) (1= complications identified through secure records or clinical examination)	Comparability of cohorts on basis of design or analysis (2 or 1 or 0) (2= study controls for baseline QOL and for patient demographics/1= study controls for baseline QOL or pt demographics)	Assessment of wellbeing outcome (1 or 0) (1=QOL assessed with <i>validated</i> self-report measure)	Long enough follow-up (1 or 0) (1= >=3 months for major surgery, >=1 month for minor surgery, 0=<3 or 1 months or big range of follow-up)	Adequacy of follow-up (or response rates) of cohorts (1 or 0) (1= at least 50% response rate for cross-sectional studies or description of non-respondents/ no more than 30% drop-out rates for longitudinal studies or description of drop-out patients)	Quality assessment Score (out of 8)
1. Bruns	1	1	1	0	1	0*	1	5
2. Liu	1	1	1	1	1	0*	1	6
3. Bloemen	1	1	1	1	1	0*	1	6
4. El-Awady	0	1	1	0	1	1	0	4
5. Scarpa	0	1	0	0	1	1	0	3
6. Siassi	1	1	0	2	1	1	1	7
7. Dasgupta	1	1	0	1	1	1	1	6
8. Rutegard	1	1	1	1	1	1	1	7
9. Pittman	1	1	0	1	1	1	1	6
10. Rea	0	1	0	2	1	1	1	6
11. Sharma	1	1	0	2	1	0	1	6

12. Avery	1	1	0	1	1	0*	1	5
13. Dubernard	0	1	1	2	1	0	1	6
14. Lim	1	1	1	0	1	0	1	5
15. Mentès	1	1	1	0	1	1	1	6
16. Viklund	1	1	1	1	1	1	1	7
17. Delaney	1	1	1	2	1	0	1	7
19. Bitzer	1	1	0	2	1	1	1	7
20. Hawn	1	1	1	2	1	1	1	8
21. Anthony	0	1	0	2	1	1	1	6
22. Champault	0	1	0	2	1	1	1	6
23. Chang	0	1	0	2	1	1	0	5
24. Douma	0	1	0	0	1	0*	0	2
25. Ince	0	1	0	1	1	0	0	3
27. Polese	1	1	1	1	1	0*	1	6
28. Kement	1	1	1	0	1	0*	1	5
29. Targarona	1	1	1	0	1	0*	1	5

CASE CONTROL STUDIES

Citation	Representativeness of exposed cohort (i.e. patients with surgical complications) (1 or 0) (1=truly or somewhat representative of the community)	Selection of non-exposed cohort (i.e. patients without surgical complications) (1 or 0) (1= drawn from same community as the exposed cohort)	Ascertainment of exposure (i.e. method of complications assessment) (1 or 0) (1= complications identified through secure records or clinical examination or validated self-report tool for assessment of pain)	Comparability of cohorts on basis of design or analysis (2 or 1 or 0) (2= study controls for baseline QOL and for patient demographics/1= study controls for baseline QOL or pt demographics)	Assessment of wellbeing outcome (1 or 0) (1=QOL assessed with <i>validated</i> self-report measure)	Long enough follow-up (1 or 0) (1= >=3 months for major surgery, >=1 month for minor surgery, 0=<3 or 1 months or big range of follow-up)	Adequacy of follow-up (or response rates) of cohorts (1 or 0) (1= at least 50% response rate for cross-sectional studies or description of non-respondents/ no more than 30% drop-out rates for longitudinal studies or description of drop-out patients)	Quality assessment score (out of 8)
18. Kalliomaki	1	0	1	1 (control for dems but not for pre-op QOL & HADS)	1	1	0	5
26. Riss	1	1	1	1	1	1	0	7

Appendix 8: Quality assessment scores of cardio-thoracic surgery papers

Citation	Representativeness of exposed cohort (i.e. patients with surgical complications) (1 or 0) (1=truly or somewhat representative of the community)	Selection of non-exposed cohort (i.e. patients without surgical complications) (1 or 0) (1= drawn from same community as the exposed cohort)	Ascertainment of exposure (i.e. method of complications assessment) (1 or 0) (1= complications identified through secure records or clinical examination or validated self-report tool for assessment of pain)	Comparability of cohorts on basis of design or analysis (2 or 1 or 0) (2= study controls for baseline QOL and for patient demographics/1= study controls for baseline QOL or pt demographics)	Assessment of wellbeing outcome (1 or 0) (1=QOL assessed with validated self-report measure)	Long enough follow-up (1 or 0) (1=3 months for major surgery, 1 month for minor surgery)	Adequacy of follow-up (or response rates) of cohorts (1 or 0) (1= at least 50% response rate for cross-sectional studies or description of non-respondents/ no more than 30% drop-out rates for longitudinal studies or description of drop-out patients)	Quality assessment score (out of 8)
1. Gjeilo	1	1	1	1*	1	1	1	6
2. Merkouris	1	1	0	0	1	1	1	5
3. Peric	0	1	1	2	1	1	1	7
4. Le Grande	0	1	1	2	1	1	1	7
5. El Baz	1	1	1	2	1	1	1	8
6a. Myles	1	1	1	2	1	1	1	8
6b. Myles	1	1	1	2	1	1	1	8
7. Jarvinen	0	1	1	2	1	1	1	7
8. Martin	0	1	0	2	1	1	1	6
9. Deaton	1	1	1	0	1	1	1	6
10. Hata	1	1	1	1	1	0	1	6
11. Ferguson	1	1	1	1	1	0*	1	6
12. Rodriguez	0	1	0	0	1	1	0	3

13. Tully	1	1	1	2	1	0	1	7
14. Moller	0	1	0	2	1	1	1	6
15. Kinney	0	1	1	2	1	1	1	7

CASE-CONTROL STUDIES

Citation	Representativeness of exposed cohort (i.e. patients with surgical complications) (1 or 0) (1=truly or somewhat representative of the community)	Selection of non-exposed cohort (i.e. patients without surgical complications) (1 or 0) (1= drawn from same community as the exposed cohort)	Ascertainment of exposure (i.e. method of complications assessment) (1 or 0) (1= complications identified through secure records or clinical examination or validated self-report tool for assessment of pain)	Comparability of cohorts on basis of design or analysis (2 or 1 or 0) (2= study controls for baseline QOL and for patient demographics/1= study controls for baseline QOL or pt demographics)	Assessment of wellbeing outcome (1 or 0) (1=QOL assessed with validated self-report measure)	Long enough follow-up (1 or 0) (1= >=3 months for major surgery, >=1 month for minor surgery, 0=<3 or 1 months or big range of follow-up)	Adequacy of follow-up (or response rates) of cohorts (1 or 0) (1= at least 50% response rate for cross-sectional studies or description of non-respondents/ no more than 30% drop-out rates for longitudinal studies or description of drop-out patients)	Quality assessment score (out of 8)
16. Jideus	1	1	0	0	1	1	0	4
17. Landoni	1	1	1	1	1	1	0	6

Appendix 9: Quality assessment scores of vascular surgery papers

Citation	Representativeness of exposed cohort (i.e. patients with surgical complications) (1 or 0) (1=truly or somewhat representative of the community)	Selection of non-exposed cohort (i.e. patients without surgical complications) (1 or 0) (1= drawn from same community as the exposed cohort)	Ascertainment of exposure (i.e. method of complications assessment) (1 or 0) (1= complications identified through secure records or clinical examination or validated self-report tool for assessment of pain)	Comparability of cohorts on basis of design or analysis (2 or 1 or 0) (2= study controls for baseline QOL and for patient demographics/1= study controls for baseline QOL or pt demographics)	Assessment of wellbeing outcome (1 or 0) (1=QOL assessed with <i>validated</i> self-report measure)	Long enough follow-up (1 or 0) (1= >=3 months for major surgery, >=1 month for minor surgery, 0=<3 or 1 months or big range of follow-up)	Adequacy of follow-up (or response rates) of cohorts (1 or 0) (1= at least 50% response rate for cross-sectional studies or description of non-respondents/ no more than 30% drop-out rates for longitudinal studies or description of drop-out patients)	Quality assessment score (out of 8)
1. Nguyen ^a	1	1	1	2	1	1	1	8
2. Nguyen ^b	1	1	1	2	1	1	1	8
3. Subramonia	1	1	1	1*	1	1	1	7
4. Lohse	1	1	0	0	1	0*	1	4

Appendix 10: Table of systematic review findings of gastro-intestinal surgery papers

Citation	Key Findings	Summary of findings	Association of complications with wellbeing (Yes/No/Confounding)	Time-points of significant effects
1. Bruns	-Patients with any type of postoperative complications (n=30) did not have significantly lower QOL than patients without (n=66) -Patients with postoperative wound (n=10) infections showed significantly lower values for both SF-12 PCS (P < 0.05) (33.0) and SF-12 MCS (P < 0.05) (43.0) compared to patients without this complication (n=85) (46.9, 54.8) and population norm.	Wound infections were associated with lower physical and mental QOL (univariate)	Y	3-36 months post-surgery
2. Liu	33% of CRC survivors (42% for ostomates and 27% for anastomoses) had low QOL. Enterocutaneous fistula, recorded in 4.2% of ostomy cases and less than 1% of anastomosis controls, was associated with lower overall QOL among ostomy cases (odds ratio (OR) 4.8; 95% CI 1.2–19.2). Patients with ostomies who had any late complications had lower overall QOL (OR 1.5; 95% CI 0.9–2.6), although the confidence interval included 1.0. This was not the case for patients with anastomoses (OR 0.9; 95% CI 0.5–1.5). Among patients with rectal cancer alone, complications of ostomy (OR 2.0; 95% CI 1.0–4.1), but not anastomosis (OR 1.0; 95% CI, 0.4–2.8), were associated with reduced HRQOL	Enterocutaneous fistula were associated with lower QOL in both ostomy and anastomosis patients. Any late complications were associated with lower QOL in ostomy but not anastomosis patients (univariate)	Y	>5 years post-surgery
3. Bloemen	-Patients with severe complications reported significantly worse physical functioning (73 vs. 85, P 0.031), more pain and more interference of this pain with daily activities (17 vs. 0, P 0.025), more fatigue (33 vs. 22, P 0.036), and more weight loss (0 vs. 0, P 0.031) than patients with no or only mild complications after surgery. -According to the univariate analysis, severe postoperative complications were significantly associated with higher scores on the fatigue symptom scale. -In a linear multivariate analysis, severe postoperative complications were independently and significantly associated with higher fatigue scores (b=28.937, 95% CI 10.52–47.34, P 0.002 and b= 13.985, 95% CI 4.05–23.92, P 0.006, respectively). -In a univariate analysis severe postoperative complications were associated with a higher score on the weight loss subscale. -In a linear multivariate analysis severe postoperative complications showed a significant and independent association with a higher weight loss score (beta 9.495, 95% CI=0.88–18.11, P 0.031).	Severe postoperative complications were associated with higher fatigue and higher weight loss in univariate and multivariate analysis.	Y	Median of 36 (range, 16–51) months post-surgery
4. El-Awady	Parameters of SF-36 did not show significant difference (NO DATA) between patients with complications (14) vs. without (26).	Postoperative complications were not associated with QOL (univariate)	N	N/A
5. Scarpa	CGQL score correlated with surgical complications. At multiple regression analysis only the disability status at admission to the hospital was shown to be an independent predictor of the health-related QOL score.	Association of complications with QOL at univariate but not at multivariate analysis	C	3 months post-surgery
6. Siassi	-In the bivariate analysis, at no time did the occurrence of complications significantly influence QOL. -In the multivariate analysis, at t2 surgical complications had a significant influence on the physical QOL (SF-36) p<0.05	Surgical complications were associated with lower physical (multivariate analysis)	Y*	3 months post-surgery
7. Dasgupta	There was little difference in functional scores between patients who did and those who did not experience a postoperative complication. Pain scores in patients with complications showed a trend towards being worse at 6 and 12 months, but the differences were not statistically significant (mean (s.d.) 2.2(30.9) versus 19.9(24.9) for patients with versus without complications at 12 months)	No significant association between patient with complications and patients without in QOL scores (univariate)	N*	N/A
8. Rutegard	The occurrence of technical surgical complications was associated with detrimental effects on dyspnoea (p=0.049), fatigue (p=0.008), nausea or vomiting (p=0.006), coughing (p<0.001), physical function (p=0.001), global quality of life (p=0.002) and role function (p=0.007); these consequences remained after multivariable adjustments.	Association of technical complications with worse scores on dyspnoea, nausea, vomiting, coughing, physical function, global quality of life and role function (univariate and multivariate)	Y	6 months post-surgery
9. Pittman	-When compared to veterans with mild complications, those who reported severe skin irritation, problems with leakage, and difficulty adjusting had significantly lower total QOL scores and lower scores on the physical, psychological, social, and spiritual domain scores. -When we entered these variables into a multiple linear regression model, many of the relationships remained significant. Having severe skin problems was a predictor of the total QOL score (p=.032) and the physical domain score (p<0.001) Having severe problems with leakage was predictive of total QOL score (p<.001), the physical domain (p<.001), and the social domain (p<.001) scores. Finally, severe difficulty with adjusting to an ostomy predicted the total QOL score (p<.001), physical domain (p<.001), psychological domain (p<.001), social domain (p<.001), and the spiritual domain of QOL (p<.002).	The severity of 3 ostomy complications (skin problems, leakage, and difficulty adjusting) was inversely related to scores on total QOL and on all 4 domains of health-related QOL (physical, social, psychological and spiritual domains) (univariate and multivariate)	Y	6 months post-surgery
10. Rea, et al.	-Patients experiencing complications within the first year following LRYGB reported significant improvement in all 8 scales of the SF-36 over preoperative levels, and mean values were greater than normalized controls. At 1 year patients with complications scored significantly lower than those without complications in one of eight scales, vitality (58.1 [± 9.1] versus 54.2 [± 10.2], respectively, p = 0.029. -2-year follow-up: Patients experiencing complications had statistically significant improvement over preoperative levels in all but three scales: social function, role—emotional, and mental health. Compared to patients at 2 years without complications, patients experiencing complications reported decreased HRQL scores in six of eight scales: role—physical, bodily pain, general health, vitality, social function, and mental health. In Multiple linear regression, all scales in patients with complications were significantly decreased except for physical function and general health.	-Association of complications with worse scores on vitality in 1 year (univariate) -Association with worse scores on physical, bodily pain, general health, vitality, social function, and mental health at 2 years (univariate) -Complications were predictive of lower QOL on all scales but physical function and general health in multivariate analysis	Y*	1 & 2 years post-surgery
11. Sharma	Presence of postoperative morbidity within 30 days of operation was found to have significant association with postoperative HADS anxiety (U = 530, p= 0.01), depression (U = 491, p < 0.005), PANAS negative effect (U = 480, p = 0.02) and FACTC FW (U = 388, < 0.005), whereas, values approaching significance were obtained for MRS (U = 597, p =0.09), FACTC SW (U = 626, p = 0.10) and FACTC CCS (U = 599, p =0.06). Multiple regression analysis confirmed that preoperative QoL scores independently predicted the	Postoperative morbidity within 30 days of operation were associated with (univariate) and independently predicted (multivariate) higher anxiety, depression	Y*	6-8 weeks post-surgery

	postoperative scores. In addition, postoperative morbidity independently predicted the postoperative HADS anxiety, HADS depression, PANAS negative affect, MRS and FACTC FW scores.	and negative affect, moods and lower QOL 6-8 weeks post-surgery		
12. Avery	Patients with morbidity (n=37) vs. Patients without morbidity (n=102) -(a) Physical 44.9 (21.8) vs. 60.5 (21.5) (p<0.001), role 17.6 (25.4) vs. 38.4 (31.0) (p<0.001), social function 38.7 (28.6) vs. 55.4 (30.3) (p=0.004) and Global QOL 41.4 (21.0) vs. 55.4 (19.0) (p<0.001) domains were significantly associated with morbidity -(b) Emotional 68.9 (23.2) vs. 75.2 (22.4) (p=0.3), Cognitive 70.7 (24.0) vs. 77.8 (21.2) (p=0.06) domains of QOL were not significantly related to morbidity	Association of postoperative morbidity with lower QOL (physical, role and social function, fatigue, nausea and global QOL) (univariate)	Y	39.6 days after treatment (range: 6–105)
13. Dubernard	No significant difference in preoperative and postoperative scores for SF-36 questionnaire was observed between women with or without postoperative complication	No association of postoperative complications with QOL (univariate)	N*	N/A
14. Lim, et al.	-Median QOL scores for those with no leaks (NL), sub-clinical leaks (SCL), and clinical leaks (CL) with ileostomy closure were similar. There was larger variation of QOL scores in the NL group compared with the latter two. Median QOL scores were significantly lower for patients with CL and no ileostomy closure (P = 0.03).	Association of lower QOL with presence of clinical leak without ileostomy closure/ Quality of life seemed to be similar for patients with no leaks and patients with successful closure irrespective of method of presentation (univariate)	C	10-18 months post-op
15. Mentis	Because the majority of the patients (232) healed without any complications, disturbances of continence, or recurrences within the time limits of this study, the incomparably small numbers in some subgroups did not permit valid statistical comparisons. Nevertheless, the 12-month total GIQLI score of the three patients who developed anal abscess/fistula after LIS (139.33 T 3.21) was similar to the GIQLI score of those without complications. The seven patients who developed a Fecal Incontinence Severity Index (FISI) score of greater than 0 also had a GIQLI score (139 T 2.88) comparable to that of the group with no complications (P = 0.056). Only three patients (whose FISI score deteriorated from 0 to 4, 21, and 7 postoperatively) had evident deterioration in FIQL.	Unclear whether anal incontinence or anal abscess/fistulas were associated with QOL, due to small sample size of patients with these complications	?	N/A
16. Viklund	-The occurrence of complications was a factor that statistically significantly reduced the mean scores of global QOL, the physical functioning and the role functioning 6 months after surgery. There were significant dose–response relationships for all these outcomes. These associations remained statistically significant after adjustment for confounding variables, except for physical functioning (p = 0.10). -The occurrence of reoperation, anastomotic leakage, infection, or respiratory insufficiency, each statistically significantly reduced both the physical functioning and the role functioning. The scores concerning the global QOL were also decreased, but reaching statistical significance for infections only. The occurrence of cardiac complications also reduced the scores regarding QOL, reaching statistical significance for global QOL. Similarly, technical complications during surgery decreased the QOL scores. The only predefined complication that did not seem to affect the QOL was the occurrence of anastomotic strictures.	-Presence of complications significantly associated with lower global QOL, physical functioning & role functioning 6 months post-op (univariate & multivariate) -Anastomotic leakage, infection, or respiratory insufficiency, each statistically significantly reduced both the physical functioning and the role functioning (multivariate) -The occurrence of cardiac complications also reduced significantly global QOL (multivariate) -Technical complications during surgery decreased the QOL scores (multivariate)	Y	6 months post-discharge
17. Delaney	-Patients who did not have any complications (major or minor) (0.14/ 0.18) by day 30 in the postoperative period had a significantly greater improvement in postoperative CGQL than those who did (0.03/0.23) p<.05. -The occurrence of a major complication and readmission within 30 days were not independent factors affecting CGQL. Multivariate analysis showed that only female gender and the occurrence of any complication (major or minor) were independent factors that were significantly associated with CGQL change at day 30. -Patients who were not re-admitted and patients without any complication by day 30 had a significantly greater improvement than patients with complications in the Current Energy Level component of CGQL. -The group without an improved postoperative CGQL had a higher proportion of patients with complications (p=0.03) and readmissions (p=0.04).	Patients with occurrence of any complications (major or minor) had lower improvement in their post-op QOL (univariate and multivariate)	Y*	30 days post-op
18. Kalliomaki	There were significant differences between the pain and control groups in all scales of SF-36, the greatest difference being in bodily pain and in role physical. The control group did better than the pain group on all scales (p=0.001). When compared with the common Swedish population, the control group had higher scores and the pain group had lower scores but these differences were not statistically significant. The mean for depression was 3.37 (SD 3.33) in the pain groups and 2.23 (SD 2.07) in controls (P50.004). The means for the anxiety scale were 4.08 (SD 3.45) in the pain group and 2.56 (SD 2.27) in controls (P50.000). Three patients had clinically relevant depression, three other patients suffered from clinically relevant anxiety and one patient had high scores on both scales; all these patients (n=57) belonged to the pain group.	Association of persistent post-op pain with lower QOL and higher anxiety & depression (univariate)	Y	Mean of 4.9 years post-surgery
19. Bitzer	In a multivariate analysis of predictors of QOL at 6 months postoperatively, self-reported postoperative complications predicted the SF-36 subscales bodily pain, role physical, and treatment satisfaction.	Postoperative complications independently predicted worse scores on bodily pain, role and physical domains (multivariate)	Y*	6 months post-surgery
20. Hawn	-Unadjusted analyses of postoperative QOL: Patients with a recurrence, complication, or both reported scores for the PCS that differed significantly from those of patients without a recurrence or complication (P <0.001). -2 years assessment of SF-36: After adjusting for the baseline preoperative score and patient demographic factors, hernia recurrence did not affect general health status. Patients with neuralgia (p<0.001) or orchitis (p<0.02) had significantly lower PCS scores, compared with patients without these events. Patients with neuralgia also had lower MCS than those without neuralgia (p<0.004).	-Occurrence of postoperative complications associated with worse scores on PCS in univariate analysis. -Neuralgia and orchitis, independently predicted lower PCS and neuralgia also independently predicted MCS at 2 years (multivariate).	Y*	2 years post-surgery
21. Anthony	(a) Perioperative complications were significantly associated with diminished 12-month FACT-C total score (p=0.003) (b) In a logistic regression analysis the occurrence of perioperative complications (odds ratio, 10.5; 95% CI, 2.1-52) and the patient's HRQL score at diagnosis (odds ratio, 1.04; 95% CI, 1.005-1.07) were associated with a decreased 12-month score. (c) Patients with complications (n=16) vs. Patients without complications (n=47): Physical wellbeing [19(1.5) vs.23(0.88), p=.01], Social/Family Wellbeing [20(1.2) vs.23(0.87), p=.02], Emotional wellbeing [20 (0.89) vs. 21(0.67), p=.31], Functional wellbeing [14(1.7) vs. 21(1.1), p=.002], Colorectal cancer concerns [19(1.4) vs.23(0.64), p=.03]	-Association of perioperative complications with lower 12 month QOL in all domains (physical, social/family, functional, colorectal cancer concerns) (univariate) -More prevalent for functional wellbeing (p<0.001) -Perioperative complications independently	Y*	12 months post-diagnosis (and following surgery)

		predicted lower decreased 12-month QOL score (multivariate)		
22. Champault	-Postoperative complications did not alter the mean score of GIQLI. -Patients with band removal for complication including erosion, slippage, and intolerance: global GIQLI score at follow-up was not significantly modified. In 10 patients having complication during the follow-up but a good result in term of weight loss, global GIQLI score increased.	-Surgical complications (with successful treatment) did not influence the QOL outcome -Band removal for complication including erosion, slippage, and intolerance in patients without adequate weight loss did not improve their QOL (univariate)	C*	2 year post-surgery
23. Chang	Regression analysis results: The physical domain was affected by the occurrence of operation-related complications (-1.158 (0.352)). Also, pain & discomfort (-0.656 (0.224)) and activities of daily leaving (-0.428 (0.146))/p<0.001	Operation-related complications independently predicted lower physical domain, pain, discomfort & activities of daily leaving (multivariate)	Y*	1, 3, 6, 12 months post-surgery
24. Douma	-The multilevel regression analyses showed that those with higher levels of physical functioning (PCS) were significantly more likely to be men (b = 0.272), to have had no complications during surgery (b = 0.405) and not to have had any comorbid conditions (b = 0.557). This multivariate model explained 20% of the variance in PCS scores (P < 0.01) -Defecation problems among surgically treated patients with FAP were significantly associated with having had surgical complications (b = 0.238) and this multivariate model explained 11% of the variance in defecation problems (P = 0.000). -Higher disease-related Social Functioning among surgically treated patients with FAP was significantly associated with a higher education level (b = 0.418), having children (b = 0.336), not having had complications (b = 0.351) and not having comorbid conditions (b = 0.313). This multivariate model explained 18% of the variance in social functioning (P < 0.01).	Complications independently predicted lower physical QOL (PCS), more defecation problems and lower disease Social Functioning (multivariate)	Y	0 to >10 years post-surgery
25. Ince	Gender, age, operation, LOS, surgeon, ASA, BMI, complications, and readmission were not separately associated with changes in PCS or MCS from preoperative values.	No association of complications with improvement in QOL 1-month post-surgery (univariate)	N*	N/A
26. Riss	In regard to the SF-12 health survey the median physical health score of patients was 46.0 (range 29.2–56.6) compared to 52.6 (range 26.7–61.9) of the controls. This difference was not statistically significant (p=0.2775). In addition, the median mental health score of patients was 50.6 (range 28.4–60.4) compared to 53.6 (range 35.2–60.8) in control subjects (p = 1.0000)	No statistically significant association of anastomotic leakage with QOL (univariate)	N	N/A
27. Polese	Anastomotic stenosis patients presented a worse quality of life on six out of the questionnaire's eight subscales with respect to surgical controls...Physical functioning 85 (80–90) vs. 79 (69–88) 0.26 Role limitations due to physical health 88 (79–96) vs. 68 (53–83) 0.02 Role limitations due to emotional problems 92 (85–99) vs. 75 (62–87) 0.01 Energy / fatigue 76 (71–82) vs. 68 (58–78) 0.13 Emotional well-being 77 (72–82) vs. 67 (58–76) 0.05 Social functioning 93 (88–98) vs. 82 (73–92) 0.04 Bodily pain 94 (88–99) vs. 77 (67–87) 0.004 GH general health 81 (74–87) vs. 51 (39–62) < 0.0001	Anastomotic stenosis was associated with worse QOL on role limitations due to physical health, role limitations due to emotional problems, emotional wellbeing, social functioning, bodily pain and general health (univariate)	Y	58 (SD ± 31) months post-surgery
28. Kement	-Most SF-36 scales were significantly worse in the severely incontinent subgroup than in the mildly incontinent subgroup. Finally, WIS had negative correlations with physical and mental component scores (p< 0.05 for both). -Mild vs. Severe: Physical component 57.91+/-1.63 53.97+/-2.22 <0.001, Mental component 50.79+/-2.09 47.17+/-1.96 <0.00, Physical functioning 57.10+/-0.00 56.89+/-0.68 0.15 Role-physical 56.20+/-0.00 56.20+/-0.00 nca Bodily pain 62.70+/-0.00 52.41+/-6.73 <0.001 General health 53.43+/-3.60 49.22+/-3.15 0.006 Vitality 51.67+/-5.34 46.42+/-2.19 0.009 Social functioning 56.81+/-1.21 48.10+/-5.40 <0.001 Role-emotional 55.30+/-0.00 55.30+/-0.00 nca Mental health 48.99+/-3.03 47.39+/-2.99 0.21	Severe incontinence 1,5 years + after LIS significantly associated with lower QOL (PCS, MCS, bodily pain, general health, vitality, social functioning) (univariate)	Y	23.3 (SD ± 7.1) months post-surgery
29. Targarona	SF-36: The results of the SF-36 were not significantly different from the standard values for the Spanish population of similar age and health status. Not was there a significant difference between the successfully treated group and the symptomatic or radiological recurrent group. GIQLI: Successfully operated patients reached a GIQLI value comparable to the standard population. However, clinically recurrent patients had significantly lower GIQLI scores than the non-recurrent group or the radiological recurrent group. GDSS: The median postoperative value was 5 (range, 3.6 –5.8) (best scores, 0; worst score, 20), with no statistically significant difference between the recurrent group and the non-recurrent group	-Clinically recurrent hernia patients had significantly lower GIGLI scores than non-recurrent ones (univariate) -No significantly different scores on SF-36 and GDSS (univariate)	Y	>=6 months post-surgery

*Study controlled for patients' preoperative wellbeing

Appendix 11: Table of systematic review findings of cardio-thoracic surgery papers

Citation	Key Findings	Summary of findings	Association of complications with wellbeing (Yes/No/Confounding)	Time-points of significant effects
1. Gjeilo	Patients reporting pain at 12 months (n=52) had significantly lower scores on the SF-36 general health (58.4 vs. 66.5) (p=0.008) and mental health (70.5 vs 77.0)(p=0.033) dimensions at baseline, while after 12 months patients reporting chronic pain had less favourable scores on all SF-36 subscales. The differences ranged from 10 to 21 points and reached statistical significance in all but one scale, the role emotional.	Patient with chronic post-surgical pain at 12 months reported lower QOL in all domains except emotional (univariate).	Y*	12 months post-surgery
2. Merkouris	The presence of postoperative in-hospital complications was not related to QOL after the operation. The presence of reported problems in the course of the immediate postoperative period (N=8) was related to QOL for the same period (4.90 vs 5.67 P=0.022).	In-hospital surgical complications were not associated with QOL. Patients with postoperative problems reported lower postoperative QOL (univariate)	N*	N/A
3. Peric	In multivariate logistic regression analysis of worsened QOL postoperative complications were predictors of worsened 6 months post-op QOL in (a) the section of social isolation (p = 0.002; OR = 4.63; CI 1.79–11.99), (b) in the section of sleep (p = 0.03; OR = 2.71; CI 1.12–6.51), (c) in the section of pain (p = 0.005; OR = 3.39; CI 1.45–7.97)	Postoperative complications were associated with lower QOL 6 months postoperatively in terms of social isolation, pain and sleep (multivariate)	Y*	6 months post-surgery
4. Le Grande	-Bivariate predictors of non-improver PCS status: atrial fibrillation (p < .10), chronic heart failure (p < .05), higher BMI (p < .10), previous MI (p < .05), higher NYHA functional status (p < .001), cardiac arrhythmia after surgery (p < .05), and higher pulmonary pressure during surgery (p < .05). -Logistic regression analysis predicting non-improver PCS status: non-participation in the workforce, lower POMS vigor-activity, higher NYHA dyspnoea class, a new cardiac arrhythmia during or following the operation, and higher pulmonary pressure during the procedure -Bivariate screening predicting non-improver MCS status: atrial fibrillation (p < .10), off-pump surgery (p < .10), previous cardiac surgery (p < .001), previous MI (p < .10), and non-attendance at CR (p < .05). -Logistic regression of non-improver MCS status: previous cardiac surgery, previous MI, lower CR attendance, manual occupation, poorer POMS depression-dejection, and poorer EFQ concentration.	-Association of not improved PCS 6 months post-op with higher NYHA dyspnoea class, experiencing a new cardiac arrhythmia during or following the operation, and higher pulmonary pressure recorded during the procedure (univariate & multivariate) -Association of not improved postoperative MCS with atrial fibrillation at univariate analysis but not at multivariate analysis.	Y*	6 months post-surgery
5. El Baz	Postoperative complications were not associated with physical score of SF-36. Poor post-CABG physical functioning was significantly predicted by re-admission 6 weeks after CABG (b=-0.158, p=0.018)/Poor physical role was predicted by readmission (b=-0.217, p=0.003). /General physical health was predicted by re-admission (b=-0.173, p=0.014) /Poor social role was associated with readmission (b=-0.025, p=0.001) and longer LOS (b= 0.160, p=0.015)/Patients who had undergone a re-exploration for tamponade or bleeding (b=-0.206, p=0.023) along with patients who had undergone sternal resuturing (b=-0.142, p=0.036), experienced poor mental health. Readmission was associated with poor mental health (b=-0.185, p=0.003)/Poor vitality was associated with re-exploration surgery (b=-0.170, p=0.024) and with readmission (b=-0.218, p=0.002)	Association of postoperative events (re-exploration for bleeding or tamponade & sternal resuturing) and readmission with poor mental QOL (not PCS). Association of re-exploration surgery with poor vitality (multivariate).	Y*	6 months post-surgery
6a. Myles	Postoperative complications were associated with poor quality of life (SF-36) at 3 months (Respiratory, 0.015, Stroke 0.045, sepsis 0.49) .In further multivariate logistic regression post-op complications were not associated with 3 months QOL.	Postoperative complications were associated with poor QOL at 3 months in univariate but not in multivariate analysis.	C*	3 months post-surgery
6b. Myles	Patients who had postoperative complications were no more likely to have a poor QOL at three years after surgery, OR 1.83 (95% CI: 0.68-4.96).	No association of postoperative complications with QOL 3 years post surgery (multivariate)	N*	N/A
7. Jarvinen	All health scores improved significantly (p<0.001) among the patients without Perioperative Myocardial Infarction (PMI). In PMI patients, significant changes were seen in all but two RAND-36 dimensions (general health and emotional well-being). Group differences were statistically significant in general health p= 0.010; physical functioning p=0.036 and role functioning/physical p= 0.011 indicating less steep improvement of these QOL dimensions in the PMI patients. Thirty PMI patients (38%) in fact showed a small negative change in their general health scores at follow-up. Multivariate regression analysis revealed PMI to be an independent predictor of this adverse change. A highly significant p= 0.001 improvement was seen in the RAND-36 MCS and PCS scores in both patient groups. However, the magnitude of change in the PMI as compared to no-PMI patients was lower in both categories, and repeated measures analysis of variance revealed a significant p=0.002 group by change interaction for the PCS score indicating a more pronounced improvement for the no-PMI group. In all, 67% of the PMI patients and 75% of those without PMI p= 0.15 had a positive change in their MCS scores, while the corresponding figures for PCS scores were 81 and 87% (p= 0.18) respectively.	PMI was associated with a negative change in general health scores 1 year post-op and multivariate logistic regression analysis revealed PMI to be (the only) independent predictor of lower score. Less improvement among PMI patients was also seen in the psycho-social (MCS) and especially in the physical (PCS) components of the QOL, as this group showed a significantly lower magnitude of change in their PCS scores (univariate & multivariate)	Y*	12 months post-surgery
8. Martin	When stratified by the presence or absence of 1 or more complications, no statistically significant changes were observed between groups after adjustment for age, sex, and severity of disease. Patients in both groups experienced statistically significant increases in QOL for all domains.	No (significant) association of perioperative complications with change in post-op QOL in open-heart surgery patients (multivariate).	N*	N/A

9. Jideus	Patients who developed Serious Wound Infections (SWIs) deviated significantly from the normative data for the general Swedish population in all but one of the eight SF-36 subscales (Body pain). QOL for the SWI patients was comparable to QOL assessed prior to CABG i.e. the control group. The CABG group, however, significantly improved their QOL one year after surgery.	At follow-up the SWI group had as low QOL as the CABG group prior surgery. The CABG group, however, significantly improved their QOL one year after surgery. Consequently, the SWI group resulted in no benefit from the cardiac operation at follow-up (univariate).	Y*	20 (Range: 7-40) months post-surgery
10. Deaton	Patients without complications had better 3-month PCS (43±8 vs 41±9, p=.025) and MCS (48±10 vs 43±11, p=.001) than those with complications.	Postoperative complications were associated with lower QOL in terms of physical and mental health (univariate).	Y	3 months post-surgery
11. Hata	Although the frequency of reoperation, postoperative LOS, infection of the surgical site, hemodialysis for acute renal failure, and paraplegia was similar between depressed and non-depressed patients, that of emergency surgery (p<0.0001), minor stroke (p=0.0062), and pneumonia (p=0.0003) was significantly higher in depressed patients. The multivariate logistic regression analysis revealed that female gender, emergency surgery and being over 70, were significant predictors for postoperative depression but neither minor stroke nor pneumonia.	Postoperative minor stroke and pneumonia were associated with postoperative depression in univariate analysis, but not in multivariate.	C	5-7 days post-surgery
12. Landoni	Perceived general health (ARF vs. No ARF): Excellent 7 (31.8%) vs. 24 (60%) p=0.06 Very good 9 (40.9%) vs. 10 (25.0%) p=0.3 Good 6 (27.3%) vs. 6 (15.0) p= 0.2 Pain during last 4 weeks 0 vs. 3 (7.5%), p= 0.3 Limitations in daily activities 3 (13.6%) vs 4 (10.0%) p=0.5 Hearing impairment 7 (31.8%)vs. 0 p=0.0003 Patients on dialysis 2 (9.1%) vs. 0 p=0.1	No significant association of acute renal failure requiring renal replacement therapy with perceived general health of SF-36 (univariate).	N	N/A
13. Ferguson	-Pulmonary complications were related to physical function score (p=0.025) and dyspnea scores (p=0.002)-In multivariate regression analysis of QOL, the occurrence of pulmonary complications was also associated with physical function outcome (Pulmonary complication, Odds ratio:5.72, CIs: 1.20–27.26, p=0.029)	Pulmonary complications were associated with lower physical function (univariate and multivariate).	Y	2.6 years post-surgery (Range: 3 months-6.4 years)
14. Rodriguez	QOL was excellent at the time of discharge, at 6 months and 12 months in 100%, 100% and 97% of patients. A statistically significant relationship between Compensatory Sweating (CS) with a worse quality of life (p = 0.083) was not found.	Compensatory sweating was not significantly associated with QOL (univariate).	N*	N/A
15. Tully	When postoperative distress was considered, a 1-point increase in anxiety-scale score translated into increased odds for developing Atrial Fibrillation (AF) of around 9% (OR, 1.09; 95% CI, 1.00 to 1.18; P % .05)	Postoperative anxiety was associated with presence of AF (multivariate).	Y*	6 days (SD=2 days) post-surgery
16. Moller	Suffering a postoperative complication was a significantly higher risk of impairment in the physical functioning (OR: 2.56, 95% CI:1.14 –5.74), general health (OR: 2.19 95% CI: 1.04–4.61), and social functioning (OR: 3.32, 95% CI: 1.57–7.02) subscales, compared with patients without postoperative complications.	Postoperative complications were associated with impairment in physical functioning, general health and social functioning (univariate).	Y*	6 months post-surgery
17. Kinney	In comparing the SF-36 scales between patients who had post-thoracotomy pain at 3 months (n=70) versus those who did not (n=29), there were three significant differences with the pain group reporting poorer measures of physical functioning (p 0.049), bodily pain (p 0.0002), and vitality (p 0.044). Cohen's d effect size was large for bodily pain (1.2), and moderate for both physical functioning (0.5) and vitality (0.6).	Chronic post-thoracotomy pain associated with lower physical functioning, higher bodily pain and lower vitality (multivariate).	Y*	3 months post-surgery

*Study controlled for patients' preoperative wellbeing

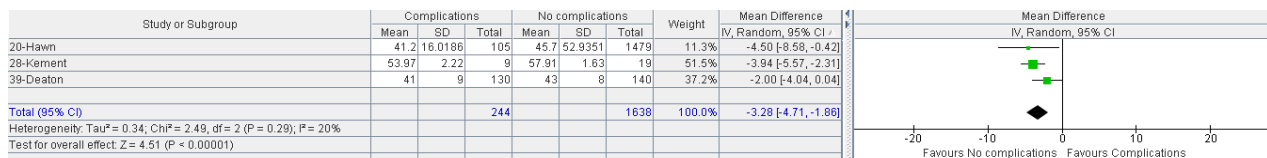
Appendix 12: Table of systematic review findings of vascular surgery papers

Citation	Key Findings	Summary of findings	Association of complications with wellbeing (Yes/No/Confounding)	Time-points of significant effects
1. Nguyen ^a	-Wound Complications (WC) were not significantly associated with lower QOL at 3 months (4.67 vs 4.79, P=.1947) and 12 months (5.02 vs 5.13, P=.2806). -Mixed regression model analysis of the overall change in mean global QOL score over one year was also found not to be statistically significant between patients with and without WC (coefficient 0.1118; 95% CI, 0.2741 to 0.0504; P=.1764) -Patients with Serious WC demonstrated significantly lower QOL at 3 months compared with patients without WC, (global score 4.43 vs 4.79, respectively, P=.0166), though this difference disappeared by 12 months (4.94 vs 5.13, P=.2411) -Mixed regression model analysis of the overall change in mean, global QOL score over 1 year was also found not to be statistically significant between SWC and patients without WC (coefficient, 0.1744; 95% CI 0.4291 to 0.0803; P=.1792)	-WC were not associated with lower QOL at 3 nor at 12 months neither in univariate or multivariate analysis. -Serious WC were associated with lower QOL at 3 months after surgery in univariate analysis but not at 12 months. SWC were not associated with change in QOL at 12 months in multivariate analysis.	C*	3 months post-surgery
2. Nguyen ^b	-The effect of Graft Related Events (GRE) on QOL was significant. At 12 months, there was a reduction in the magnitude of QOL improvements in patients who developed critical graft stenosis (>70% on ultrasonography or angiography; +1.98 vs +2.40; P < .0001), loss of primary patency (+2.03 vs +2.33; P = .0006), loss of primary assisted patency (+1.70 vs +2.34; P < .0001), and loss of secondary patency (+1.70 vs +2.31; P < .0001). -Overall, patients free from any GRE had a greater increase in 12-month QOL than patients with a GRE (+2.40 vs +2.0; P < .0001). -Patients who underwent successful graft revision had lower QOL at 12 months than patients free from any GRE (+2.17 vs + 2.40; P = .0164). -Multivariable analysis showed that diabetes (P < .001 for all models) and GRE (P < .0001 for all models) were related to a reduction in the QoL benefit experienced at 12 months.	Association of GREs with lower QOL improvement at 12 months (multivariate)	Y*	12 months post-surgery
3. Subramonia	-The sample was divided into those with sensory abnormalities (group 1) and those without sensory abnormalities (group 2) for analysis. There was no significant difference between group 1 and group 2 either in the degree of improvement in the QOL score or in the proportion of patients with an improved score -Postoperative bruising at first follow-up was recorded in 58 patients. These patients were divided into two groups: those who bruised less than the median value of 438 cm2 (group A) and those who bruised more than the median value (group B). There was no significant difference between group A and group B either in the degree of improvement in the QOL score or in the proportion of patients with an improved score. -At second follow up persistent bruising was noted in 26% (16/62) of patients. All of them showed an improvement in the postoperative QOL score (mean change in QOL score, 10.29; mean change for the entire sample, 7.54). -There was no significant difference in the degree of improvement in the QOL score between those with and without bruising at second follow-up (mean change in QOL score, 10.29 and 6.58; SE, 1.6 and 1.0, respectively; 95% CI for difference, 7.58 to 0.16; P .06)	Sensory abnormalities and bruising did not adversely influence the improvement in QOL that occurs after superficial venous surgery (univariate)	N*	N/A
4. Lohse	-Non-significant associations of SF-36 PCS or MCS with: postoperative myocardial infarction, postoperative pneumonia, postoperative stroke	Perioperative complications were not associated with lower SF-36 PCS & MCS (univariate)	N	N/A

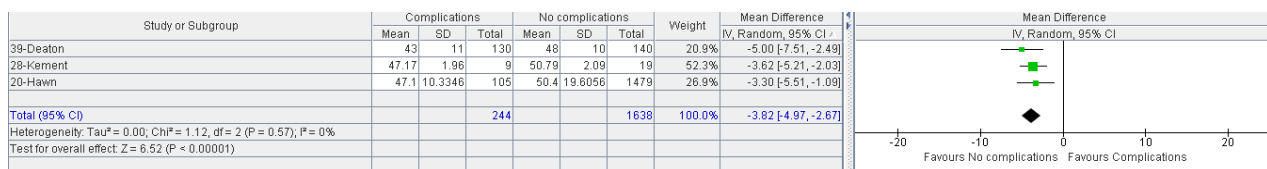
*Study controlled for patients' preoperative wellbeing

Appendix 13: Forest plots of meta-analyses on impact of complications on patients' psychosocial wellbeing

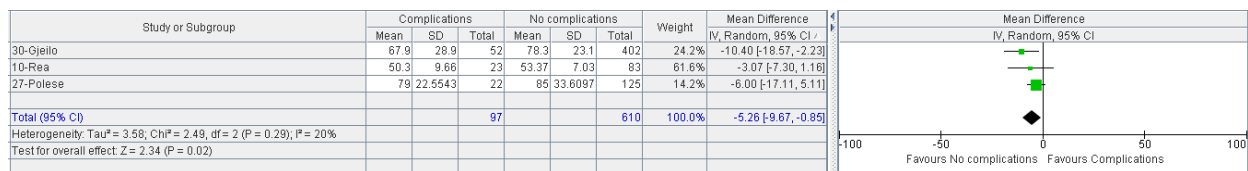
Physical summary score (SF PCS)



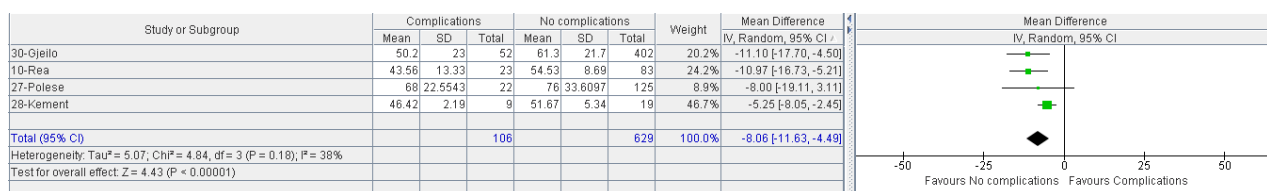
Mental summary score (SF MCS)



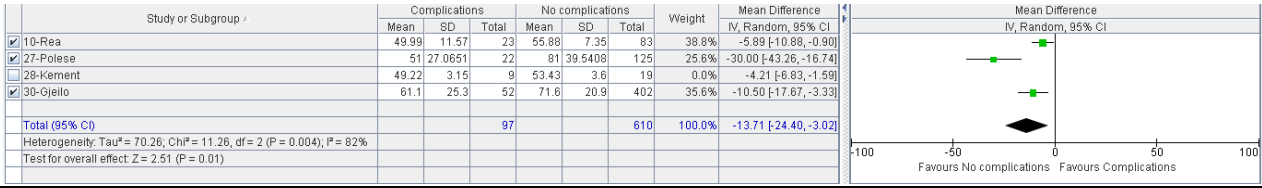
Physical functioning (SF PF)



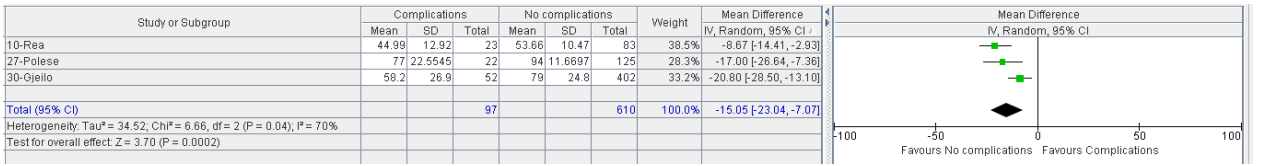
Vitality (SF VT)



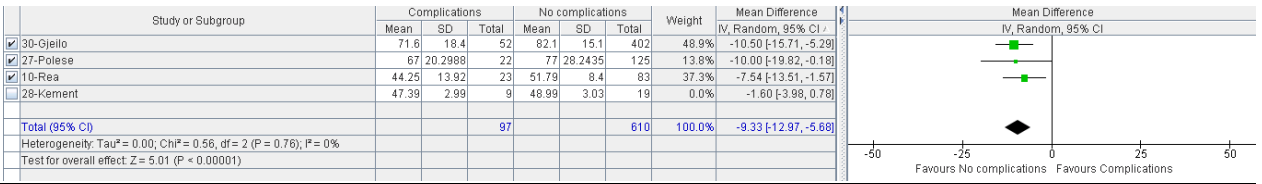
General Health (SF GH)



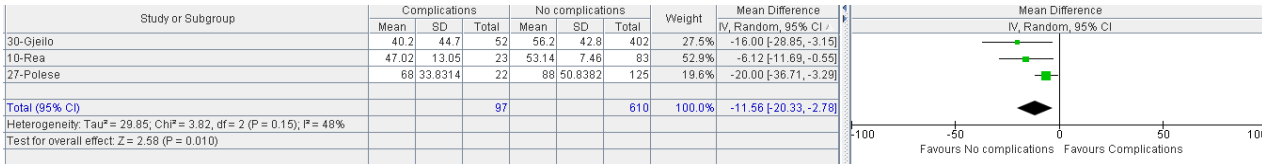
Bodily Pain (SF BP)



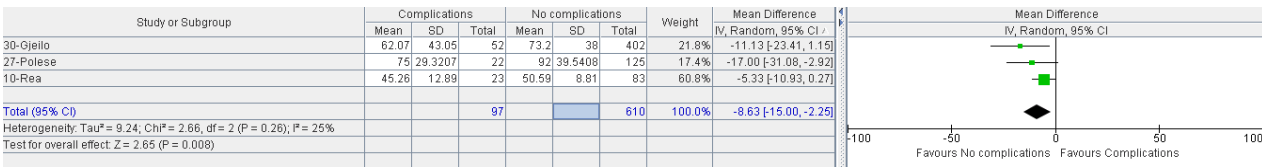
Mental Health (SF MH)



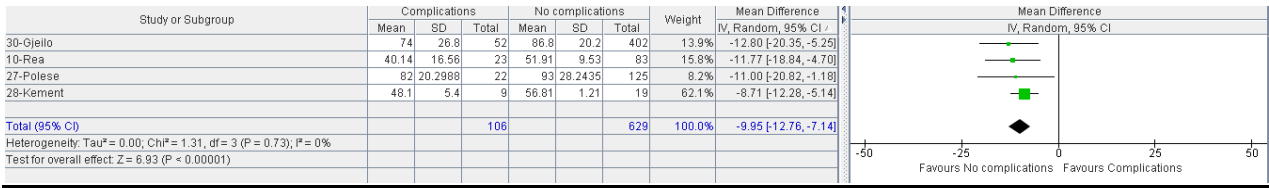
Role physical (SF RP)



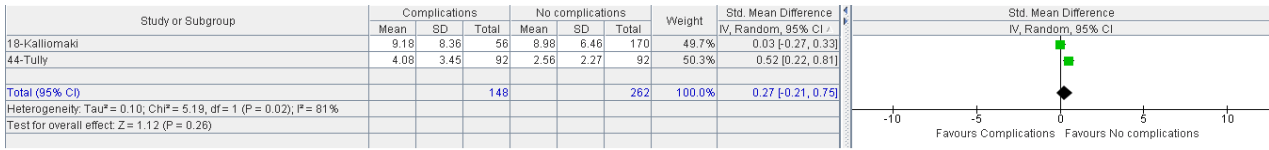
Role emotional (SF RE)



Social functioning (SF SF)



Anxiety



Appendix 14: Interview schedule for interview study on surgeons' experiences of surgical complications

Surgeons' experiences of surgical complications: Interview topics

Key Research Questions:

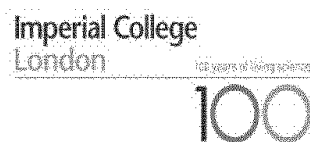
1. Do you have any experience of serious surgical complications? (for junior surgeons)
2. How do such incidents **affect** you personally and professionally?
3. How do you **cope** with their consequences on a personal and professional level?
4. How would you like to be **supported** by your institution in the event of such incidents?
5. What challenges do you face in your communication with **patients/families**?

ROLE
Please could you give your name and job title?
How many years of experience do you have as a consultant/registrar?
What is your specialty?
EXPERIENCE OF SERIOUS SURGICAL COMPLICATIONS
<i>Do you have any experience of serious surgical complications? (for junior surgeons)</i>
What does being involved in a serious patient surgical complication mean to you?
Can you describe a surgical case of the past where something went wrong that affected you professionally and/or personally?
⇒ How long ago did it happen?
⇒ How did you respond to the event?
⇒ How did it impact on you on a personal and/or professional level?
⇒ What needs did you experience on a personal and/or professional level?

⇒ How were your needs addressed?
PERSONAL AND PROFESSIONAL IMPACT OF INCIDENTS
How do you usually respond to serious surgical complications on a personal and/or professional level?
⇒ How do they impact on you? e.g. emotional reactions, performance, relationships, behaviours, thoughts, positive impact
⇒ To what extent stress resulting from serious complications affects the quality of care that you provide (reciprocal cycle of symptoms)?
What factors affect your responses to incidents?
⇒ unexpected vs. expected outcome, mistake vs. usual complication (causal attributions of incident) → see matrix of surgical complications
⇒ elective vs. emergency surgery
⇒ institutional culture
⇒ litigation
⇒ patient/family reactions
⇒ colleagues
⇒ experience/seniority
⇒ family/friends
COPING WITH INCIDENT-RELATED STRESS
How do you usually cope with the challenges imposed by such incidents on a personal and/or professional level?
⇒ Who do you usually turn for support?
⇒ What other mechanisms do you use to deal with stress?
⇒ What actions do you take in order to alleviate the stress that you experience?
⇒ What thoughts do you make in order to alleviate the stress that you experience?
What factors facilitate or hinder your coping with serious surgical incidents?
⇒ e.g. professional training, personality, incident, patient/family reactions, institution, litigation

What do you think is the best approach for surgical staff to learn to handle surgical adverse events on a personal and/or professional level?
INSTITUTIONAL SUPPORT
What is your experience to date with institutions' support for staff who are affected by serious surgical incidents on a personal and/or professional level?
⇒ How would you describe your institution in terms of available support for staff?
How would you describe your institution's culture in response to serious surgical incidents (e.g. punitive vs. open culture)?
What kind of institutional support would you wish to receive in the event of a serious surgical incident?
RELATIONSHIP WITH PATIENTS/FAMILIES
What challenges do you generally face in your communication with patients/families in the event of a serious surgical complication?
⇒ Are you personally involved in communicating the incident to the patient/family?
⇒ What factors facilitate and/or hinder your communication with patients/families in the event of a serious surgical complication? e.g. institution, culture, training, personality, patient reactions, incident type.
To what extent do you think that existing patient and family support (NHS) structures could be improved?
⇒ In what ways do you think that existing patient and family support (NHS) structures could be improved?
CLOSING REMARKS
Is there anything else that you would like to share about your experiences of serious surgical complications?

Appendix 15: Questionnaire for survey study on surgeons' wellbeing in relation to their most recent major complications



Surgical complications & surgeon wellbeing

Dear participant,

Thank you for taking part in this study. This study aims to investigate the association of surgeons' perceived major complications with personal and professional wellbeing in order to inform how best to support surgeons when serious surgical complications occur as well as how best to prepare surgical trainees to deal with their consequences effectively.

This questionnaire will ask you about your experiences of the most recent major surgical complication that you have had in your practice, your reactions to it and your ways of coping. It should take around 10-15 minutes to complete.

Thank you very much in advance for your participation.

*Prof. Charles Vincent
Mr. Omar Faiz
Mr. Colin Bicknell
Anna Pinto*

Imperial College London
Centre for Patient Safety & Service Quality
Contact: Anna Pinto a.pinto@imperial.ac.uk



Section A: Participant information

1. NHS Trust that you are working for:
2. Gender: Male ☐ Female ☐
3. Age: years
4. Nationality: a. British ☐ b. Other ☐ If other, please specify:
5. Relationship status: a. Single ☐ b. In a relationship ☐ c. Married ☐ d. Divorced ☐ e. Widowed ☐
6. Do you have children? Yes ☐ No ☐
7. Surgical specialty:
8. Clinical position: a. Consultant ☐ b. Specialist trainee ☐ c. Other ☐ If other, please specify:
9. Years of experience in this clinical position (as per Q8):
10. Hours of clinical work per week (including on call work):
11. Academic position (if any):

Section B: Experiences of a major complication

12. Have you ever had a **major surgical complication** in your practice (i.e. any major deviation from the normal postoperative course e.g. anastomotic leakage after bowel surgery, heart failure after cardiac surgery)? Yes ☐ No ☐

If you answered 'yes' please **continue**, if you answered 'no' turn to Q23.

13. When did the **most recent major complication** that you have had in your practice take place?

- a. In the last month ☐ c. In the last 6 months ☐
b. In the last 3 months ☐ d. Over a year ago ☐

14. How would you describe this complication?

15. What was the **impact** of this complication on the patient: a. The patient died ☐
b. The patient developed morbidity with lasting disability ☐
c. The patient developed morbidity but recovered fully ☐

16. What do you see as the **cause** of this complication?

17. Please answer the following questions **about the cause of this complication** (circle as appropriate). Was the cause:

All to do with you?	1	2	3	4	5	6	7	All to do with other people or external factors?
Completely controllable by you?	1	2	3	4	5	6	7	Completely uncontrollable by you

18. Have you been involved in any legal proceedings as a result of this complication? Yes ☐ No ☐

Section C: Reactions to the complication

19. Below is a list of comments made by people after stressful life events. Please check each item, indicating how frequently these comments were true for you **the month following the complication** that you described above.

	Not at all	Rarely	Sometimes	Often
I thought about it when I didn't mean to.				
I avoided letting myself get upset when I thought about it or was reminded of it.				
I tried to remove it from memory.				
I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.				
I had waves of strong feelings about it.				
I had dreams about it.				
I stayed away from reminders of it.				
I felt as if it hadn't happened or it wasn't real.				
I tried not to talk about it.				
Pictures about it popped into my mind.				
Other things kept making me think about it.				
I was aware that I still had a lot of feelings about it, but I didn't deal with them.				
I tried not to think about it.				
Any reminder brought back feelings about it.				
My feelings about it were kind of numb.				

20. These items deal with ways you've been coping with the stress related to the complication to which you are referring. Each item says something about a particular way of coping. We want to know to what extent you've been doing what the item says **in the period following the complication** that you described above. **How much or how frequently.** Please circle as appropriate.

	I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
I've been turning to work or other activities to take my mind off things.	1	2	3	4
I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4
I've been saying to myself "this isn't real."	1	2	3	4
I've been using alcohol or other drugs to make myself feel better.	1	2	3	4
I've been getting emotional support from others.	1	2	3	4
I've been giving up trying to deal with it.	1	2	3	4
I've been taking action to try to make the situation better.	1	2	3	4
I've been refusing to believe that it has happened.	1	2	3	4
I've been saying things to let my unpleasant feelings escape.	1	2	3	4
I've been getting help and advice from other people.	1	2	3	4
I've been using alcohol or other drugs to help me get through it.	1	2	3	4
I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4
I've been criticizing myself.	1	2	3	4
I've been trying to come up with a strategy about what to do.	1	2	3	4
I've been getting comfort and understanding from someone.	1	2	3	4
I've been giving up the attempt to cope.	1	2	3	4
I've been looking for something good in what is happening.	1	2	3	4
I've been making jokes about it.	1	2	3	4
I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	1	2	3	4
I've been accepting the reality of the fact that it has happened.	1	2	3	4
I've been expressing my negative feelings.	1	2	3	4
I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4
I've been trying to get advice or help from other people about what to do.	1	2	3	4
I've been learning to live with it.	1	2	3	4
I've been thinking hard about what steps to take.	1	2	3	4
I've been blaming myself for things that happened.	1	2	3	4
I've been praying or meditating.	1	2	3	4
I've been making fun of the situation.	1	2	3	4

21. The following question asks you about **sources of support that you might have used in relation to the complication** to which you are referring. Please tick how strongly you agree with each of the statements. For those that you have not used or were not available to you, please select "not applicable".

	Strongly disagree	Disagree	Neither	Agree	Strongly agree	Not applicable
Taking a break from clinical duties after the complication helped me deal with it						
Receiving information about the processes that are followed in the investigation of serious adverse events helped me deal with it						
Personal legal advice helped me deal with it						
Guidance/mentoring by senior clinical people helped me deal with it						
Discussing the complication with non clinical friends outside work helped me deal with it						
Discussing the complication with my partner helped me deal with it						
Discussing the complication with colleagues helped me deal with it						
Discussing the complication at a Morbidity & Mortality meeting helped me deal with it						
Discussing the complication with clinical friends outside work helped me deal with it						
Counselling, psychological or psychiatric services helped me deal with it						
Chaplaincy support helped me deal with it						
Attending a training programme on communicating with patients/families after adverse events helped me deal with it						
A debriefing on the complication helped me deal with it						

22. The following question asks you about **your institution's response to surgical complications in general**. Your institution refers to the one where the complication that you described took place. Please tick how strongly you agree with each of the statements.

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
Surgeons feel like their complications are held against them.					
When a complication is reported, it feels like the person is being investigated, not the problem.					
Surgeons worry that their complications are kept in their personnel file.					

Section D: Wellbeing

23. Please read each item below and tick the box that comes closest to **how you have been feeling this past week**.

I feel tense or wound up	Most of the time	A lot of the time	From time to time, occasionally	Not at all
I still enjoy the things that I used to enjoy	Definitely as much	Not quite as much	Only a little	Hardly at all
I get a frightened feeling as if something awful is about to happen	Very definitely and quite badly	Yes, but not too badly	A little but it doesn't worry me	Not at all
I can laugh and see the funny side of things	As much as I always could	Not quite so much now	Definitely not so much now	Not at all

Worrying thoughts go through my mind	A great deal of the time	A lot of the time	From time to time, but not too often	Only occasionally
I feel cheerful	Not at all	Not often	Sometimes	Most of the time
I can sit at ease and feel relaxed	Definitely	Usually	Not often	Not at all
I feel as if I am slowed down	Nearly all the time	Very often	Sometimes	Not at all
I get a sort of feeling like 'butterflies' in the stomach	Not at all	Occasionally	Quite often	Very often
I have lost interest in my appearance	Definitely	I don't take as much care as I should	I may not take quite as much care	I take just as much care as ever
I feel restless as I have to be on the move	Very much indeed	Quite a lot	Not very much	Not at all
I look forward with enjoyment to things	As much as I ever did	Rather less than I used to	Definitely less than I used to	Hardly at all
I get sudden feelings of panic	Very often indeed	Quite often	Not very often	Not at all
I can enjoy a good book or radio or TV programme	Often	Sometimes	Not often	Very seldom

24. Below is a list of **comments made by surgeons about their job**. Please check each item, indicating how frequently these comments are true for you.

	Never	A few times a year	Monthly	A few times a month	Every week	A few times a week	Every day
I deal very effectively with the problems of my patients							
I feel I treat some patients as if they were impersonal objects							
I feel emotionally drained from my work							
I feel fatigued when I get up in the morning and have to face another day on the job							
I've become more callous towards people since I took this job							
I feel I'm positively influencing other people's lives through my work							
Working with people all day is really a strain for me							
I don't really care what happens to some patients							
I feel exhilarated after working closely with my patients							
I think of giving up surgery for another career							
I reflect on the satisfaction I get from being a surgeon							
I regret my decision to have become a surgeon							

Section E: Participant feedback

Please use the space below to further describe anything that you think may be important for us to know or to comment about this survey. Please write as much as you like in the space below. Your feedback will be very valuable to us.

Also, if you are interested in contacting us further to learn more about the study or talk to us about the issues raised in this survey in more depth please do not hesitate to contact Anna Pinto on a.pinto@imperial.ac.uk.

Thank you for your participation!

Appendix 16: Spearman's correlations between coping and psychological outcomes

	Self- distraction	Active coping	Denial	Substance Use	Emotional support	Instrumental support	Behavioural Disengagement	Venting	Positive Reframing	Planning	Humour	Acceptance	Religion	Self- blame
Traumatic stress (IES Total)	.48 **	.26	.25	.04	.08	.15	.13	.28	.14	.23	.04	.15	-.11	.30
Anxiety	.50 **	.42 **	.32 *	.28	.38 *	.45 **	.23	.39 *	.26	.41 **	.18	.07	.05	.43 **
Depression	.33 *	-.12	.33 *	.35 *	.24	.22	.33 *	.26	.14	-.12	.44 **	-.05	.06	.29
Burnout/ Personal accomplishment	-.08	.20	-.34 *	-.07	.07	.00	-.18	-.02	-.21	.05	-.07	.12	-.02	-.10
Burnout/ Depersonalisation	.19	-.19	.37 *	.22	.12	.13	.06	.06	-.16	-.18	.10	-.05	-.20	.05
Burnout/ Emotional Exhaustion	.30	.18	.23	.21	.30 *	.32 *	.06	.22	-.07	.10	.13	.15	.12	.22
Satisfaction with Surgery	.28	.20	.05	.16	.25	.40 **	.16	.18	.12	.32 *	.14	.34 *	.12	.30 *

* $p < .05$

** $p < .01$

Appendix 17: Traumatic stress of clinical concern and coping, perceived support and punitive response to complications

	IES normal		IES borderline		<i>U</i>	<i>p</i>
Coping strategies	Median (<i>Range</i>)	Valid n	Median (<i>Range</i>)	Valid n		
Self-distraction	2. (3)	25	3.5 (3)	16	278.500	.006
Active coping	4.5 (5)	22	5 (6)	16	212.500	.284
Denial	2 (1)	24	2 (4)	16	205.500	.548
Substance use	2 (4)	25	2 (4)	16	205.500	.822
Emotional support	3 (6)	25	2.5 (5)	16	186.500	.704
Instrumental support	4 (6)	25	4 (6)	16	208.500	.817
Behavioural disengagement	2 (3)	25	2 (2)	16	229.000	.283
Venting	3 (6)	24	4 (6)	16	214.500	.518
Positing reframing	3 (6)	25	3 (4)	16	205.000	.890
Planning	5 (6)	25	5 (6)	16	217.000	.644
Humour	2(2)	25	2 (5)	16	202.000	.947
Acceptance	5(6)	25	6(6)	16	204.000	.913
Religion	2 (2)	25	2(3)	15	158.000	.213
Self-blame	5 (2)	25	4.5 (6)	16	236.000	.326
Sources of support						
Break from clinical duties	2 (3)	20	3 (4)	11	154.500	.066
Information about investigation of SUIs	3 (4)	17	3 (3)	11	109.500	.458
Personal legal advice	1.5 (3)	14	2 (4)	8	66.000	.525
Guidance/mentoring by senior clinical people	4 (4)	22	4 (3)	15	210.000	.171
Discussing with non-clinical friends outside work	2 (3)	24	2 (3)	12	131.000	.679
Discussing with my partner	3 (4)	21	4 (4)	14	169.500	.454
Discussing with colleagues	4 (4)	25	4 (3)	15	225.500	.230
Discussing at a Morbidity & Mortality meeting	3.5 (4)	20	3 (4)	14	114.500	.377
Discussing with clinical friends outside work	4 (4)	21	4 (4)	13	130.000	.834
Counselling, psychological services	1 (2)	15	2 (2)	11	83.500	.959
Chaplaincy support	1 (2)	13	1 (1)	10	62.000	.879
Training on communicating with patients/families after adverse	2 (3)	15	2 (3)	10	76.000	.954
Debriefing	3 (4)	17	4 (4)	13	123.000	.621
Punitive Response to complications	3.66 (4)	25	4 (3.67)	17	279.500	.080

Appendix 18: Spearman's correlations between perceptions of support, punitive response to complications and psychological outcomes

	Break from clinical duties	Information about investigation of SUIs	Personal legal advice	Guidance by senior clinical	Discussing with non-clinical friends	Discussing with my partner	Discussing with colleagues	Discussing at a Morbidity & Mortality	Discussing with clinical friends outside work	Psychological services	Chaplaincy support	Training on communicating with	Debriefing	Punitive Response to complications
1. Traumatic stress	.30	.27	.07	.21	-.07	.04	.05	-.06	-.07	-.07	-.19	-.01	.15	.31*
2. Anxiety	.34	.31	.47*	-.03	-.11	.08	-.05	-.17	-.10	.48**	.39	.30	.30	.17
3. Depression	.37*	.33	.45*	.04	.00	.10	-.04	-.21	-.09	.47*	.39	.37	.22	.17
4. Burnout/Personal accomplishment	-.28	-.01	-.15	-.12	-.13	-.01	-.31*	-.06	-.16	-.24	-.05	.04	-.10	.14
5. Burnout/Depersonalisation	.04	.11	-.06	.12	.26	.23	.34*	.05	.11	-.11	-.34	-.16	.07	.27
6. Burnout/Emotional Exhaustion	.11	.10	.14	.16	.05	.22	.24	-.09	-.02	-.05	-.18	-.10	.13	.23
7. Satisfaction with Surgery	-.07	.35	.18	.18	-.24	.08	.11	.02	-.07	-.04	-.09	-.02	.21	.07

* $p < .05$

** $p < .01$

Appendix 19: Borderline anxiety/depression and coping, perceived usefulness of support and punitive response to complications

	Anxiety						Depression					
	Normal		Borderline		U	p	Normal		Borderline		U	P
	Median (Range)	Valid n	Median (Range)	Valid n			Median (Range)	Valid n	Median (Range)	Valid n		
Coping strategies												
Self-distraction	2 (3)	32	3.5 (3)	10	252.000	.005	3 (3)	37	3.5 (3)	4	99.500	.274
Active coping	4 (6)	29	5 (4)	10	202.500	.059	6 (6)	36	4 (3)	4	53.000	.419
Denial	2 (4)	31	2 (1)	10	190.000	.300	2 (4)	37	2.5 (1)	4	104.000	.203
Substance use	2 (4)	32	2 (4)	10	206.500	.172	2 (4)	38	3 (4)	4	106.500	.199
Emotional support	2.5 (3)	32	4.5 (6)	10	233.500	.028	3 (6)	38	4.5 (4)	4	107.500	.184
Instrumental support	4 (6)	32	6 (6)	10	242.000	.014	4 (6)	38	5.5 (4)	4	114.000	.110
Behavioural disengagement	2 (3)	32	2 (2)	10	202.500	.213	2 (3)	38	3 (2)	4	103.000	.268
Venting	4 (2)	31	4.5 (6)	10	241.000	.008	3 (6)	37	4.5 (6)	4	101.000	.255
Positing reframing	3 (6)	32	4.5 (4)	10	208.500	.154	3 (6)	38	4 (2)	4	101.000	.307
Planning	4.5 (6)	32	6.5 (4)	10	233.500	.028	5 (6)	38	5 (2)	4	92.000	.521
Humour	2 (3)	32	2 (5)	10	190.000	.374	2 (4)	38	4.5 (4)	4	142.500	.001
Acceptance	5 (6)	32	6 (4)	10	193.500	.328	5 (6)	38	6.5 (2)	4	103.500	.249
Religion	2 (2)	31	2 (2)	10	146.500	.800	2 (3)	37	2 (2)	4	83.000	.719
Self-blame	4 (5)	32	6 (4)	10	252.000	.005	4 (6)	38	5.5 (5.5)	4	114.000	.110
Sources of support												
Break from clinical duties	2 (3)	23	3 (4)	10	155.000	.123	2 (4)	29	4 (3)	3	56.000	.457
Information about investigation of SULs	2 (4)	21	4 (3)	8	127.500	.032	3 (4)	26	4.5 (1)	2	46.000	.085
Personal legal advice	1 (3)	18	2.5 (3)	6	89.000	.018	2 (4)	21	3 (2)	2	32.500	.237
Guidance/mentoring by senior clinical people	4 (4)	28	4 (3)	10	139.500	.987	4 (4)	33	4 (1)	4	82.500	.435
Discussing with non-clinical friends outside work	2 (3)	27	2 (3)	11	112.500	.251	2 (3)	33	2 (3)	4	64.000	.944
Discussing with my partner	3.5 (4)	28	4 (4)	9	148.000	.453	4 (4)	32	3 (2)	4	56.000	.716

Discussing with colleagues	4 (4)	31	4 (2)	11	206.000	.322	4 (4)	37	4 (1)	4	76.000	.949
Discussing at a Morbidity & Mortality meeting	4 (4)	27	3 (2)	8	74.000	.192	3 (4)	32	4 (2)	3	50.000	.934
Discussing with clinical friends outside work	4 (4)	26	3 (4)	10	110.500	.497	4 (4)	31	3 (3)	4	63.000	1.000
Counselling, psychological services	1 (2)	18	2 (2)	10	130.000	.057	1 (2)	24	2 (2)	3	46.000	.483
Chaplaincy support	1 (2)	17	2 (2)	8	90.500	.194	1 (2)	22	2 (2)	2	28.500	.522
Training on communicating with patients/families after adverse events	2 (3)	19	2 (1)	9	96.000	.307	2 (3)	24	2.5 (1)	2	33.500	.394
Debriefing	3 (4)	23	4 (3)	9	156.000	.027	3 (4)	29	4 (1)	3	56.000	.457
Punitive Response to complications	3.67 (4)	32	4 (2.67)	11	196.000	.592	3.66 (4)	39	3.83 (1)	4	94.500	.505

Appendix 20: Spearman's correlations between psychological outcomes and causal attributions

	Traumatic stress	Anxiety	Depression	Personal accomplishment	Depersonalisation	Emotional Exhaustion	Satisfaction with surgery
Internality of causes	.083	-.002	-.173	.293	-.191	-.197	-.092
Controllability of causes	-.082	.091	-.149	.166	-.006	-.134	-.042

* $p < .05$

** $p < .01$

Appendix 21: Interview schedule for interview study on patients' experiences of surgical complications

Surgical complications and patients' wellbeing: Interview topics

Key Research Themes:

- A. Life before surgery
- B. Experience of hospital stay
- C. Life after surgery

PARTICIPANT INFORMATION
Please could you give me your name, your age and your telephone number (for follow-up)?
What is the reason for having had surgery?
LIFE BEFORE SURGERY
What was your life like before surgery?
⇒ What symptoms/problems did you experience in relation to your health?
⇒ When did they start?
⇒ How concerned were you about your health condition?
⇒ How did your symptoms impact on your day-to-day life? (i.e. daily activities)
⇒ How did they impact on you emotionally? (i.e. make you angry, scared, upset, depressed)
⇒ How were you coping with the stress resulting from your condition?
⇒ How did you decide to have surgery? (e.g. who referred you?)
⇒ What were your expectations of surgery?
⇒ How well prepared do you think you were to undergo surgery?

EXPERIENCE OF HOSPITAL STAY
What has your experience of surgery been like?
⇒ How has your recovery from surgery been?
⇒ How have your symptoms changed after surgery?
⇒ How much pain (or disability) have you been in after surgery?
⇒ Have you experienced any complications/side-effects related to your surgery?
⇒ How concerned are you about these complications/side-effects?
⇒ What support have you received from your clinical care team? <i>(before and after surgery)</i>
⇒ What support have you received from your family and friends? <i>(before and after surgery)</i>
⇒ Is there anything else that they could have done that would have been helpful?
⇒ What other forms of support would have been helpful in relation to your surgery?
⇒ How have you been coping with your recovery since your surgery?
⇒ How concerned are you about your health condition now? (e.g. optimistic vs. pessimistic)
LIFE AFTER SURGERY (telephone follow-up, 1 month post-op)
How is your life after surgery? (i.e. since you returned home)
⇒ How has your recovery been?
⇒ How have your symptoms changed after surgery?
⇒ How much pain (or disability) have you been in after surgery?
⇒ Have you experienced any complications/side-effects related to your surgery?
⇒ How concerned are you about these complications/side-effects?

⇒ What forms of support have you received since you returned home? (i.e. family, friends, doctors)
⇒ What other forms of support would have been helpful?
⇒ How concerned are you about your health condition now? (e.g. optimistic vs. pessimistic)
⇒ How does your condition affect your day-to-day life (i.e. daily activities)?
⇒ How does it affect you emotionally? (angry, upset, scared, depressed etc.)
⇒ How have you been coping with your condition since you returned home?
⇒ Have your expectations from surgery been met?

Appendix 22: Preoperative questionnaire of longitudinal study on surgical complications and patients' psychological wellbeing



Imperial College
London

100 years of living science

100

Surgery & patients' wellbeing (t1:pre-operative)

Dear participant,

Thank you for taking part in this study. This study aims to investigate the association of surgical outcome with patients' wellbeing. This questionnaire will ask you about your surgery and its outcome, your current wellbeing, the support you receive and your coping strategies in relation to your surgery. It should take around 15 minutes to complete.

Your answers will be very valuable as they will contribute towards better understanding how patients recover after major surgery. This will allow us to make informed recommendations about the improvement of services for surgical patients.

Responses are confidential and all data will be recorded and reported anonymously.

Sincerely,
Anna Pinto
Mr. Omar Faiz
Mr. Colin Bicknell
Prof. Charles Vincent

Imperial College London
Centre for Patient Safety & Service Quality
Contact: Anna Pinto a.pinto@imperial.ac.uk

CPSSQ

Centre for Patient Safety & Service Quality

Patient ID No: _____

Version 3.0-07 August 2012

Patient information

The following questions ask you about yourself. This is for us to be able to analyse the data on the basis of some demographic information which is shown in the literature to explain a lot of the outcomes that we are investigating in this study. We need your name, telephone number and home address in order to send you follow-up questionnaires after your discharge. This will help us keep track of your recovery and general wellbeing over a period of time.

1. Patient Initials:		2. Contact number:	
3. Home address:		4. Gender:	Male ☐ Female ☐
5. Age:	years	6. Do you have children?	Yes ☐ No ☐
7. Relationship status:		8. Job status	
a. Single	☐	a. Employed	☐
b. In a relationship	☐	b. Unemployed	☐
c. Married	☐	c. Retired	☐
d. Divorced	☐	d. Student	☐
e. Widowed	☐	e. Other (please specify)	
9. Ethnicity			
a. White British	☐	j. Asian/Asian British (all other)	☐
b. White (other)	☐	k. Black/Black British (Caribbean)	☐
c. Mixed (White & Black Caribbean)	☐	l. Black/Black British (African)	☐
d. Mixed (White & Black African)	☐	m. Black/Black British (all other)	☐
e. Mixed (White & Asian)	☐	n. Chinese	☐
f. Mixed (all other)	☐	o. Not given	☐
g. Asian/Asian British (Indian)	☐	p. Other (please specify)	
h. Asian/Asian British (Pakistani)	☐		
i. Asian/Asian British (Bangladeshi)	☐		
10. Education			
a. GCSE	☐	d. Postgraduate degree	☐
b. A Levels	☐	e. Professional qualification	☐
c. Undergraduate degree	☐	f. No qualifications	☐
		g. Other (please specify)	

Patient ID No: _____

Version 3.0-07 August 2012

Illness perceptions

11. What is the condition/illness for which you need surgery?

12. What type of surgery are you having?

13. For the following questions, please circle the number that best corresponds to your views:

a) How much does your illness affect your life?	No affect at all	0 1 2 3 4 5 6 7 8 9 10	Affects my life severely
b) How long do you think your illness will continue?	Forever	0 1 2 3 4 5 6 7 8 9 10	A very short time
c) How much control do you feel you have over your illness?	Absolutely no control	0 1 2 3 4 5 6 7 8 9 10	Extreme amount of control
d) How much do you think surgery can help your illness?	Not at all helpful	0 1 2 3 4 5 6 7 8 9 10	Extremely helpful
e) How much do you experience symptoms from your illness?	No symptoms at all	0 1 2 3 4 5 6 7 8 9 10	Many severe symptoms
f) How concerned are you about your illness?	Not at all concerned	0 1 2 3 4 5 6 7 8 9 10	Extremely concerned
g) How well do you feel you understand your illness?	Don't understand at all	0 1 2 3 4 5 6 7 8 9 10	Understand very clearly
h) How much does your illness affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)	Not at all affected	0 1 2 3 4 5 6 7 8 9 10	Extremely affected

Please list in rank-order the three most important factors that you believe caused your illness. *The most important causes for me:*

1. _____
2. _____
3. _____

Wellbeing

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

14. In general, would you say your health is (please tick one):

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

15. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
Climbing <u>several</u> flights of stairs			

16. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
<u>Accomplished less</u> than you would like					
Were limited in the <u>kind</u> of work or other activities					

17. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
<u>Accomplished less</u> than you would like					
Did work or other activities <u>less carefully than usual</u>					

18. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely

19. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?					
b) Did you have a lot of energy?					
c) Have you felt downhearted and blue?					

20. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time

21. The following questions ask you about **how you have been feeling in the past week**. There are no right or wrong answers. Please be as truthful as you can.

a. I feel tense or wound up	Most of the time	A lot of the time	From time to time, occasionally	Not at all
b. I still enjoy the things that I used to enjoy	Definitely as much	Not quite as much	Only a little	Hardly at all
c. I get a frightened feeling as if something awful is about to happen	Very definitely and quite badly	Yes, but not too badly	A little but it doesn't worry me	Not at all
d. I can laugh and see the funny side of things	As much as I always could	Not quite so much now	Definitely not so much now	Not at all
e. Worrying thoughts go through my mind	A great deal of the time	A lot of the time	From time to time, but not too often	Only occasionally
f. I feel cheerful	Not at all	Not often	Sometimes	Most of the time
g. I can sit at ease and feel relaxed	Definitely	Usually	Not often	Not at all
h. I feel as if I am slowed down	Nearly all the time	Very often	Sometimes	Not at all
i. I get a sort of feeling like 'butterflies' in the stomach	Not at all	Occasionally	Quite often	Very often
j. I have lost interest in my appearance	Definitely	I don't take as much care as I should	I may not take quite as much care	I take just as much care as ever
k. I feel restless as I have to be on the move	Very much indeed	Quite a lot	Not very much	Not at all
l. I look forward with enjoyment to things	As much as I ever did	Rather less than I used to	Definitely less than I used to	Hardly at all
m. I get sudden feelings of panic	Very often indeed	Quite often	Not very often	Not at all
n. I can enjoy a good book or radio or TV programme	Often	Sometimes	Not often	Very seldom

Coping with surgery-related stress

22. The following items deal with ways you've been coping with the stress DUE TO THE SURGERY that you are about to have. There are many ways to try to deal with problems. These items ask what you've been doing to cope with this one. Each item says something about a particular way of coping. We want to know to what extent you've been doing what the item says since you decided to have surgery for your illness. How much or how frequently. Don't answer on the basis of whether it seems to be working or not—just whether or not you're doing it. Make your answers as true FOR YOU as you can.

	1 I haven't been doing this at all	2 I've been doing this a little bit	3 I've been doing this a medium amount	4 I've been doing this a lot
a. I've been turning to work or other activities to take my mind off things.	1	2	3	4
b. I've been concentrating my efforts on doing something about the situation I'm in.	1	2	3	4
c. I've been saying to myself "this isn't real."	1	2	3	4
d. I've been using alcohol or other drugs to make myself feel better.	1	2	3	4
e. I've been getting emotional support from others.	1	2	3	4
f. I've been giving up trying to deal with it.	1	2	3	4
g. I've been taking action to try to make the situation better.	1	2	3	4
h. I've been refusing to believe that it has happened.	1	2	3	4
i. I've been saying things to let my unpleasant feelings escape.	1	2	3	4
j. I've been getting help and advice from other people.	1	2	3	4
k. I've been using alcohol or other drugs to help me get through it.	1	2	3	4
l. I've been trying to see it in a different light, to make it seem more positive.	1	2	3	4
m. I've been criticizing myself.	1	2	3	4
n. I've been trying to come up with a strategy about what to do.	1	2	3	4
o. I've been getting comfort and understanding from someone.	1	2	3	4
p. I've been giving up the attempt to cope.	1	2	3	4
q. I've been looking for something good in what is happening.	1	2	3	4
r. I've been making jokes about it.	1	2	3	4
s. I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.	1	2	3	4
t. I've been accepting the reality of the fact that it has happened.	1	2	3	4
u. I've been expressing my negative feelings.	1	2	3	4
v. I've been trying to find comfort in my religion or spiritual beliefs.	1	2	3	4
w. I've been trying to get advice or help from other people about what to do.	1	2	3	4
x. I've been learning to live with it.	1	2	3	4
y. I've been thinking hard about what steps to take.	1	2	3	4
z. I've been blaming myself for things that happened.	1	2	3	4
aa. I've been praying or meditating.	1	2	3	4
bb. I've been making fun of the situation.	1	2	3	4

Support

23. Below are some questions about the kind of help and support you have available to you in coping with your life at present. The questions refer to two different groups of people who might have been providing support to you **since you decided to have surgery** for your condition/illness. For each item, please tick the answer which best shows how you feel.

Firstly, think of **your family and closest friends**, especially the 2 -3 who are most important to you.

	Not enough	Too often	It was just right
a. How often did they really listen to you when you talked about your problems or worries about surgery?			
b. How often did you feel that they were really trying to understand you?			
c. How often did they make you feel loved?			
d. How often did they help you in practical ways, like doing things for you or helping you to cope with stress due to surgery?			
e. How often did they give you advice about your problems or worries about surgery?			
f. How often could you use them as examples of how to deal with problems or worries about surgery?			

Now, think about the **health/medical professionals** who take care of you, including your **surgeon**.

	Not enough	Too often	It was just right
g. How often did they really listen to you when you talked about your problems or worries about surgery?			
h. How often did you feel that they were really trying to understand you as an individual?			
i. How often did they help you in practical ways, like reducing your pain or symptoms, or helping you to get other services?			
j. How often did they give you clear and useful advice and information?			
k. How often could you use them as examples of how to deal with problems e.g. how to cope with surgery or worry?			

Feedback

24. Please use the space below to further describe anything that you think may be important for us to know about this survey. Your feedback will be very valuable to us. Also, if you are interested in contacting us further to learn more about the study or talk to us about the issues raised in this survey in more depth please do not hesitate to contact Anna Pinto on a.pinto@imperial.ac.uk or on 02075949725.

Thank you for filling out this survey!

Appendix 23: Dindo's grading system of complications

Classification of Surgical Complications	
Grade	Definition
Grade I	Any deviation from the ideal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring HDU/ICU management
Grade IVa	Single organ dysfunction (including dialysis or assisted ventilation and inotropes)
Grade IVb	Multiorgan dysfunction
Suffix "d"	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix "d" (for "disability") is added to the respective grade of complication.
*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks. CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.	

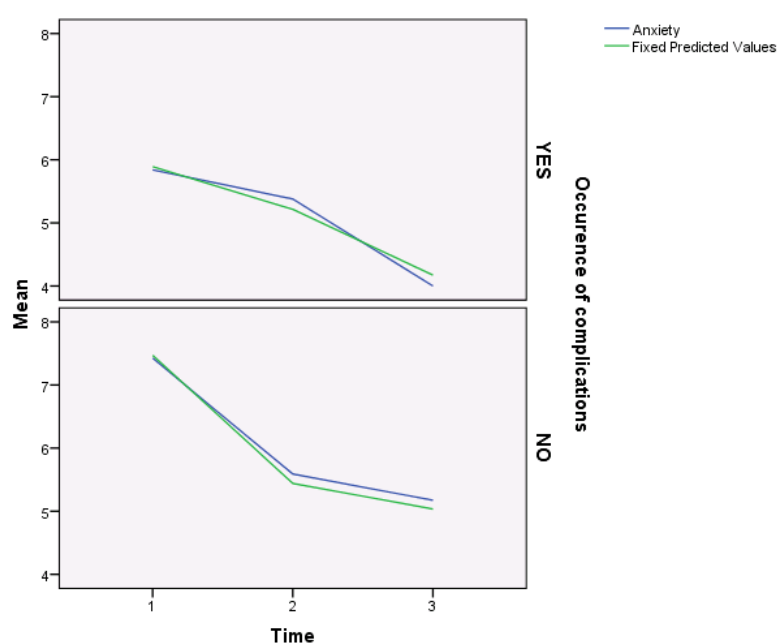
Appendix 24: Surgical Complications Log

Complications [please describe any complications (i.e. any deviation from the ideal postoperative course) that the patient experienced secondary to their surgery/use a separate row for each complication and add as many rows as necessary]	System (please select one) 1=Cardiac 2=Respiratory 3=Neurological 4=Renal 5=Gastro-intestinal 6=Other (if other please specify)	Start Date dd/mm/yyyy & Stop Date dd/mm/yyyy	Management (please select all that apply) 1= Conservative management without pharmacological intervention 2=Conservative management with pharmacological intervention 3=Re-operation 4=Requiring HDU 6=Requiring ITU 7=Other (please specify)	Outcome (please select all that apply) 1=Recovered quickly and was discharged without delays 2=Recovered with delayed discharge 3=Recovered with temporary disability/disfigurement 4=Recovered with permanent disability/disfigurement 5=Died 6=Other (please describe)	Severity Grading I II III (IIIa or IIIb) IV (IVa or IVb) V Add suffix d if appropriate.	Does the patient suffer from the complication at discharge? (Yes/No) If yes please explain.
1.						
2.						
3.						
4.						
5.						

Appendix 25: Multilevel Mixed Linear models analysis on anxiety: MODEL 1

Model description:

A linear mixed model with random coefficients was fit on anxiety with the occurrence of any complications and surgical specialty as fixed factors, time as a covariate and the intercept as random with unstructured covariance in order to account for individual variability in anxiety change over time. Based on this model, there was a significant main effect of surgical specialty with vascular and cardio-thoracic patients reporting higher levels of anxiety than gastro-intestinal patients at all time-points and a significant effect of time with anxiety significantly reducing after surgery. There was no significant main effect of the occurrence of any complications or any interactions between the occurrence of complications and time, which suggests that the change in anxiety levels post-surgery was similar for both patients who suffered complications and those who did not. The variance of the intercept was significant which indicated that there was significant variability amongst individuals with regard to the change of anxiety over time. A graphic representation of the observed values of anxiety against the fixed predicted values suggests that this model is relatively accurate in the prediction of the observed values even though the lines of observed and predicted values are slightly diverging from each other.



Model Dimension^a

		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	1	Identity	1	id
	Surgery_specialty	3		2	
	Complications_YesNo_Notes	2		1	
	Time	1		1	
	Days_baseline	1		1	
	Complications_YesNo_Notes * Time	2		1	
	Complications_YesNo_Notes * Days_baseline	2		1	
	Random Effects Intercept	1		1	
	Residual			1	
Total		13		10	

a. Dependent Variable: Anxiety.

Information Criteria^a

-2 Restricted Log Likelihood	1200.683
Akaike's Information Criterion (AIC)	1204.683
Hurvich and Tsai's Criterion (AICC)	1204.740
Bozdogan's Criterion (CAIC)	1213.434
Schwarz's Bayesian Criterion (BIC)	1211.434

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: Anxiety.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	176.161	111.859	.000
Surgery_specialty	2	94.922	3.954	.022
Complications_YesNo_Notes	1	175.134	2.821	.095
Time	1	132.052	7.955	.006
Days_baseline	1	131.885	.907	.343
Complications_YesNo_Notes * Time	1	132.642	2.225	.138
Complications_YesNo_Notes * Days_baseline	1	132.522	1.876	.173

a. Dependent Variable: Anxiety.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	8.296571	1.156424	211.317	7.174	.000	6.016965	10.576176
[Surgery_specialty=.0]	1.895843	.745221	98.379	2.544	.013	.417047	3.374639
[Surgery_specialty=1.0]	2.034338	.903259	93.398	2.252	.027	.240746	3.827930
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	- 2.618778	1.559160	175.134	-1.680	.095	-5.695940	.458384
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
Time	- 2.330378	.696781	133.067	-3.344	.001	-3.708579	-.952178
Days_baseline	.032316	.018109	133.002	1.785	.077	-.003502	.068134
[Complications_YesNo_Notes=0] * Time	1.610652	1.079749	132.642	1.492	.138	-.525102	3.746407
[Complications_YesNo_Notes=1] * Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0] * Days_baseline	-.038102	.027816	132.522	-1.370	.173	-.093122	.016918
[Complications_YesNo_Notes=1] * Days_baseline	0 ^b	0	.	.	.	.	.

a. Dependent Variable: Anxiety.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	7.684054	1.003659	7.656	.000	5.948535	9.925922
Intercept [subject = id] Variance	6.684170	1.571240	4.254	.000	4.216544	10.595914

a. Dependent Variable: Anxiety.

Appendix 26: Multilevel Mixed Linear models analysis on anxiety: MODEL 2

Model Dimension ^a						
		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables	
Fixed Effects	Intercept	1	Identity	1	id	
	Surgery_specialty	3		2		
	Complications_YesNo_Notes	2		1		
	Time	1		1		
	Days_baseline	1		1		
	Complications_YesNo_Notes * Time	2		1		
	Complications_YesNo_Notes * Days_baseline	2		1		
	Illness_d_surgerycontrol_t1	1		1		
	Coping_selfdistraction_t1	1		1		
	Coping_InstrumSupport_t1	1		1		
	Coping_SubstanceUse_t1	1		1		
	Coping_venting_t1	1		1		
	Random Effects	Intercept		1		1
	Residual					1
Total		18		15		

Information Criteria ^a	
-2 Restricted Log Likelihood	1133.379
Akaike's Information Criterion (AIC)	1137.379
Hurvich and Tsai's Criterion (AICC)	1137.438
Bozdogan's Criterion (CAIC)	1146.034
Schwarz's Bayesian Criterion (BIC)	1144.034

The information criteria are displayed in smaller-is-better forms.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	119.481	1.166	.282
Surgery_specialty	2	81.451	3.409	.038
Complications_YesNo_Notes	1	160.071	4.108	.044
Time	1	134.713	7.681	.006
Days_baseline	1	138.076	.735	.393
Complications_YesNo_Notes * Time	1	134.888	2.872	.092
Complications_YesNo_Notes *	1	137.603	2.750	.100
Days_baseline	1	137.603	2.750	.100
Illness_d_surgerycontrol_t1	1	105.612	.003	.957
Coping_selfdistraction_t1	1	93.075	9.600	.003
Coping_InstrumSupport_t1	1	90.662	.336	.564
Coping_SubstanceUse_t1	1	73.748	4.180	.044
Coping_venting_t1	1	95.217	16.350	.000

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	T	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	2.80938 1	2.201727	127.269	1.276	.204	-1.547351	7.166112
[Surgery_specialty=.0]	1.52187 5	.606312	84.588	2.510	.014	.316280	2.727470
[Surgery_specialty=1.0]	1.34036 4	.722059	80.423	1.856	.067	-.096464	2.777192
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes =0]	- 8	3.08198	160.071	-2.027	.044	-6.085124	-.078852
[Complications_YesNo_Notes =1]	0 ^b -	0	.	.	.	.	.
Time	2.42358 7	.709468	133.471	-3.416	.001	-3.826841	-1.020332
Days_baseline	.034987	.018245	137.418	1.918	.057	-.001089	.071064
[Complications_YesNo_Notes =0] * Time	1.83668 1	1.083855	134.888	1.695	.092	-.306866	3.980228
[Complications_YesNo_Notes =1] * Time	0 ^b	0	.	.	.	.	.

[Complications_YesNo_Notes =0] * Days_baseline	- .046121	.027810	137.603	-1.658	.100	-.101110	.008869
[Complications_YesNo_Notes =1] * Days_baseline	0 ^b	0	.	.	.	.	.
Illness_d_surgerycontrol_t1	- .009819	.180280	105.612	-.054	.957	-.367257	.347620
Coping_selfdistraction_t1	.490042	.158164	93.075	3.098	.003	.175963	.804121
Coping_InstrumSupport_t1	.099542	.171758	90.662	.580	.564	-.241651	.440734
Coping_SubstanceUse_t1	.361932	.177024	73.748	2.045	.044	.009183	.714681
Coping_venting_t1	.801524	.198224	95.217	4.044	.000	.408011	1.195036

a. Dependent Variable: Anxiety.

b. This parameter is set to zero because it is redundant.

Covariance Parameters

Estimates of Covariance Parameters^a

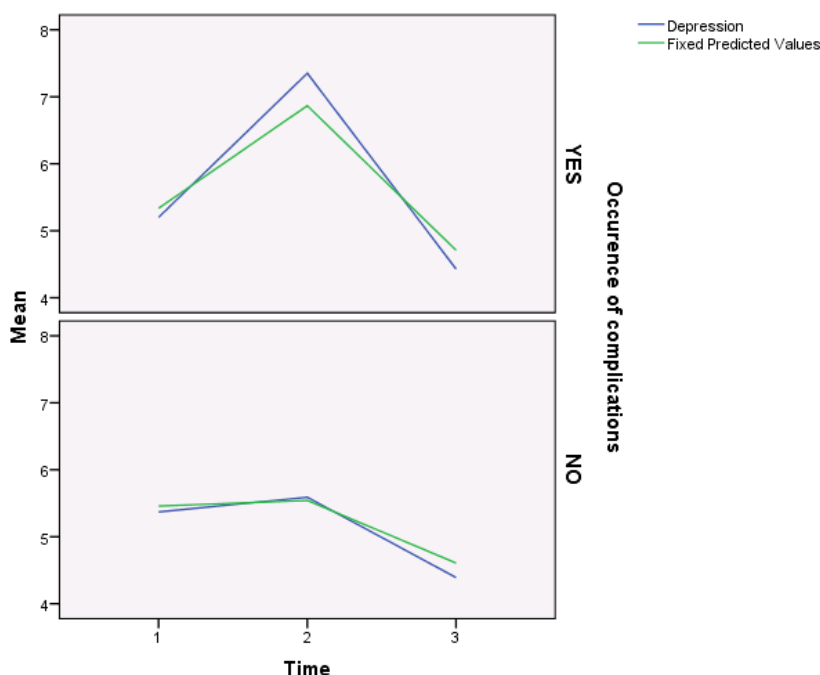
Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	7.828109	1.025645	7.632	.000	6.055246	10.120033
Intercept [subject = id] Variance	2.651499	1.067072	2.485	.013	1.204851	5.835119

a. Dependent Variable: Anxiety.

Appendix 27: Multilevel Mixed Linear models analysis on depression: MODEL 1

Model description

A linear mixed model with random coefficients was fit on depression with the occurrence of any complications and surgical specialty as fixed factors, time as a covariate and the intercept as random (unstructured covariance). There was a significant effect of surgical specialty ($p < .01$) with vascular and cardio-thoracic patients reporting higher levels of depression than gastro-intestinal patients over time. There were no significant main effects of time, the occurrence of any complications, or any interactions between the occurrence of any complications and time ($p > .05$). The variance of the intercept was significant which indicated that there was significant variability amongst individuals in depression levels over time. A graphic representation of the observed values of depression against the fixed predicted values suggests that the model is not very accurate in the prediction of the observed values of depression for patients who suffered complications.



Model Dimension^a

		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	1	Identity	1	id
	Surgery_specialty	3		2	
	Complications_YesNo_Notes	2		1	
	Time	1		1	
	Days_baseline	1		1	
	Complications_YesNo_Notes * Time	2		1	
	Complications_YesNo_Notes * Days_baseline	2		1	
Random Effects	Intercept	1		1	
Residual				1	
Total		13		10	

a. Dependent Variable: Depression.

Information Criteria^a

-2 Restricted Log Likelihood	1215.425
Akaike's Information Criterion (AIC)	1219.425
Hurvich and Tsai's Criterion (AICC)	1219.482
Bozdogan's Criterion (CAIC)	1228.176
Schwarz's Bayesian Criterion (BIC)	1226.176

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: Depression.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	167.125	25.558	.000
Surgery_specialty	2	90.956	5.513	.005
Complications_YesNo_Notes	1	166.384	.969	.326
Time	1	137.398	4.005	.047
Days_baseline	1	139.057	6.578	.011
Complications_YesNo_Notes	1	138.066	3.281	.072
* Time	1	138.066	3.281	.072
Complications_YesNo_Notes	1	139.796	3.507	.063
* Days_baseline	1	139.796	3.507	.063

a. Dependent Variable: Depression.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	3.685777	1.219903	201.596	3.021	.003	1.280372	6.091183
[Surgery_specialty=.0]	2.072427	.696296	94.628	2.976	.004	.690035	3.454819
[Surgery_specialty=1.0]	2.270119	.839651	89.318	2.704	.008	.601832	3.938406
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	1.664967	1.691746	166.384	-.984	.326	-5.005023	1.675088
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
Time	.116289	.773801	138.310	.150	.881	-1.413721	1.646298
Days_baseline	-.010770	.020099	140.242	-.536	.593	-.050506	.028966
[Complications_YesNo_Notes=0]	2.172432	1.199397	138.066	1.811	.072	-.199129	4.543993
* Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
* Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	-.057835	.030883	139.796	-1.873	.063	-.118894	.003224
* Days_baseline	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
* Days_baseline	0 ^b	0	.	.	.	.	.

a. Dependent Variable: Depression.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	9.732181	1.267053	7.681	.000	7.540332	12.561164
Intercept [subject = id] Variance	4.390630	1.433156	3.064	.002	2.315710	8.324717

a. Dependent Variable: Depression.

Information Criteria^a

-2 Restricted Log Likelihood	1183.754
Akaike's Information Criterion (AIC)	1187.754
Hurvich and Tsai's Criterion (AICC)	1187.812
Bozdogan's Criterion (CAIC)	1196.448
Schwarz's Bayesian Criterion (BIC)	1194.448

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: Depression.

Appendix 28: Multilevel Mixed Linear models analysis on depression: MODEL 2

Model Dimension ^a				
	Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	Identity	1	id
	Surgery_specialty		2	
	Complications_YesNo_Notes		1	
	Coping_selfdistraction_t1		1	
	SocialSupport_family_t1		1	
	Time		1	
	Days_baseline		1	
	Complications_YesNo_Notes * Time		1	
	Complications_YesNo_Notes * Days_baseline		1	
Random Effects	Intercept		1	
Residual			1	
Total	15		12	

a. Dependent Variable: Depression.

Information Criteria ^a	
-2 Restricted Log Likelihood	1182.035
Akaike's Information Criterion (AIC)	1186.035
Hurvich and Tsai's Criterion (AICC)	1186.092
Bozdogan's Criterion (CAIC)	1194.739
Schwarz's Bayesian Criterion (BIC)	1192.739

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: Depression.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	118.912	12.224	.001
Surgery_specialty	2	84.452	5.651	.005
Complications_YesNo_Notes	1	160.091	1.598	.208
Coping_selfdistraction_t1	1	85.607	7.504	.007
SocialSupport_family_t1	1	89.295	6.976	.010
Time	1	139.004	3.631	.059
Days_baseline	1	141.918	6.038	.015
Complications_YesNo_Notes *	1	138.518	4.577	.034
Time	1	138.518	4.577	.034
Complications_YesNo_Notes *	1	141.689	4.491	.036
Days_baseline	1	141.689	4.491	.036

a. Dependent Variable: Depression.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	6.762909	2.242383	131.273	3.016	.003	2.327027	11.198791
[Surgery_specialty=.0]	2.079842	.642496	87.165	3.237	.002	.802845	3.356839
[Surgery_specialty=1.0]	1.860045	.783902	82.963	2.373	.020	.300885	3.419206
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes =0]	-2.133086	1.687294	160.091	-1.264	.208	-5.465311	1.199139
[Complications_YesNo_Notes =1]	0 ^b	0	.	.	.	.	.
Coping_selfdistraction_t1	.400520	.146211	85.607	2.739	.007	.109843	.691198
SocialSupport_family_t1	-1.619438	.613141	89.295	-2.641	.010	-2.837681	-.401195
Time	-.140949	.787344	139.396	-.179	.858	-1.697629	1.415732
Days_baseline	-.005295	.020359	142.396	-.260	.795	-.045541	.034951
[Complications_YesNo_Notes =0] * Time	2.590265	1.210719	138.518	2.139	.034	.196386	4.984144
[Complications_YesNo_Notes =1] * Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes =0] * Days_baseline	-.065905	.031098	141.689	-2.119	.036	-.127381	-.004429
[Complications_YesNo_Notes =1] * Days_baseline	0 ^b	0	.	.	.	.	.

a. Dependent Variable: Depression.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	9.907856	1.292381	7.666	.000	7.672713	12.794120
Intercept [subject = id] Variance	2.749296	1.242539	2.213	.027	1.133764	6.666845

a. Dependent Variable: Depression.

Parameter Estimates

Dependent Variable: Depression

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	3.828	.724	5.286	.000	2.402	5.254
[Complications_YesNo_Notes=0] * [Time=1]	1.245	.895	1.392	.165	-.517	3.007
[Complications_YesNo_Notes=0] * [Time=2]	3.807	.946	4.023	.000	1.943	5.670
[Complications_YesNo_Notes=0] * [Time=3]	1.172	1.064	1.102	.272	-.923	3.268
[Complications_YesNo_Notes=1] * [Time=1]	1.369	.879	1.557	.121	-.363	3.101
[Complications_YesNo_Notes=1] * [Time=2]	2.128	.929	2.292	.023	.299	3.957
[Complications_YesNo_Notes=1] * [Time=3]	0 ^a	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Estimated Marginal Means

Estimates

Dependent Variable: Depression

Occurrence of complications	Time	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
YES	1	5.073	.526	4.037	6.108
	2	7.634	.609	6.435	8.833
	3	5.000	.780	3.464	6.536
NO	1	5.197	.499	4.213	6.180
	2	5.956	.581	4.811	7.100
	3	3.828	.724	2.402	5.254

Pairwise Comparisons

Dependent Variable: Depression

Time	(I) Occurrence of complications	(J) Occurrence of complications	Mean Difference (I-J)	Std. Error	Sig. ^b	95% Confidence Interval for Difference ^b	
						Lower Bound	Upper Bound
1	YES	NO	-.124	.725	.864	-1.552	1.304
	NO	YES	.124	.725	.864	-1.304	1.552
2	YES	NO	1.679*	.842	.047	.021	3.337
	NO	YES	-1.679*	.842	.047	-3.337	-.021
3	YES	NO	1.172	1.064	.272	-.923	3.268
	NO	YES	-1.172	1.064	.272	-3.268	.923

Based on estimated marginal means

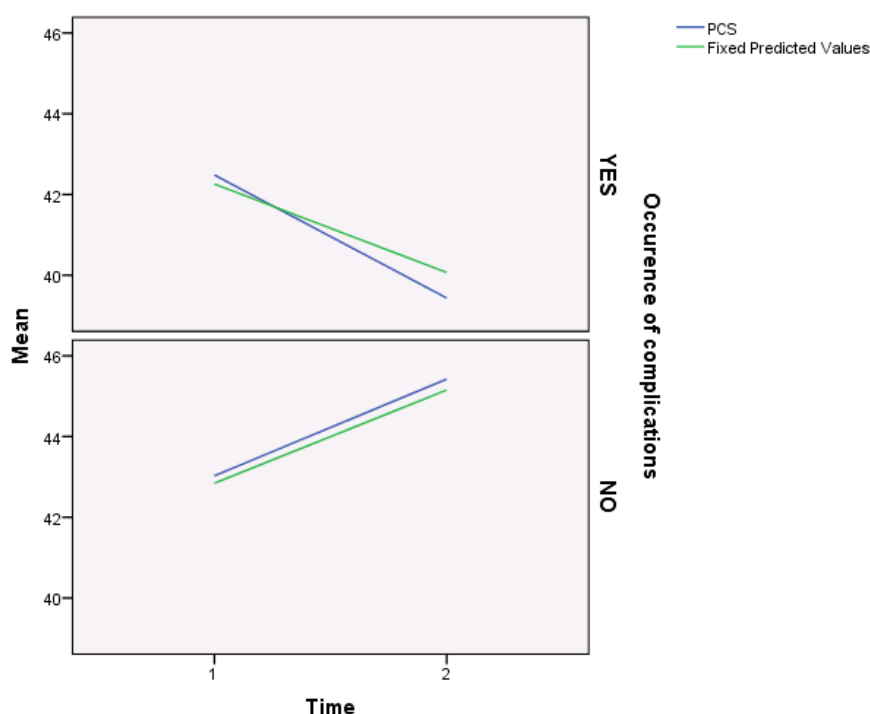
*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

Appendix 29: Multilevel Mixed Linear models analysis on physical QOL: MODEL 1

Model description

A linear mixed model with random coefficients was fit on the physical component of QOL with the occurrence of any complications and surgical specialty as fixed factors, time as covariate and the intercept as random. This model found a significant main effect of surgical specialty ($p < .05$) with vascular and cardio-thoracic patients reporting worse physical QOL than gastro-intestinal patients over time. There were no significant main effects of time or the occurrence of complications, nor were there any significant interactions between them ($p > .05$). The variance of the intercept was not significant which indicated that there was not significant variability amongst individuals on their physical quality of life over time. A graphic representation of the observed values of PCS against the fixed predicted values suggests that this model is relatively accurate in the prediction of the observed values.



Model Dimension^a

		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	1	Variance Components	1	id
	Surgery_specialty	3		2	
	Complications_YesNo_Notes	2		1	
	Time	1		1	
	Days_baseline	1		1	
	Complications_YesNo_Notes * Time	2		1	
	Complications_YesNo_Notes * Days_baseline	2		1	
Random Effects	Intercept ^b	1		1	
Residual				1	
Total		13		10	

a. Dependent Variable: PCS.

Information Criteria^a

-2 Restricted Log Likelihood	944.966
Akaike's Information Criterion (AIC)	948.966
Hurvich and Tsai's Criterion (AICC)	949.069
Bozdogan's Criterion (CAIC)	956.541
Schwarz's Bayesian Criterion (BIC)	954.541

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: PCS.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	75.188	6.900	.010
Surgery_specialty	2	70.615	4.236	.018
Complications_YesNo_Notes	1	75.544	3.042	.085
Time	1	74.318	.647	.424
Days_baseline	1	73.075	.705	.404
Complications_YesNo_Notes * Time	1	74.560	2.754	.101
Complications_YesNo_Notes * Days_baseline	1	73.053	3.213	.077

a. Dependent Variable: PCS.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	59.194961	14.429160	77.314	4.102	.000	30.464695	87.925227
[Surgery_specialty=.0]	-7.206489	2.505317	74.730	-2.876	.005	-12.197632	-2.215345
[Surgery_specialty=1.0]	-5.539367	2.956491	68.799	-1.874	.065	-11.437713	.358979
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	-	25.087581	75.544	-1.744	.085	-93.730134	6.212123
[Complications_YesNo_Notes=1]	43.759005	0 ^b	.	.	.	.	.
Time	-	13.947875	76.040	-.759	.450	-38.361369	17.197356
Days_baseline	10.582007	.179760	76.813	.836	.406	-.207621	.508304
[Complications_YesNo_Notes=0] * Time	.150341	24.777879	74.560	1.660	.101	-8.242905	90.486768
[Complications_YesNo_Notes=1] * Time	41.121932	0 ^b	.	.	.	.	.
[Complications_YesNo_Notes=0] * Days_baseline	-	.315405	73.053	-1.793	.077	-1.193985	.063203
[Complications_YesNo_Notes=1] * Days_baseline	-.565391	0 ^b	.	.	.	.	.

a. Dependent Variable: PCS.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	75.738291	22.678359	3.340	.001	42.115285	136.204438
Intercept [subject = id] Variance	43.437246	26.098806	1.664	.096	13.379101	141.025501

a. Dependent Variable: PCS.

Appendix 30: Multilevel Mixed Linear models analysis on physical QOL: MODEL 2

Model Dimension ^a				
	Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	Variance Components	1	id
	Surgery_specialty		2	
	Complications_YesNo_Notes		1	
	Time		1	
	Days_baseline		1	
	Complications_YesNo_Notes * Time		1	
	Complications_YesNo_Notes * Days_baseline		1	
	Coping_Religion_t1		1	
Random Effects	Intercept ^b		1	
Residual			1	
Total	14		11	

a. Dependent Variable: PCS.

Information Criteria ^a	
-2 Restricted Log Likelihood	920.125
Akaike's Information Criterion (AIC)	924.125
Hurvich and Tsai's Criterion (AICC)	924.232
Bozdogan's Criterion (CAIC)	931.633
Schwarz's Bayesian Criterion (BIC)	929.633

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: PCS.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	76.727	7.508	.008
Surgery_specialty	2	63.353	4.795	.012
Complications_YesNo_Notes	1	74.187	2.439	.123
Time	1	74.131	.706	.403
Days_baseline	1	72.966	.770	.383
Complications_YesNo_Notes *	1	73.242	2.201	.142
Time	1	71.778	2.637	.109
Complications_YesNo_Notes *	1	71.778	2.637	.109
Days_baseline	1	71.778	2.637	.109
Coping_Religion_t1	1	81.827	2.178	.144

a. Dependent Variable: PCS.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	59.270402	14.541449	78.124	4.076	.000	30.321324	88.219480
[Surgery_specialty=.0]	-7.802910	2.528657	67.276	-3.086	.003	-12.849749	-2.756072
[Surgery_specialty=1.0]	-5.369306	2.948504	62.479	-1.821	.073	-11.262384	.523771
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	-39.560918	25.333658	74.187	-1.562	.123	-90.037216	10.915381
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
Time	-8.086731	14.062108	75.229	-.575	.567	-36.098490	19.925028
Days_baseline	.119635	.181346	75.863	.660	.511	-.241559	.480828
[Complications_YesNo_Notes=0] * Time	37.127609	25.023529	73.242	1.484	.142	-12.741434	86.996652
[Complications_YesNo_Notes=1] * Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0] *	-.517364	.318589	71.778	-1.624	.109	-1.152493	.117764
Days_baseline							
[Complications_YesNo_Notes=1] *	0 ^b	0	.	.	.	.	.
Days_baseline							
Coping_Religion_t1	-.825530	.559352	81.827	-1.476	.144	-1.938294	.287234

a. Dependent Variable: PCS.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

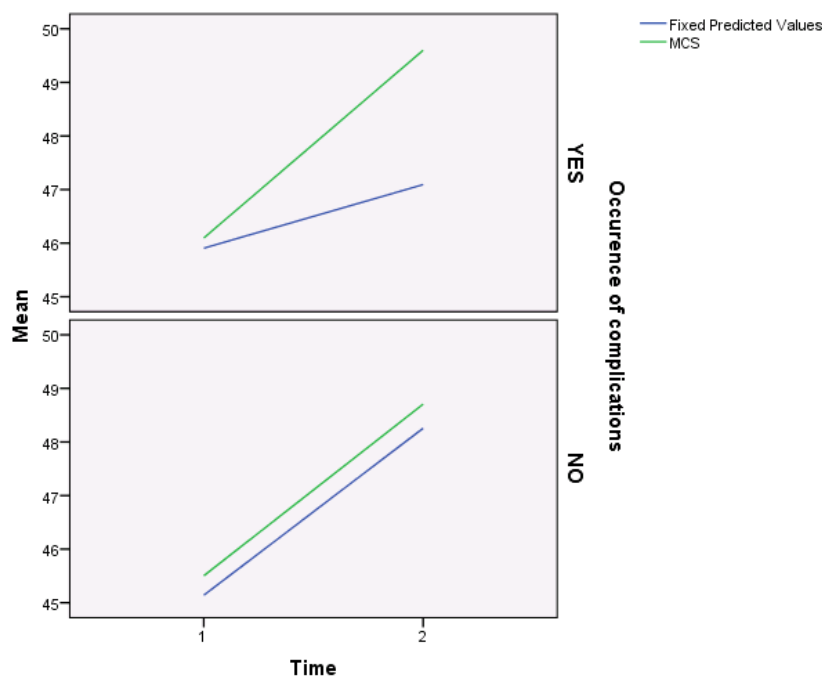
Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	78.133828	24.410163	3.201	.001	42.355631	144.134203
Intercept [subject = id] Variance	40.216624	27.855960	1.444	.149	10.347195	156.310649

a. Dependent Variable: PCS.

Appendix 31: Multilevel Mixed Linear models analysis on mental QOL: MODEL 1

Model description

A linear mixed model with random coefficients was fit on the mental component of QOL with the occurrence of any complications and surgical specialty as fixed factors, time as covariate and the intercept as random (unstructured covariance). Significant main effects or interactions were not found. The variance of the intercept was significant which indicated that there was significant variability amongst individuals with regard to their mental quality of life over time. A graphic representation of the observed values of mental QOL against the fixed predicted values suggests that this model is not very accurate in the prediction of the observed values especially for patients with any complications.



Model Dimension^a

		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	1	Variance Components	1	id
	Surgery_specialty	3		2	
	Complications_YesNo_Notes	2		1	
	Time	1		1	
	Days_baseline	1		1	
	Complications_YesNo_Notes * Time	2		1	
	Complications_YesNo_Notes * Days_baseline	2		1	
Random Effects	Intercept ^b	1		1	
Residual				1	
Total		13		10	

a. Dependent Variable: MCS.

Information Criteria^a

-2 Restricted Log Likelihood	933.607
Akaike's Information Criterion (AIC)	937.607
Hurvich and Tsai's Criterion (AICC)	937.709
Bozdogan's Criterion (CAIC)	945.182
Schwarz's Bayesian Criterion (BIC)	943.182

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: MCS.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	50.856	11.983	.001
Surgery_specialty	2	87.931	.819	.444
Complications_YesNo_Notes	1	51.027	.031	.860
Time	1	49.599	.963	.331
Days_baseline	1	48.820	.660	.421
Complications_YesNo_Notes	1	49.715	.034	.854
* Time	1	48.782	.019	.891
Complications_YesNo_Notes	1	48.782	.019	.891
* Days_baseline	1	48.782	.019	.891

a. Dependent Variable: MCS.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	35.892272	11.878470	54.379	3.022	.004	12.081175	59.703368
[Surgery_specialty=.0]	-2.503329	2.641923	90.080	-.948	.346	-7.751908	2.745249
[Surgery_specialty=1.0]	-3.852269	3.145131	87.171	-1.225	.224	-10.103385	2.398847
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	3.634004	20.504520	51.027	.177	.860	-37.530018	44.798025
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
Time	11.776988	11.403691	50.702	1.033	.307	-11.120147	34.674122
Days_baseline	-.121557	.147044	50.684	-.827	.412	-.416805	.173691
[Complications_YesNo_Notes=0]	-3.729585	20.188212	49.715	-.185	.854	-44.284564	36.825394
* Time							
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
* Time							
[Complications_YesNo_Notes=0]	.035158	.256127	48.782	.137	.891	-.479607	.549922
* Days_baseline							
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
* Days_baseline							

a. Dependent Variable: MCS.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	38.235960	10.079713	3.793	.000	22.807589	64.100972
Intercept [subject = id] Variance	84.506315	19.258650	4.388	.000	54.063449	132.091409

a. Dependent Variable: MCS.

Appendix 32: Multilevel Mixed Linear models analysis on mental QOL: MODEL 2

Model Dimension ^a					
		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables
Fixed Effects	Intercept	1	Variance Components	1	id
	Surgery_specialty	3		2	
	Complications_YesNo_Notes	2		1	
	Time	1		1	
	Days_baseline	1		1	
	Complications_YesNo_Notes * Time	2		1	
	Complications_YesNo_Notes * Days_baseline	2		1	
	Coping_venting_t1	1		1	
	Coping_Planning_t1	1		1	
	Coping_Selfblame_t1	1		1	
	Coping_selfdistraction_t1	1		1	
	Random Effects	Intercept ^b		1	
Residual			1		
Total		17		14	

a. Dependent Variable: MCS.

Information Criteria ^a	
-2 Restricted Log Likelihood	898.752
Akaike's Information Criterion (AIC)	902.752
Hurvich and Tsai's Criterion (AICC)	902.861
Bozdogan's Criterion (CAIC)	910.225
Schwarz's Bayesian Criterion (BIC)	908.225

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: MCS.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	52.521	20.208	.000
Surgery_specialty	2	76.136	.399	.672
Complications_YesNo_Notes	1	46.699	.064	.801
Time	1	45.031	.594	.445
Days_baseline	1	44.308	.358	.553
Complications_YesNo_Notes *	1	45.495	.052	.821
Time	1	44.704	.034	.854
Complications_YesNo_Notes *	1	44.704	.034	.854
Days_baseline	1	44.704	.034	.854
Coping_venting_t1	1	82.877	2.549	.114
Coping_Planning_t1	1	78.817	.746	.390
Coping_Selfblame_t1	1	81.991	1.175	.282
Coping_selfdistraction_t1	1	82.429	1.410	.238

a. Dependent Variable: MCS.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	48.760414	12.316509	58.685	3.959	.000	24.112372	73.408456
[Surgery_specialty=.0]	-1.915566	2.493161	79.397	-.768	.445	-6.877693	3.046561
[Surgery_specialty=1.0]	-2.315884	2.939463	75.330	-.788	.433	-8.171174	3.539405
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0]	5.308559	20.952033	46.699	.253	.801	-36.848656	47.465774
[Complications_YesNo_Notes=1]	0 ^b	0	.	.	.	.	.
Time	10.348863	11.444296	51.036	.904	.370	-12.626132	33.323857
Days_baseline	-.103013	.147516	51.141	-.698	.488	-.399144	.193119
[Complications_YesNo_Notes=0] * Time	-4.712366	20.705679	45.495	-.228	.821	-46.403218	36.978486
[Complications_YesNo_Notes=1] * Time	0 ^b	0	.	.	.	.	.
[Complications_YesNo_Notes=0] *	.048749	.262613	44.704	.186	.854	-.480276	.577775
Days_baseline							
[Complications_YesNo_Notes=1] *	0 ^b	0	.	.	.	.	.
Days_baseline							

Coping_venting_t1	-1.244812	.779623	82.877	-1.597	.114	-2.795485	.305861
Coping_Planning_t1	-.556595	.644451	78.817	-.864	.390	-1.839389	.726200
Coping_Selfblame_t1	-.731776	.675109	81.991	-1.084	.282	-2.074784	.611232
Coping_selfdistraction_t1	-.831296	.700073	82.429	-1.187	.238	-2.223856	.561264

a. Dependent Variable: MCS.

b. This parameter is set to zero because it is redundant.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	40.946376	11.650732	3.514	.000	23.443244	71.517652
Intercept [subject = id] Variance	65.728609	19.153816	3.432	.001	37.128537	116.359285

a. Dependent Variable: MCS.

Appendix 33: Multilevel Mixed Linear models analysis on anxiety/major complications: MODEL 2

Model Dimension ^a						
		Number of Levels	Covariance Structure	Number of Parameters	Subject Variables	
Fixed Effects	Intercept	1	Identity	1	id	
	Surgery_specialty	3		2		
	Time	1		1		
	Days_baseline	1		1		
	Coping_selfdistraction_t1	1		1		
	Coping_InstrumSupport_t1	1		1		
	Coping_SubstanceUse_t1	1		1		
	Coping_venting_t1	1		1		
	Serious_Comp_AboveIII *	2		1		
	Time	2		1		
	Serious_Comp_AboveIII *					2
	Days_baseline					
	Serious_Comp_AboveIII	2		1		
Random Effects	Intercept	1		1		
Residual			1			
Total		17	14			

a. Dependent Variable: Anxiety.

Information Criteria ^a	
-2 Restricted Log Likelihood	1119.651
Akaike's Information Criterion (AIC)	1123.651
Hurvich and Tsai's Criterion (AICC)	1123.711
Bozdogan's Criterion (CAIC)	1132.297
Schwarz's Bayesian Criterion (BIC)	1130.297

The information criteria are displayed in smaller-is-better forms.

a. Dependent Variable: Anxiety.

Type III Tests of Fixed Effects^a

Source	Numerator df	Denominator df	F	Sig.
Intercept	1	199.103	.282	.596
Surgery_specialty	2	83.089	4.953	.009
Time	1	140.226	.510	.476
Days_baseline	1	143.090	.162	.688
Coping_selfdistraction_t1	1	87.228	11.802	.001
Coping_InstrumSupport_t1	1	94.011	.300	.585
Coping_SubstanceUse_t1	1	76.010	2.960	.089
Coping_venting_t1	1	95.603	14.786	.000
Serious_Comp_AboveIII * Time	1	140.711	4.026	.047
Serious_Comp_AboveIII *	1	143.164	2.656	.105
Days_baseline	1	143.164	2.656	.105
Serious_Comp_AboveIII	1	158.310	4.763	.031

a. Dependent Variable: Anxiety.

Estimates of Fixed Effects^a

Parameter	Estimate	Std. Error	df	t	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Intercept	1.822535	1.162875	180.212	1.567	.119	-.472067	4.117137
[Surgery_specialty=.0]	1.767385	.578477	90.509	3.055	.003	.618228	2.916542
[Surgery_specialty=1.0]	1.443288	.720604	79.248	2.003	.049	.009031	2.877545
[Surgery_specialty=2.0]	0 ^b	0	.	.	.	.	.
Time	-2.028679	.584477	134.020	-3.471	.001	-3.184671	-.872687
Days_baseline	.022860	.015101	136.283	1.514	.132	-.007003	.052722
Coping_selfdistraction_t1	.543649	.158246	87.228	3.435	.001	.229130	.858169
Coping_InstrumSupport_t1	.094023	.171746	94.011	.547	.585	-.246982	.435028
Coping_SubstanceUse_t1	.301540	.175255	76.010	1.721	.089	-.047509	.650589
Coping_venting_t1	.797264	.207338	95.603	3.845	.000	.385681	1.208848
[Serious_Comp_AboveIII=1] * Time	2.990986	1.490626	140.711	2.007	.047	.044068	5.937903
[Serious_Comp_AboveIII=2] * Time	0 ^b	0	.	.	.	.	.
[Serious_Comp_AboveIII=1] * Days_baseline	-.060703	.037250	143.164	-1.630	.105	-.134334	.012928
[Serious_Comp_AboveIII=2] * Days_baseline	0 ^b	0	.	.	.	.	.
[Serious_Comp_AboveIII=1]	-4.375650	2.004947	158.310	-2.182	.031	-8.335544	-.415755
[Serious_Comp_AboveIII=2]	0 ^b	0	.	.	.	.	.

Estimates of Covariance Parameters^a

Parameter	Estimate	Std. Error	Wald Z	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Residual	7.788374	1.020406	7.633	.000	6.024559	10.068581
Intercept [subject = id] Variance	2.635137	1.053002	2.502	.012	1.204100	5.766919

a. Dependent Variable: Anxiety.

Parameter Estimates

Dependent Variable: Anxiety

Parameter	B	Std. Error	t	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Intercept	4.182	.583	7.175	.000	3.034	5.330
[Serious_Comp_AboveIII=1] * [Time=1]	1.682	1.010	1.666	.097	-.307	3.670
[Serious_Comp_AboveIII=1] * [Time=2]	2.418	1.156	2.092	.037	.141	4.695
[Serious_Comp_AboveIII=1] * [Time=3]	.929	1.414	.657	.512	-1.857	3.715
[Serious_Comp_AboveIII=2] * [Time=1]	2.563	.711	3.603	.000	1.162	3.964
[Serious_Comp_AboveIII=2] * [Time=2]	1.036	.746	1.388	.166	-.434	2.505
[Serious_Comp_AboveIII=2] * [Time=3]	0 ^a	.	.	.	.	.

a. This parameter is set to zero because it is redundant.

Estimates

Dependent Variable: Anxiety

Complication above III	Time	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
yes	1	5.864	.824	4.240	7.487
	2	6.600	.998	4.634	8.566
	3	5.111	1.289	2.573	7.650
no	1	6.744	.408	5.942	7.547
	2	5.217	.465	4.301	6.134
	3	4.182	.583	3.034	5.330

Appendix 34: Questionnaire on management of after-effects of serious patient safety incidents in the NHS

Managing the aftermath of serious patient safety incidents in the NHS

Questionnaire study on the management of serious patient safety incidents i...

Imperial College London
Centre for Patient Safety & Service Quality

Project supervisor: Prof Charles Vincent
Contact: Anna Pinto a.pinto@imperial.ac.uk

Managing the aftermath of serious patient safety incidents in the NHS

Information about the study

Thank you for taking part in this study. This study aims to investigate how serious patient safety incidents are currently managed in the NHS (i.e. being open with patients and families, support for patients, families and staff) and whether the existing systems could be improved. This questionnaire will ask you about your experiences with and perceptions of the management of the aftermath of serious patient safety incidents in your trust. It should take around 15 minutes to complete.

Throughout the questionnaire the term serious patient safety incidents is used to refer to incidents that result in unexpected or avoidable patient death, permanent long-lasting harm, outcome that requires major life-saving intervention, prolonged pain or psychological harm, as per the NPSA's 2010 national framework for reporting and learning from serious incidents requiring investigation. Such incidents will be the result of treatment or care rather than the result of a patient's illness or underlying condition.

Examples of serious patient safety incidents include: never events such as wrong site surgery, misplaced naso-gastric or oro-gastric tube not detected prior to use, maternal death from post-partum haemorrhage but also patient safety incidents that result in severe long-lasting harm (e.g. paralysis caused by epidural) or injuries from which the patient is most likely to make a full recovery (e.g. a serious adverse drug reaction which results in short-term harm).

Also, the term 'being open' is used to refer to "honestly telling patients and/or their families about serious patient safety incidents".

With the above definitions in mind, please provide your answers to the following questions.

Responses are confidential and all data will be recorded and reported anonymously.

Your responses cannot be saved, so please allow sufficient time to complete the survey in one session and don't navigate away from the page or use the browsers forward/backwards buttons whilst completing the survey.

Managing the aftermath of serious patient safety incidents in the NHS

Section A: Participant information

*1. Current Job title

*2. Years of experience in healthcare (Please tick one)

- ☐ 0-11 months
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 6-9 years
- ☐ 10-20 years
- ☐ 21 or more years

*3. Years of experience in current position (Please tick one)

- ☐ 0-11 months
- ☐ 1-2 years
- ☐ 3-5 years
- ☐ 6-9 years
- ☐ 10-20 years
- ☐ 21 or more years

*4. Professional background (Please tick all those that apply)

- ☐ nursing
- ☐ medicine
- ☐ law
- ☐ management
- ☐ Other (please specify)

*5. Previous work position (Please tick one)

- ☐ healthcare/NHS
- ☐ industry
- ☐ management
- ☐ health & safety
- ☐ Other (please specify)

Managing the aftermath of serious patient safety incidents in the NHS

***6. Which of the following best describes your trust? (Please tick one)**

- ☐ Acute trust
- ☐ Ambulance trust
- ☐ Mental Health & Learning Disabilities trust
- ☐ Primary Care trust
- ☐ Other (please specify)

***7. Is your trust a foundation trust? (Please tick one)**

- ☐ Yes
- ☐ No

8. What is the approximate number of staff in your trust?

Managing the aftermath of serious patient safety incidents in the NHS

Section A: Being open facts and policies

This section will ask you about your trust's facts and policies regarding being open with patients and/or families about serious patient safety incidents.

***9. Please provide an estimate of how many serious patient safety incidents have been reported in your trust over the preceding 12 months.**

***10. Based on the number that you reported for question 1, please provide an estimate of how many serious patient safety incidents have been openly discussed with patients and/or families in your trust over the preceding 12 months.**

***11. In which direction do you think that the number of open discussions of serious patient safety incidents with patients and/or families has changed in your trust over the past 2 years? Please tick one.**

- ☐ Decreased a lot ☐ Decreased slightly ☐ No change ☐ Increased slightly ☐ Increased a lot

***12. Are you familiar with the 'Being Open' guidance issued by the NPSA? Please tick the appropriate box below.**

- ☐ Yes
☐ No

***13. To what extent is the above guidance followed by your trust when a serious patient safety incident occurs? Please tick one.**

- ☐ Never ☐ Less than half the time ☐ Half the time ☐ More than half the time ☐ All the time ☐ Not applicable

***14. Is there a board-approved policy in your trust about being open with patients and/or families about serious patient safety incidents? Please tick the appropriate box below.**

- ☐ Yes, there is an established policy
☐ Not yet, but there is one under development
☐ No, there is none
☐ Other (please specify)

Managing the aftermath of serious patient safety incidents in the NHS

Section B: Being open and patient support practices

This section will ask you about your experiences with patient support practices and being open in your trust.

We appreciate that the answers for many of the questions below are dependent on a wide range of characteristics. Nevertheless, we are asking you to provide a rough description of frequency and forms of typical open discussions in your trust. Please bear in mind that responses of lower/higher frequency do not necessarily indicate a negative/positive answer.

*** 15. How often are the following types of serious patient safety incidents openly discussed with patients and/or families in your trust? Please tick one for each type of incidents.**

	Never	Less than half the time	Half the time	More than half the time	All the time
Deaths	☐	☐	☐	☐	☐
Severe long-lasting injuries	☐	☐	☐	☐	☐
Injuries from which the patient is likely to make a full recovery	☐	☐	☐	☐	☐

*** 16. Please select those people who are routinely involved in open discussions of serious patient safety incidents with patients and/or families. Please tick all those that apply.**

- ☐ An executive director
- ☐ Clinical person(s) conducting the investigation
- ☐ Clinical person(s) involved in the incident
- ☐ Non- clinical person(s) conducting the investigation
- ☐ Risk manager(s)
- ☐ Other (please specify)

*** 17. How many 'being open' meetings with patients and/or families are usually held for serious patient safety incidents in your trust? Please tick one.**

- ☐ One-off meeting
- ☐ 2-3
- ☐ > 3
- ☐ As many as the patient and the family wish
- ☐ Other (please specify)

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***18. How soon after the incident does an open discussion with patients and/or families take place? Please tick one.**

- ☐ Within 24 hours
- ☐ Within 1-3 weeks
- ☐ Straight after the investigation
- ☐ 3-6 months after the investigation
- ☐ Other (please specify)

***19. For each type of serious patient safety incidents below please rate how often each of the listed elements are part of typical open discussions with patients and/or families. Please select one for each listed element and each type of incident.**

	Deaths	Severe long-lasting injuries	Injuries from which the patient will make a full recovery
Acknowledge harm			
Apologise			
Asking the patient/family member their fears and concerns			
Checking how the patient/family member is			
Promise for system improvement			
Promise to share investigation results			
Provide explanation			
Share findings from incident investigation			
Take responsibility for harm			
Other (please specify)			

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*** 20. For each of the serious patient safety incidents below please rate how often each of the listed actions are taken after typical open discussions with patients and/or families. Please select one for each listed element and each type of incidents.**

	Deaths	Severe long-lasting injuries	Injuries from which the patient will make a full recovery
Provide additional clinical treatment			
Provide details of a person of contact			
Provide details of support groups			
Provide details of regulatory agencies			
Provide information about lawyers			
Provide ex gratia payments			
Long-term follow-up			
Other (please specify)			

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Section D: Barriers for being open

This section will ask you about your perceptions of barriers for being open in your trust.

***21. Please rate the extent to which you agree that each of the listed elements constitute barriers for open discussions of serious patient safety incidents with patients and/or families in your trust. Please tick one for each listed element.**

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
Clinical staff are afraid of being blamed	☐	☐	☐	☐	☐
Clinical staff are afraid of litigation	☐	☐	☐	☐	☐
Clinical staff are afraid of negative patient/family reactions	☐	☐	☐	☐	☐
Clinical staff are worried that they will be accused of malpractice	☐	☐	☐	☐	☐
Clinical staff are worried that they will face institutional repercussions	☐	☐	☐	☐	☐
Clinical staff feel embarrassed	☐	☐	☐	☐	☐
Clinical staff feel guilty	☐	☐	☐	☐	☐
Incident-related data is not kept anonymous	☐	☐	☐	☐	☐
Incident-related data is not kept confidential	☐	☐	☐	☐	☐
There is not adequate institutional support for being open	☐	☐	☐	☐	☐
Your trust board is concerned about adverse publicity	☐	☐	☐	☐	☐
Your trust board is concerned about costs	☐	☐	☐	☐	☐

Other (please specify)

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Section E: Support for staff

This section will ask you about your perceptions of staff support in relation to serious patient safety incidents in your trust.

As with section C, we appreciate that the answers for the questions below are dependent on a wide range of characteristics. Nevertheless, we are asking you to provide a rough description of frequency and importance of staff support practices in your trust. Please bear in mind that responses of lower/higher frequency or importance do not necessarily indicate a negative/positive answer.

***22. Please rate how often each of the listed forms of support are available to staff who are involved in serious patient safety incidents in your trust. By 'being available' we mean that 'each listed option of support is in place for staff to access it if they want to'. Please tick one for each listed form of support.**

	Never	Less than half the time	Half the time	More than half the time	All the time
Chaplaincy support	☐	☐	☐	☐	☐
Counselling, psychological or psychiatric services	☐	☐	☐	☐	☐
Exemption from clinical duties following the incident	☐	☐	☐	☐	☐
Information about the processes that are followed after serious patient safety incidents	☐	☐	☐	☐	☐
Occupational health services	☐	☐	☐	☐	☐
Peer support groups	☐	☐	☐	☐	☐
Personal legal advice	☐	☐	☐	☐	☐
Prompt debriefing	☐	☐	☐	☐	☐
Stress management groups	☐	☐	☐	☐	☐
Supportive guidance/mentoring by senior clinical people/line managers	☐	☐	☐	☐	☐
Training programmes on being open	☐	☐	☐	☐	☐

Other (please specify)

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***23. Please rate how important you think use each of the listed forms of support are for staff who are involved in serious patient safety incidents in your trust. Please tick one for each listed form of support.**

	Very unimportant	Unimportant	Neither important or unimportant	Important	Very important
Chaplaincy support	☐	☐	☐	☐	☐
Counselling, psychological or psychiatric services	☐	☐	☐	☐	☐
Exemption from clinical duties following the incident	☐	☐	☐	☐	☐
Information about the processes that are followed after serious patient safety incidents	☐	☐	☐	☐	☐
Occupational health services	☐	☐	☐	☐	☐
Peer support groups	☐	☐	☐	☐	☐
Personal legal advice	☐	☐	☐	☐	☐
Prompt debriefing	☐	☐	☐	☐	☐
Stress management groups	☐	☐	☐	☐	☐
Supportive guidance/mentoring by senior clinical people/line managers	☐	☐	☐	☐	☐
Training programmes on being open	☐	☐	☐	☐	☐

Other (please specify)

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Section E: Participant feedback

24. Please use the space below to further describe anything that you think may be important for us to know about:

- a. open discussions with patients and/or families of serious patient safety incidents in your trust (e.g. processes, barriers)**
- b. support for staff who are involved in serious patient safety incidents in your trust**
- c. if and how the above could be improved**
- d. or to comment about this survey**

Please write as much as you like. Your feedback will be very valuable to us.



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Thank you for your participation!

Thank you very much for filling out our survey. If you are interested in contacting us further to learn more about the study or talk to us about the issues raised in this survey in more depth please do not hesitate to contact Anna Pinto on a.pinto@imperial.ac.uk.

Appendix 35: Patient safety managers' comments on the implementation of *being open*

- "...There is no clear process for sharing SUI (serious untoward incident) investigation reports with patients or families. There is also no clear defined process for recording contact, discussion, feedback with patients/ families that can be linked to an incident..." (Participant 6)
- "...It is important to note that initiatives such as Being Open, whilst admirable and needed, are introduced nationally without the resources to always implement at a local level, and these functions tend to get added on to an existing role, which in itself can lead to a dilution of the effectiveness of the process..." (Participant 8)
- "...There are occasions where we are unable to have a being open dialogue with relatives when there is a police or coroner's enquiry particularly...In these situations it is usually a delayed approach as cases can take longer to be investigated than our desire to disclose as early as we can..." (Participant 48)
- "...The policy is not well embedded in the organisation; this has been identified and the work is ongoing with senior clinicians. However, there is a genuine misunderstanding of the need to engage in the principles of being open, and some staff have commented that this would lead to them appearing unprofessional..." (Participant 224)
- "...This should be part of basic training for all health professionals not an 'add on' when qualified. There is a general fear of admitting liability and a lack of understanding particularly around disclosure and legal processes. Staff generally want to be open but the problems in the NHS and the prevailing culture across the NHS do not help. People are worried that they may lose their jobs and therefore income and are worried how they will be perceived or judged or that they will be made scapegoats for institutional errors, shortcomings etc..." (Participant 199)