Communication, wellbeing and adverse events in healthcare: How can we support maternity healthcare professionals disclosing news to patients that an adverse event has occurred?

Raabia Sattar

Submitted in accordance with the requirements for the degree of Doctor of Philosophy

The University of Leeds

School of Psychology

October 2020

The candidate confirms that the work submitted is her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

The systematic review reported in chapter 2 has been published:

Sattar, R., Johnson, J., & Lawton, R. (2020). The views and experiences of patients and health-care professionals on the disclosure of adverse events: A systematic review and qualitative meta-ethnographic synthesis. *Health Expectations*.
doi: https://doi.org/10.1111/hex.13029

All authors developed the concept for the systematic review. RS designed the study and conducted the searches, screening, data extraction and analysis with input from J.J and R.L. R.S drafted the publication and thesis manuscript. All authors provided comments and approved final versions.

The guidance developed for conducting a meta-ethnographic synthesis presented in Appendix 4 has been submitted for publication and is currently under review. All authors developed the concept for the guidance document. RS designed the study with input from J.J, R.L and M.P. RS drafted the publication and thesis manuscript. All authors provided comments and approved final versions.

Abstract

Adverse events within any area of healthcare are inevitable as humans are fallible (Robertson & Long, 2018), and maternity services within the UK are no exception. Within the past few years, maternity care within the UK has been in the spotlight due to high profile failings in care. Evidence from the NHS litigation authority suggests that maternity claims represent the third-highest number of clinical negligence claims. The increasing number of negligence claims is of a great burden to the NHS. Maternity is a high-risk environment, and adverse events occur and will continue to occur. However, an important element in managing the consequences of an adverse event is the disclosure to the patient involved and/or their family. Despite this, as few as 30% of adverse events may currently be disclosed to patients (Birks et al., 2014).

This thesis aimed to investigate how healthcare professionals within UK maternity services can be supported to communicate the news to patients that an adverse event has occurred through a series of studies. *Study 1 systematically reviewed the literature on the views and experiences of patients and healthcare professionals on adverse event disclosure.* The findings of this review suggested that although healthcare professionals advocated disclosure, several barriers prevented healthcare professionals from conducting effective disclosure. Potential ways to facilitate disclosure in order to meet patients' needs for disclosure include clarity regarding the legal aspects of disclosure, modelling appropriate disclosure practices, an open and transparent culture and providing training on adverse event disclosure.

Study 2 explored the views and experiences of UK maternity healthcare professionals on adverse event disclosure through the use of a qualitative interview study. The findings of this study illuminated the need to provide clarity on the Duty of Candour regulation within the UK, a need for transparency surrounding the emotional consequences of adverse events and disclosure, a need for training specific to adverse event disclosure, and difficulties drawing the line between adverse events and complications within the speciality of maternity.

Using the MRC guidelines for complex interventions, (MRC, 2008), a training intervention to enhance maternity healthcare professionals skills with the disclosure of adverse events was developed. *Study 3 involved delivering the training intervention to maternity healthcare professionals and assessing the acceptability and feasibility of the intervention*. Preliminary investigations suggest that this was perceived as acceptable by maternity healthcare professionals and was perceived as being useful. The training workshop had the potential to

improve knowledge of adverse event disclosure and improve healthcare professional's confidence in conducting disclosure.

In combination, the findings of this PhD suggest that one of the potential ways to support maternity healthcare professionals with the disclosure process is by providing adverse event disclosure training.

Table of contents

List of tables

List of figures

Chapter 1

Chapter 2

Chapter 3

Chapter 4

Chapter 5

List of Abbreviations

IOM	Institute of Medicine
WHO	World Health Organisation
NRLS	National Reporting and Learning system
PHE	Public Health England
MHRA	Medicines and Healthcare Products Regulatory Agency
PSIRF	Patient Safety Incident Response Framework
NPSA	National Patient Safety Agency
CQC	Care Quality Commission
CASP	Critical Appraisal Skills Programme
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
GMC	General Medical Council
NMC	Nursing & Midwifery Council
ACGME	Accreditation Council for Graduate Medical Education
MRC	Medical Research Council
CBT	Cognitive Behavioural Therapy
SCT	Social Cognitive Theory
RS	Raabia Sattar
JJ	Judith Johnson
RL	Rebecca Lawton
MP	Maria Panagioti

Publications and Presentations

Peer reviewed publications

Sattar, R., Johnson, J., & Lawton, R. (2020). The views and experiences of patients and health-care professionals on the disclosure of adverse events: A systematic review and qualitative meta-ethnographic synthesis. *Health Expectations*, *23*(3), 571-583.
doi: https://doi.org/10.1111/hex.13029

Sattar, R., Lawton, R., Panagioti, M., & Johnson, J. (2021). Meta-ethnography in healthcare research: a guide to using a meta-ethnographic approach for literature synthesis. *BMC Health Services Research*, *21*(1), 1-13.
doi: 10.1186/s12913-020-06049-w

Presentations

Oral presentations

Sattar, R., Johnson, J. and Lawton, R. (2017). Communication, wellbeing and adverse events in healthcare: How can we support maternity healthcare professionals disclosing news to patients that an adverse event has occurred? Postgraduate Psychology Conference, University of Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2017). Communication, wellbeing and adverse events in healthcare: How can we support maternity healthcare professionals disclosing news to patients that an adverse event has occurred? Three Minute Thesis, University of Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2018). The views and experiences of patient's and healthcare professional's on adverse event disclosure: A systematic review & qualitative meta-ethnographic synthesis. Postgraduate Psychology Conference, University of Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2018). The views and experiences of patient's and healthcare professional's on adverse event disclosure: A systematic review & qualitative meta-ethnographic synthesis. White Rose Postgraduate Researcher Conference: Annual Conference, University of York, UK.

Sattar, R., Johnson, J. and Lawton, R. (2018). Adverse event disclosure within the UK: A qualitative study exploring the experiences of maternity healthcare professionals. St James Hospital, Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2018). Communication, wellbeing and adverse events in healthcare: How can we support maternity healthcare professionals disclosing news to patients that an adverse event has occurred? Yorkshire & Humber Sector Led Improvement Annual Conference, UK.

Sattar, R., Johnson, J. and Lawton, R. (2019). The development of a training communication intervention to enhance maternity healthcare professional's skills for disclosing adverse events. St James Hospital, Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2019). The development of a training communication intervention to enhance maternity healthcare professional's skills for disclosing adverse events. Improvement Academy, Bradford Institute for Health Research, UK.

Poster presentations

Sattar, R., Johnson, J. and Lawton, R. (2018). Adverse event disclosure within the UK: A qualitative study exploring the experiences of maternity healthcare professionals. Leeds Doctoral College Showcase, University of Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2019). Communication, wellbeing and adverse events in healthcare: How can we support maternity healthcare professionals disclosing news to patients that an adverse event has occurred? Faculty of Medicine and Health Postgraduate Researchers Conferece, University of Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2019). The views and experiences of patient's and healthcare professional's on adverse event disclosure: A systematic review & qualitative meta-ethnographic synthesis. Improving Patient Safety: New horizons, New perspectives, Leeds, UK.

Sattar, R., Johnson, J. and Lawton, R. (2019). The views and experiences of patient's and healthcare professional's on adverse event disclosure: A systematic review & qualitative meta-ethnographic synthesis. NIHR PSTRC (*Patient Safety Translational Research Centre*) PhD Network Event.

Chapter 1: Overview of the thesis

1.1 Chapter summary: *This chapter provides an overview of the current literature on patient safety within healthcare, and provides a background to adverse event disclosure. The overall aim of this thesis was to investigate how healthcare professionals within maternity services can be supported to communicate the news to patients that an adverse event has occurred. The research studies that were conducted to explore this aim are outlined in the thesis aims and objectives.*

1.2 Improving the quality & safety of patient care

Statistics suggest that approximately 1 in 10 patients who are admitted into hospital within the UK will experience some form of unintended harm and it is thought that approximately half of these cases could be preventable (Vincent, Neale & Woloshynowych, 2001). This estimate clearly represents a significant proportion of patients and the need to reduce avoidable harm and improve the delivery of safe patient care has been repeatedly highlighted in several reports around the world over the past two decades. These include the well-known seminal report 'To Err is Human' (Donaldson, Corrigan & Kohn, 1999) which is a landmark publication for patient safety, the Berwick report 'A promise to learn, a commitment to act – Improving the safety of patients in England (Berwick, 2013) and 'Crossing the Quality Chasm (Institute of Medicine, 2001). These have placed patient safety and quality of care onto policy agendas and national and international campaigns to reduce harm within organisations (Lamont & Waring, 2015). The pursuit of a safer healthcare has been a global endeavor by the World Alliance for Patient Safety (World Health Organisation, 2020). The Institute of Medicine (IOM) has defined patient safety as the prevention of harm to patients (Donaldson et al., 2000).

Patient safety is now being recognised as something that every healthcare professional must hold at the very heart of what they do (World Health Organisation, 2020), which has progressively resulted in improved patient outcomes (Vincent & Amalberti, 2016). These include interventions that have successfully reduced catheter-related bloodstream infections in intensive care units in Michigan (Pronovost et al., 2010; Pronovost et al., 2006). Surgical mortality and complication rates have been reduced globally by the introduction of surgical checklists such as the World Health Organisation (WHO) surgical checklist (Haynes et al., 2009). However, considering the magnitude of the problems faced, the progress is still underwhelming

(Landrigan et al., 2010; Shojania & Thomas, 2013) and a great deal more needs to be done to improve patient safety (Vincent & Amalberti, 2016). Preventable patient deaths due to errors and harm are still a global issue (Hogan et al, 2012; Makaray & Daniel, 2016). Research suggests that within the NHS in 2009, there were 11,859 preventable deaths of adults (Hogan et al., 2012) and, in the US, medical errors are the third leading cause of death (Makaray & Daniel, 2016). Recent high profile government reports in the UK have also highlighted poor quality care and failure to maintain patient safety within NHS organisations. These include the well-publicised Francis Inquiry which identified deficiencies in patient care (Francis, 2013) and the Keogh report (Keogh, 2013) which found that there was significant scope for improvement in certain NHS organisations.

1.3 Defining harm

Medical errors and adverse events are inevitable within healthcare as humans are fallible (Robertson & Long, 2018). Clinical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (Reason, 1990). Although several classifications of clinical errors have been presented, the most used is the following published by the IOM (Kohn, Corrigan and Donaldson, 1999). The term clinical error is an umbrella term for all types of errors including diagnostic errors (e.g. error or delay in diagnosis, treatment errors (e.g. error in the performance of an operation, procedure or test), preventive errors (e.g. inadequate monitoring or follow-up of treatment) and other (e.g. equipment failures or failure of communication). Among the problems that commonly occur during the course of providing healthcare are adverse drug events, improper transfusions, surgical injuries and wrong-site injuries, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities (Donaldson et al., 2000). Not all errors result in harm, but those which do result in harm to a patient are known as adverse events. An adverse event is defined as an unintended or unexpected incident that causes harm to a patient and may lead to temporary or permanent disability (Vincent, 2010). Adverse events are therefore not due to the underlying condition of the patient. Adverse events may be due to medical errors, in which case they are preventable, or to factors that are not preventable (Garrouste-Orgeas et al., 2012). An example of a preventable adverse event is a delay in treatment and diagnosis, whereas an example of an unpreventable adverse event would include medication side effects (Forster, Rose, Van Walraven & Stiell, 2007). There are also unplanned events that occur but do not result in injury, illness, or damage but had the potential to do so. These are known as near misses. The focus of this thesis, however, is adverse events that are preventable and which result in actual harm. The IOM provides a formal definition of a near miss as ‘an act of commission or omission

that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation' (Aspden, 2004).

Throughout this thesis, unless specified, the term healthcare professional encompasses any healthcare professional who provides a healthcare service to a patient.

1.4 Promoting patient safety in the NHS

Prior to the start of this thesis, a number of policy documents and reports were in place which made credible efforts to highlight and promote the importance of patient safety within the NHS. The seminal report *'An organisation with a memory'* (Donaldson, 2000) was published in 2000 and urged the NHS to learn from other critical safety sectors and adopt a modernised approach to learning from failure. This report led to the establishment of the National Reporting and Learning System (NRLS), which is a central database of incident reports. NHS organisations report incidents (including adverse events) to the NRLS. This information is used to identify emerging patterns and develop guidance to reduce risks and harm to patients (NHS improvement, 2017). The reports and data from the NRLS are shared with a number of national bodies including NHS England, Public Health England (PHE), the Medicines and Healthcare products Regulatory Agency (MHRA), Care Quality Commission (CQC), and the Royal Colleges to identify hazards and develop patient safety guidance and solutions (NHS improvement, 2017). Increased transparency through reporting is fundamental for learning from experiences and preventing future incidents (Wolf & Hughes, 2008). The NRLS is a foundation for achieving patient safety through learning. Reporting systems can raise awareness of incidents and generate a culture of safety (Vincent, 2007). Research suggests that it is equally as important to report errors which do not result in harm (near misses) as this can provide valuable information on how to reduce errors (Barach & Small, 2000). However, there are barriers to reporting incidents which include fear of negative consequences such as fear of punishment and reprisal (Wolf & Hughes, 2008) and fear of disciplinary actions and possible litigation (Hughes & Ortiz, 2005; Robinson et al., 2002). NHS improvement supports NHS organisations within the UK to provide patients with consistently safe, high quality, compassionate care within health systems that are financially stable (NHS improvement, 2020).

During the period in which the research within this thesis was being conducted, more recent policies were introduced within the UK which include the NHS resolution, '*Being fair*' report which was introduced in 2019 and provides guidance on supporting a just and learning culture for healthcare professionals and patients following an adverse event. It is proposed that fairly treating healthcare professionals, supports openness and learning within the NHS and enables

them to feel confident to speak up when things go wrong within care, prevents blame, and encourages learning from adverse events (NHS Resolution, 2019). Also introduced in 2019 was the NHS Patient Safety Strategy (NHS England & NHS improvement, 2019) which describes how the NHS will continue to improve patient safety by building on the foundations of a patient safety culture and patient safety systems. It is envisioned that by improving safety based on the principles of this strategy, there is a potential to save 1000 extra lives and £100 million in care costs each year from 2023/24 and reduce claims provision by around £750 million per year by 2025 (NHS England & NHS improvement, 2019). Another new patient safety initiative that was developed earlier this year is the Patient Safety Incident Response Framework (PSIRF) (NHS England & NHS improvement, 2020) which provides updated guidance on how NHS organisations should respond to incidents and how and when investigations should take place. These policies have supported the uptake of findings within this thesis and each are discussed later on in the thesis, within the discussions of the relevant chapters.

1.5 Disclosure of adverse events

When an error has resulted in an adverse event, as well as reporting the adverse event, the healthcare professional involved has the responsibility of disclosing the mistake to the patient or family (Petronio et al., 2013). There is an important difference between reporting and disclosing adverse events. Reporting of an adverse event involves providing an account of the mistake which conveys details of the occurrence, and reasons for reporting are learning and preventing recurrence of adverse events (Wolf & Hughes, 2008). On the other hand, disclosure refers to the process by which an adverse event is communicated to the patient and/or their families (Wu, Boyle, Wallace & Mazor, 2013). Within this thesis, disclosure will be discussed in relation to errors that result in adverse events. As discussed previously, within any healthcare process, adverse events resulting from clinical errors are inevitable. However, an important element in managing the consequences of a clinical error is the disclosure of such events to the patient involved and/or their family. Despite this as few as 30% of adverse events may currently be disclosed to patients (Birks et al., 2014). There is currently limited research which examines the attitudes and rates of disclosure in the UK (Birks et al., 2014). On an international level, failure to disclosure of adverse events takes place at a scale as low as 2.7% (Pham et al., 2011) and disclosure is based on the severity or the obvious nature of harm, being a motivator to disclose (Linthorst et al., 2012). Unless serious harm occurs, there is still hesitancy to disclose adverse events (Birks et al., 2014). Whilst supportive environments seem to encourage healthcare professionals to disclose adverse events to colleagues within their organisation, disclosure to patients still lags behind (Kroll, Singleton, Collier & Rees Jones, 2008). Currently, evidence also suggests that healthcare professionals are not adequately equipped to handle

disclosure of adverse events effectively and there may be some level of defensiveness which interferes with competent disclosure (Allman, 1998; Kaldijan et al., 2007; Penson, Svendsen, Chabner, Lynch & Levinson, 2001; Hannawa, 2009; Delbanco & Bell, 2007).

1.6 Disclosure policies

Professional and legislative efforts within several countries set an expectation that if an adverse event occurs, healthcare professionals have a duty to disclose it to the patient or family (Gallagher, Studdert & Levinson, 2007). Frameworks have been developed in different countries to promote and guide the disclosure of adverse events. In the USA the American Medical Association Code of Medical Ethics endorses the disclosure of adverse events to patients and (American Medical Association, 2019). Earlier, in Canada, the Canadian Patient Safety Institute published the Canadian Disclosure Guidelines were published which provide guiding principles for disclosure (Canadian Patient Safety Institute, 2011). Likewise, the Australian Open Disclosure Framework has been designed to allow health service organisations and doctors to communicate openly with patients when the healthcare provided contributes towards an unexpected adverse incident (Australian Commission on Safety and Quality in Health Care, 2013). This framework describes eight guiding principles to support healthcare organisations with the disclosure process.

In 2009 the Being Open framework was launched in the UK by the National Patient Safety Agency ([NPSA], 2009). This framework describes how to strengthen a culture of openness within healthcare organisations. Best practice guidance on how to create an open and honest environment is provided through ten key principles. These include acknowledging the incident, providing a timely and genuine apology, keeping patients and/or their carers informed about the progress made with the incident investigation, reassuring patients and/or carers that the incident is being taken seriously, and ensuring that measures are taken to prevent it from occurring again (Birks et al., 2014; NPSA, 2009). Within the UK, despite professional and indemnifying bodies advocating openness as a professional obligation, disclosure does not always occur. In response to a persisting lack of consistency in openness over adverse events, a statutory Duty of Candour was introduced in the UK, in 2015. This aims to support doctors, nurses, and midwives with the disclosure of adverse events in an open and transparent way (Care Quality Commission [CQC], 2015). This statutory duty states that individuals must offer information on what has happened, provide an apology, report these events to prevent them from occurring again, and clinical leaders must encourage a culture of reporting and learning. These policies and frameworks encourage and mandate disclosure, communication, and

openness when dealing with patients and/or their family. Despite the universal endorsement of disclosing adverse events, disclosure of adverse events is still uncommon (Fein et al., 2007; Wu et al., 1992; Hobgood, Xie, Weiner & Hooker, 2004).

1.7 Impact of adverse events on healthcare professionals

Adverse events associated with medical errors have a negative emotional impact on patients and also on the healthcare professional involved (Mira, Ferrús, Silvestre & Olivera, 2017). The term 'second victim' is used to describe the experience of the healthcare professional who becomes emotionally overwhelmed and distressed as a result of being involved in an adverse incident (Scott et al, 2009). While studies have examined the burden of adverse events on patients for a long time (Dinning et al 2005, Mazor, Goff, Dodd, Velten & Walsh, 2010; Dusclos et al., 2005; Delbanco & Bell, 2007; Fortescue et al., 2003), research assessing the impact of adverse events on healthcare professionals became an increasingly researched topic later on (Schwappach, 2008). Until the end of the 20th century, the emotional impact of errors on physicians was rarely discussed in academic literature or even amongst providers themselves (Rowe, 2004).

Three previous literature reviews (Schwappach & Boluarte, 2008; Sirriyeh et al., 2010; Seys et al., 2013) have evaluated the evidence of the impact of involvement in medical errors on healthcare professionals. A number of qualitative and quantitative studies report that being involved in a medical error or adverse event often incites intense emotional responses in healthcare professionals, such as distress, confusion, self-doubt, fear, remorse, guilt feelings of failure and depression, anger, shame, and inadequacy that often persists for longerperiods of ti(Ullström, Sachs, Hansson, Øvretveit & Brommels, 2014; Wu et al., 1991; Wolf, Serembus, Smetzer, Cohen & Cohen, 2000; Rassin, Kanti & Silner, 2005; Waterman et al., 2007; Gazoni, Amato, Malik & Durieux, 2012). Research also suggests that the impact of these events can extend into the healthcare professional's personal and professional life, diminishing their professional confidence, job satisfaction, impairing their performance, and causing detachment from patients (Aasland & Førde, 2005; Schelbred & Nord, 2007; Scott et al., 2009; Waterman et al., 2007). Previous research has shown that healthcare professionals report an overall decrease in quality of life after being involved in an adverse event (Seys et al., 2012; Sirriyeh et al., 2010; West et al., 2006). Following an adverse event, healthcare professionals may ruminate about the mistake (Bell, Moorman, & Delbanco, 2010; Gallagher, Waterman, Ebers, Fraser, & Levinson, 2003). This can lead to prolonged, clinically significant levels of anxiety which is worrisome as emotional distress may negatively affect patient care and lead to a higher risk of making future

errors (Fahrenkopf et al., 2008). Whilst in the grip of such strong reactions, composing and preparing oneself for a disclosure conversation with the patient and/or their family can be incredibly difficult and these emotional responses may affect healthcare professional's ability to disclose effectively (Wu et al, 2009).

The psychological explanation of the impact of adverse events

An adverse event is a stressor, and healthcare professionals will react to it like any other stressor; with a physiological and psychological stress response (Weiner, 1995; Worthington & Scherer, 2004; Allan & McKillop, 2010). During the physiological stress response, healthcare professionals may experience increased cardiovascular activity (e.g. increased blood pressure and heart rate) after being involved in an adverse event, due to an increase in the secretion of cortisol. Being in this physiological state may make it challenging for healthcare professionals to face the patient and/or family.

The psychological stress response consists of cognitive and behavioural facets. The cognitive response involves individuals trying to find out what happened, what went wrong, how serious the event was, and who/what is to blame (Weiner, 1995; Strang & Sherman, 2003; Wemmers, 1997). This cognitive investigation continues until the matter is resolved and closure is achieved. Healthcare professionals may attribute blame to themselves. In the case of self-blame, they may experience emotions of depression and anxiety (Kiecolt-Glaser, McGuire, Robles & Glaser, 2002) as well as guilt and shame (Tangney, Wagner, Fletcher & Gramzow, 1992). At a behavioural level, individuals who experience a stressful situation will face the fight or flight response. In the case of an adverse event as a stressor, healthcare professionals may flee from the situation, in which case they may display avoidance behaviours. They may try to avoid the patient and family/carers associated with them, preventing them from delivering optimal care and treatment (Allan & McKillop, 2010). This form of stress response may also lead to withdrawal from others including colleagues and therefore missing out on the support that is of fundamental importance to individuals who are experiencing a crisis (Allan & McKillop, 2010; Ryan & Deci, 2000). These responses can negatively impact the wellbeing of a healthcare professional and their ability to disclose the adverse event to patients and/or their families.

Research that has explored the impact of emotions on patient safety suggests that the emotions that healthcare professionals experience can directly influence their safety behaviour. Healthcare professionals may be unwilling to disclose adverse events to patients if their emotional needs are left unaddressed (Heyhoe et al., 2016). When healthcare professionals do conduct disclosure with patients whilst under emotional distress, it may result in an ineffective

or incomplete disclosure, resulting in additional distress for those involved (Wu et al., 2009; Birks et al., 2014).

1.8 A culture of perfectionism and blame

Healthcare professionals, particularly doctors are trained well in history taking, physical examination skills, and technical procedures in medical school. However, research shows that students are not adequately prepared in medical school for dealing with real or perceived medical errors (Smith & Forster, 2000). Despite the belief of human fallibility, mistakes are not tolerated by the healthcare delivery system (Wu et al., 2000; Classen & Kilbridge, 2002). In medical school, doctors are taught to have high expectations. They are expected to function without making any errors, therefore when such events take place, this is viewed as a failure of character (Hobgood, Peck, Gilbert, Chappel & Zou, 2002). Also, previously, medical education had built a culture where doctors were taught that they were the primary decision-makers, rather than decision making being a part of the team process (Becher & Chassin, 2001). Therefore when an error or an adverse event occurred, the blame was solely placed on the individual doctor as he/she was the primary decision-maker. The focus within healthcare systems still remains on allocating blame to individual healthcare professionals rather than improving knowledge and skills (Classen & Kilbridge, 2002). The doctor who has been singled out may experience a sense of personal failure and strive for future perfection (Becher & Chassin, 2001). State practice laws within the US also place an emphasis on individual accountability for adverse events, rather than the overall care team (Classen & Kilbridge, 2002; Becher & Chassin, 2001). Therefore this culture of perfectionism is still upheld (Robertson & Long, 2018). Perfectionism can be a positive trait when it is used for self-improvement. However, perfectionism can also be maladaptive (Robertson & Long, 2018).

Perfectionism is not only expected from medical training and the healthcare system (Robertson & Long, 2018). Media, the general community, and even doctors themselves expect perfection (Wu, 2000; Dubovsky & Schrier, 1983). Therefore, public scrutiny of any mistakes made by the doctor can make them fearful of making future mistakes. This can further instigate the inner perfectionism of the healthcare professional, which can lead to maladaptive traits and behaviours including low self-esteem, guilt, and self-doubt (Dubovsky & Shrier, 1983; Peters & King, 2012). After being involved in an adverse event, a doctor who possesses this perfectionistic trait may experience decreased work efficiency, reduced confidence levels, fear of judgement, depression, and in severe cases, even suicidal thoughts (Peters & King, 2012; Craiovan, 2014; Pereira, Fonseca & Carvalho, 2011; Clara, Cox & Enns, 2007). The doctor may

feel isolated without receiving support from their organisation. This can lead to the development of maladaptive coping techniques (Peters & King, 2012) which include avoidance of the issue, bury their emotions, or result in the use of drugs and alcohol (Wu, Folkman, McPhee & Low, 1993). Due to this sense of perfectionism, as suggested by Finkelstein, Wu, Holtzman & Smith (1997), one of the reasons for non-disclosure may be that acknowledging responsibility for an adverse event may damage healthcare professional's confidence and self-esteem and render them as less effective.

One organisational approach has been to seek out adverse events, identify the responsible healthcare professional and punishment follows (Boysen, 2013). However, instead of solving the problem, this punitive approach causes damage to both the healthcare professional and the safety of the healthcare organisation (Boysen, 2013). Although an individual may be at fault, this is in combination with the faults of the system (Boysen, 2013). Within the report 'To Err is Human' (Donaldson et al., 1999), it is emphasised that errors within the system, rather than individuals are responsible for most preventable adverse events that occur. Most adverse events are made by healthcare professionals who have good intentions and a number of factors contribute towards the adverse event. These include system factors include factors such as inadequate staffing, unmanageable workloads, and equipment unavailability (Pronovost et al, 1999; Carayon & Gurses, 2005). However, healthcare professionals who have been involved in medical errors have been treated with shame, abandonment, and blame (Denham, 2007). It has been emphasised that the culture which surrounds attributing individual blame when errors occur, must end and there needs to be a shift towards a culture which acknowledges system errors (Donaldson et al., 2000). However, a culture of individual blame still exists in healthcare organisations (Khatri, Brown & Hicks, 2009; Liang, 2002; Hoffman & Kanzaria, 2014; Oxtoby, 2018; Radhakrishna, 2015).

Such a culture within organisations is damaging as healthcare professionals face personal difficulties to be open about adverse events in such a culture (Kirkup, 2019; McLennan, Diebold, Rich & Elger, 2016; Fein et al., 2005; Coffey, Thompson, Tallet & Matlow, 2010). In an attempt to move away from this blame culture, within the NHS, a more balanced and reflective approach to learning from incidents and supporting healthcare professionals has been which is known as a Just Culture (Petschonek et al., 2013). This approach supports a culture of fairness, openness, and learning within the NHS and aims to make healthcare professionals feel confident to speak up when things go wrong, and does not seek to blame individuals involved (NHS improvement, 2018). Supporting healthcare professionals in this way allows openness about adverse events,

and provides the opportunity to learn from mistakes (NHS improvement, 2018). The NHS resolution, 'Being fair' report is one of the guidance documents which sets out the argument for the need for a Just Culture and describes what can be done differently in healthcare (NHS resolution, 2019).

1.9 Insufficient training on communication skills

Healthcare professionals struggle with disclosure and are not sufficiently trained on how to discuss adverse events with patients or families (Ock, Kim, Jo & Lee, 2016; McLennan et al., 2016; Harrison, Birks, Bosanquet & Iedema, 2017; Fein et al., 2007). When healthcare professionals are not provided with training on how to communicate certain adverse events, they do not feel comfortable conducting these conversations with patients (White et al., 2011; White et al., 2008). Disclosing negative outcomes that are due to a clinical error requires tact and good communication skills (Herbert, 2001). Disclosure should be made easier for healthcare professionals, so they can learn from mistakes and improve patient care (Herbert, 2001). It is imperative to provide healthcare professionals with support for the difficult and complex communication task of disclosure. Interestingly, in addition to the original injury, one of the significant factors why patients sought legal help was due to ineffective and poor communication after an adverse event (Levinson, Roter, Mullooly, Dull & Frankel, 1997; Vincent & Phillips, 1994). There are a large number of models within the general communication literature on how to break bad news, explain complex information (Silverman et al.G, 1991), and conflict resolution (Lazare, 1995), but there is little evidence on how to optimise the process of disclosing adverse events. Despite the introduction of the Duty of Candour (CQC, 2015) within the UK, there is limited research available which focuses on disclosure attitudes and practices within the UK.

1.10 The importance of disclosure

1.10.1 Importance of disclosure for healthcare professionals

Disclosure of adverse events to patients is imperative for several reasons. Healthcare professionals have a legal duty, to be honest, and open with patients when things go wrong in their care which have caused or could lead to significant harm in the future (CQC, 2015). Disclosure is an important part of patient-centred medical care and is an essential requirement for maintaining trust (Kim, Myung, Eo & Chang, 2017). Disclosure of adverse events to patients is also considered to be a central feature of high quality and safer patient care (Birks, 2014). Disclosure of harm which has resulted from healthcare delivery is also intrinsic to maintaining the trust between patients and healthcare professionals (Wu et al., 2013). Research also

suggests that disclosing mistakes may also help the healthcare professional to heal. By admitting the mistake, the healthcare professional may be relieved to hear that the patient or family member has forgiven him or her (Hannawa et al., 2016). Research suggests that failing to communicate effectively with patients following adverse events can have negative outcomes for all those involved, including distress among patients and healthcare professionals, and an increase in the pursuit of litigation by patients (Birks, 2014; Kaldijan, Jones & Rosenthal, 2006) 2006).

1.10.2 Importance of disclosure for patients

Being transparent and open with patients is important as patients have the right to know what has happened, what will happen next, and where they can seek support and advice (CQC, 2015). Patients have a right to be informed about all aspects of their healthcare including adverse events outcomes (Birks et al., 2014). Research also suggests that disclosing adverse events to patients is not only ethical but may also help patients or patients' families heal and move on from the adverse event (Hannawa, Shigemoto & Little, 2016). Disclosure also allows patients to obtain timely and appropriate treatment which may be needed after an adverse outcome, and it enables better-informed consent for any further treatment that may be required after the adverse event (Witman, Park & Hardin, 1996). Conducting the disclosure conversation with patients enables patients the right to make their own choices and take actions based on their own personal views (Sorrell, 2017). E.g. disclosure is important as it may allow the patient to seek appropriate compensation or the adverse outcomes that have occurred (Kraman & Hamm, 1999).

1.11 The disclosure gap

Although healthcare professionals describe disclosure as a moral and ethical duty, this enthusiasm may not be reflected in practice (Birks, 2014). Despite clear messages from patients on what they require from healthcare professionals, disclosure remains an elusive concept and disclosure does not always meet patient's expectations (Gallagher et al, 2006; Garbutt et al, 2007). This discrepancy is known as the 'disclosure gap'. There are a number of apparent reasons for this disclosure gap. As compassionate and trained individuals, healthcare professionals have a professional and personal commitment to helping patients. Therefore, it is psychologically difficult for healthcare professionals to admit that they have caused harm to a patient (Birks et al., 2014). Healthcare professionals describe receiving training on 'breaking bad news' to patients (Baile et al, 2000; Faulkner, Maguire & Regnard, 1994; Ptacek, Ptacek & Ellison, 2001), however, there is a lack of training which extends to conducting the challenging adverse event disclosure conversation with patients (Ock et al., 2016; McLennan et al., 2016;

Harrison et al., 2017; Fein et al., 2005). Although both types of conversations involve disclosing unfavourable news to patients, there is an important distinction between the two. Breaking bad news within healthcare is defined as the delivery of any bad, sad, or significant information that negatively alters people's expectations or perceptions of their present and future (Fallowfield & Jenkins, 2004). Bad news is related to the patients underlying medical condition, whereas adverse events result from medical intervention. Therefore, different emotions are involved when disclosing adverse events as patient harm occurs under the provision of a regulated activity and is not due to their underlying medical condition. However, the lack of training available for healthcare professionals on adverse event disclosure makes this difficult conversation even more challenging (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2007).

1.12 Maternity services

Adverse events can take place within any area of healthcare. There have been growing concerns in regards to the safety of maternity services in England due to a number of high profile failings in care (The Kings Fund, 2007). A well-known major investigation known as the Morecambe Bay investigation (Kirkup, 2015) was established to examine concerns raised by the occurrence of serious incidents within maternity services provided by the University Hospital of Morecambe Bay NHS Foundation Trust. These incidents included the deaths of sixteen babies and three maternal deaths. The investigation revealed that many factors including substandard clinical competence, deficient knowledge and skills, and poor working relationships led to the unnecessary deaths of mothers and babies, and different clinical care would have prevented most of these deaths (Kirkup, 2015). This inquiry stated that lessons must be learned in order to improve the safety of maternity services and to reduce the risk of similar events occurring in the NHS in the future. A number of recommendations were proposed which included reviewing skills and knowledge of healthcare professionals working within maternity, measures for multi-disciplinary working, addressing incident reporting, and reviewing the Trust's policy of openness and honesty to ensure that was in line with the Duty of Candour (CQC, 2015) regulation (Kirkup, 2015).

A second major case that occurred was the Shropshire maternity scandal, which is known as possibly one of the largest scandals in NHS history. An investigation was conducted which examined the care provided at the Shrewsbury and Telford NHS Trust (Wise, 2019). The investigation was initially conducted within 2017 and due to the number of avoidable failings that were uncovered, the scope of the investigation was widened from 23 cases to hundreds and

examined maternity failings from 1979 to present. Examples of the consequences of such failings include the death of around 42 babies and 3 mothers, and deprivation of oxygen led to brain injuries to a further 50 children (Wise, 2019). These incidents were deemed to have been avoidable, adequate care been provided. To avoid the repetition of mistakes, hospitals must learn lessons from what has gone wrong in the past. This involves the need to uphold a culture of openness and honesty and informing patients when things go wrong within their care and learning from these incidents. However, this did not take place adequately at the Shrewsbury and Telford Trusts (Wise, 2019).

Maternity services in the UK have been strongly criticised for having a 'lack of safety culture', and the Department of Health reports that in a number of tragic cases such as those mentioned above, the standard of care fell far below than what is expected. NHS Resolution is a body within the Department of Health and Social Care which supports the NHS by providing expertise on resolving concerns and disputes in a fair manner and sharing learning for improvement (NHS Resolution, 2020a). Statistics from the annual report and accounts in 2019/2020 suggest that maternity claims represent around 9% of the total number of clinical negligence claims received by NHS resolution each year, and represent 50% of the total value of new claims (NHS resolution, 2020b). The total value of maternity claims continues to rise, and in 2019/2020, the value of maternity claims was £1,822 million (NHS Resolution, 2020b). This suggests that a significant number of adverse events occur within maternity services and can have an impact on both the affected patients and the NHS healthcare professionals involved. This increasing number of negligence claims is of great concern and a massive burden on the NHS.

The link between inappropriate and inadequate disclosure and increased litigation claims has been suggested within the literature by several authors (Ushie et al., 2013; Berlin et al., 2014; Birks, 2014; Johnson et al., 2014; Youngson, 2014; Birks et al., 2015; Mira et al., 2017). However, these studies do not provide evidence that disclosure impacts litigation (Birks, Aspinal & Bloor, 2018). More recent research suggests that while some patients and or/families sought litigation to address the financial consequences of adverse events, another reason to litigate was to obtain answers and receive explanations for the adverse event, which they had failed to receive from healthcare professionals and organisations (Birks et al., 2018). Qualitative research examining the effects of communication skills on litigation also indicates that open communication which includes an apology and offers support can prevent unnecessary litigation. The findings also suggest that poor communication can have a negative impact on litigation (Birks et al., 2018). Evidence also suggests that the behaviour and attitudes of healthcare professionals could drive

litigation, especially when patients felt that they had been lied to, incidents had been covered up, and when they felt that healthcare professionals did not acknowledge their pain and distress (Birks et al., 2018). Although further research within the area of disclosure communication and litigation needs to be conducted, and there is currently limited empirical evidence surrounding the effectiveness of communication as a factor alone to reduce litigation claims, these findings indicate the need to increase transparency and openness and improve communication of adverse events.

1.13 Research methodology

The epistemological position taken within this thesis was pragmatism. Pragmatism considers the practical application of knowledge to be fundamental to meaning and truth (Dures, Rumsey, Morris & Gleeson, 2011). Pragmatism focuses on the purpose and consequences of knowledge, the importance of identifying solutions to problems, and the extent to which knowledge 'works' at the time (Creswell, 2009; Dures et al., 2011). Pragmatism views reality as both singular and multiple and believes that there may be a theory to explain the phenomenon being studied, but individual input into the nature of the phenomenon should also be assessed (Cresswell & Clark, 2011). As pragmatism is not aligned to any single philosophy or reality, it enables researchers to draw on both qualitative and quantitative assumptions to fully understand an issue (Creswell, 2009) and allows for a flexible and practical approach to data collection (Cresswell & Clark, 2011). Therefore, it is well suited to applied health research and is considered to provide a logic and epistemological justification for conducting mixed-methods research (Johnson, Onwuegbuzie & Turner, 2007). A pragmatic approach was also chosen as it allows for findings from applied health research to be translated into the healthcare setting.

Pragmatism is based on the assumption that whatever methods are needed to provide a relevant approach to a given research question can be employed (Salkind, 2010). Therefore, the choice of pragmatism as a methodology, allowed the researcher (PhD student) to choose the relevant and appropriate research methods that addressed each of the research questions that were proposed (Fielzer, 2010). Within this thesis, based on the assumptions of pragmatism, qualitative research methods were used to synthesise and to explore the in-depth and rich experiences of patients and healthcare professional's views and experiences on disclosure. Mixed methods were used to better understand the feasibility and acceptability of the training intervention. This is consistent with the MRC guidelines for complex interventions which suggest that a mixture of qualitative and quantitative methods are likely to be needed to assess feasibility (MRC, 2008). As recommended by pragmatism, in order to assess the feasibility and acceptability of the intervention, the results from both the quantitative and qualitative elements

were integrated (Creswell and Plano Clark, 2011; Tashakkori and Teddle, 1998). Central to the application of mixed methods research in pragmatism is the development of research questions that can be answered by integrating the results of quantitative and qualitative research (Creswell and Plano Clark, 2011; Tashakkori and Teddlie, 1998)

1.14 Aims, objectives and thesis structure

The overall aim of this thesis was to investigate how healthcare professionals within maternity services can be supported to communicate the news to patients that an adverse event has occurred. It aimed to understand the current disclosure practices within UK maternity services, how adverse event disclosure affects the wellbeing of healthcare professionals and whether providing training in this area had the potential to enhance skills in disclosing adverse events to patients.

This thesis aimed to address the following research objectives:

1. To explore the views and experiences of patients and healthcare professionals on the disclosure of adverse events within healthcare.

Within this thesis, the literature on experiences of adverse event disclosure was systematically reviewed and a meta-ethnographic approach was used to synthesise the findings. This aided understanding of patients and healthcare professionals' experiences of adverse event disclosure, and the barriers to disclosure faced by healthcare professionals. The findings from this systematic review revealed that there was a disconnect between the perspectives of patients and healthcare professionals on how disclosure should be conducted and what the disclosure conversation should entail. Although healthcare professionals advocated disclosure they faced a number of barriers to disclosure. The ideal disclosure practice involves providing relevant information about the adverse event, accountability, and an apology, and a commitment to preventing future recurrences. To meet patients' needs for disclosure, the facilitators for healthcare professionals include clarity regarding the legal aspects of disclosure, development of an open and transparent culture, and providing training on adverse event disclosure.

2. To understand the current views and experiences of adverse event disclosure within UK maternity services, the current training available, and how the disclosure process affects healthcare professional's wellbeing.

A qualitative study was conducted, where semi-structured interviews were carried out with midwives and obstetricians working within UK maternity services to understand the views and

experiences of adverse event disclosure within the UK. The findings of this study suggest that although healthcare professionals believed that honesty, transparency, and openness were important principles of disclosure, midwives and obstetricians struggled with this process. Within the UK, there is currently a lack of clarity and support surrounding the disclosure process. There is a need for support and guidance from an organisational level in terms of the investigation process, current legal processes within the UK, how to approach disclosure when there is uncertainty about whether an adverse event or complication has occurred, and the Duty of Candour regulation. Training programmes and guidance which takes into account these factors need to be developed.

3. To identify the most important components of a training intervention within the area of disclosure and develop a communication training intervention to support maternity healthcare professionals with the disclosure process.

The MRC guidelines (MRC, 2008) for developing complex interventions were used to develop a training intervention to support maternity healthcare professionals with adverse event disclosure. The literature on adverse event disclosure interventions was reviewed, a coherent theoretical basis was identified. These were combined with primary research and the current UK policies and requirements for disclosure, to develop a novel training intervention with the support of maternity healthcare professionals. The training intervention aimed to enhance maternity healthcare professional's skills with the disclosure of adverse events within the UK. A 3-hour training intervention was designed which included a mixture of interactive lecture-based components with facilitated group discussions and exercises. The training intervention consisted of the following components: (1). Defining adverse events and principles of Duty of Candour, (2). Exploring the emotional impact of involvement in an adverse event, and (3). Psychological self-management strategies to feel calmer and more confident to disclose to the patient and/or family.

4. To pilot and evaluate the new training intervention to assess the feasibility and acceptability by healthcare professionals within maternity services.

The developed training intervention was delivered to maternity healthcare professionals and the acceptability and feasibility of the intervention was assessed using a mixed-methods research approach. This study also assessed the extent to which the training intervention had the potential to enhance knowledge of adverse event disclosure and self-efficacy (confidence) to disclose. The findings from this study suggest that this novel training intervention was acceptable to healthcare professionals. The findings indicate that it is not feasible to deliver the training intervention to midwives due to the difficulties associated with recruiting midwives. An alternative mode of recruiting and delivering the training to midwives is needed. These findings

suggest that it might not be feasible to recruit and deliver this training intervention to a single Trust as part of a larger evaluation due to the difficulty of recruiting a group of midwives and/or obstetricians to be available together at the same time. An alternative includes delivering the intervention at a regional level where maternity healthcare professionals from a number of Trusts are invited to attend. This study also provided preliminary evidence that the training intervention had the potential to improve knowledge of disclosure and increase self-efficacy to disclose adverse events.

Each of the research questions within this thesis, the research methods adopted and the justification for the choice of methods is displayed in table 1.1

Table 1. 1: Research questions and research methods within the thesis

Research question	Research methods	Justification
1. What are the views and experiences of patients and healthcare professionals on the disclosure of adverse events within healthcare?	Qualitative meta-ethnographic synthesis	Using this qualitative synthesis approach was appropriate as it allowed the synthesis of rich, in-depth qualitative studies to provide evidence on experiences of disclosure. This approach helped to provide important theoretical and conceptual contributions to improve healthcare policy and practice. Using a m eta-ethnographic approach also allowed the researcher to draw together the different perspectives of patients and healthcare professionals.
2. What are the current views and experiences of adverse event disclosure within UK maternity services and the current support available?	Qualitative semi-structured interviews	Semi-structured interviews are recommended when subjective knowledge surrounding a phenomena or experience is lacking (Morse & Field, 1995; Richards & Morse, 2012). Using semi-structured interviews was the most appropriate approach as it allowed the opportunity to gain an insight and obtain in-depth detail into the experiences of midwives and obstetricians on adverse event disclosure within the UK. No previous studies had been conducted

		with maternity healthcare professionals addressing this research question.
3. What are the most important components of a training intervention in the area of disclosure? How can a training intervention be developed to support maternity healthcare professionals with the disclosure process?	Scoping review exercise	A scoping review exercise was the most appropriate approach as it allowed the identification and mapping of the available evidence on previous disclosure interventions, including the nature and extent to which research on these interventions exists.
4. How acceptable and feasible is a training intervention to enhance maternity healthcare professional's skills with the disclosure of adverse events?	Mixed-methods approach	A mixed methods approach was used to explore feasibility and acceptability of the training intervention, and the extent to which the intervention had the potential to enhance knowledge and self-efficacy to disclose. The use of quantitative methods was the most appropriate to assess whether there was an increase in knowledge and self-efficacy, pre and post intervention and to obtain brief descriptive data on feedback of the training intervention. In order to capture rich information to further obtain feedback, understand the strengths of the training intervention and aspects which could be improved in the future, semi-structured qualitative interviews were utilised.

The MRC guidelines (MRC, 2008) for developing complex interventions were used as a framework throughout this research. The stages for developing an intervention as proposed by the MRC guidelines were followed. The relevant existing evidence base was identified (study 1), this was supplemented with new primary research (study 2), the intervention to support

maternity healthcare professionals with disclosure was developed based on the existing evidence and theoretical approaches (study 3) and the intervention was then delivered to explore feasibility and acceptability (study 4). Figure 1.1 highlights how each of the studies are sequentially linked.

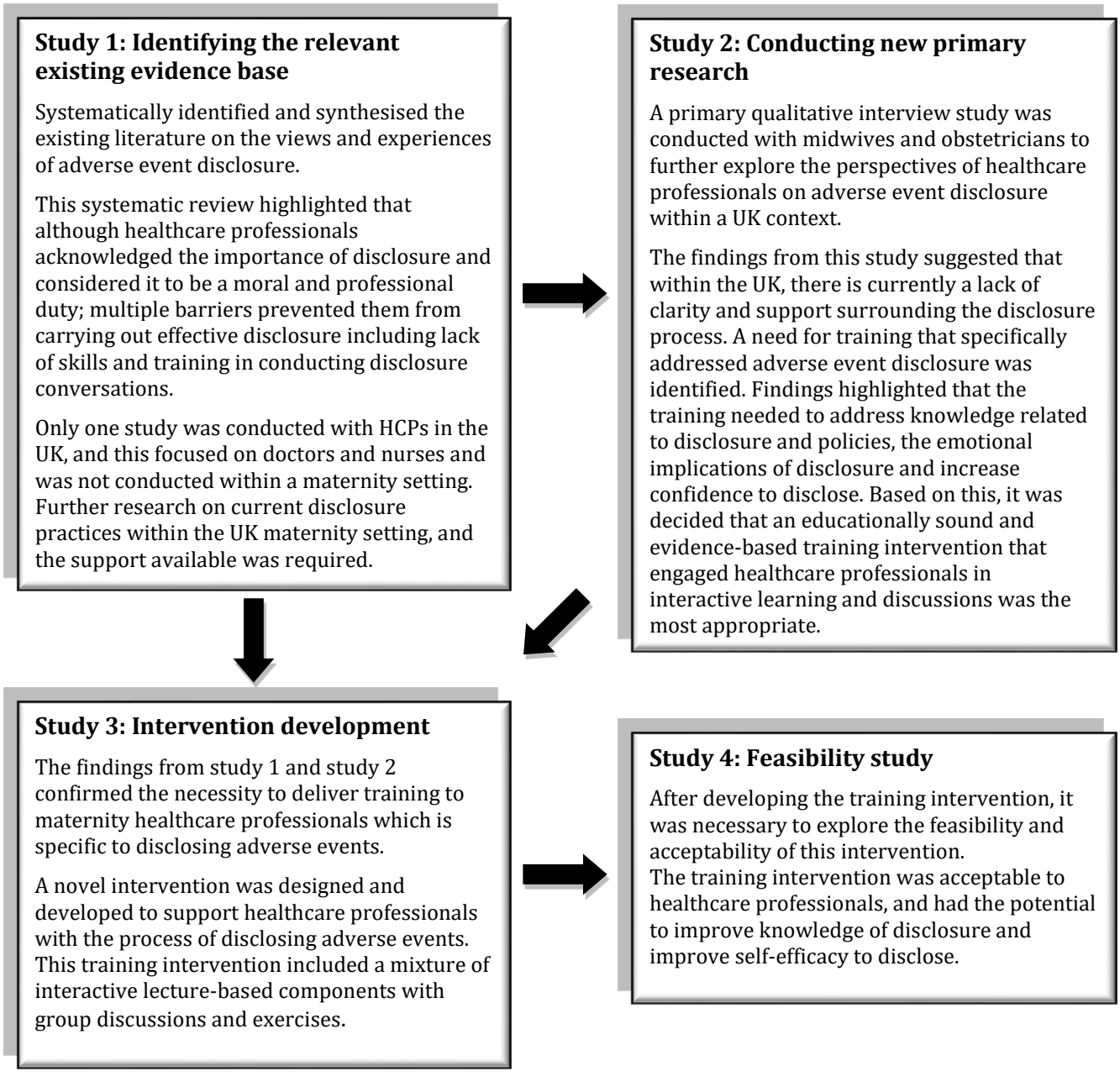


Figure 1. 1: Sequential link between studies

Chapter 2: The views and experiences of patients and healthcare professionals on the disclosure of adverse events: A systematic review & qualitative meta-ethnographic synthesis

2.1 Chapter summary:

Chapter 1 provided an introduction to patient safety within healthcare and the disclosure of adverse events. This chapter reports on study 1 – a systematic review of patient's and healthcare professional's views and experiences of adverse event disclosure. A qualitative meta-ethnographic approach was used to synthesise the findings. The results of this review are presented and discussed, and the implications and recommendations for clinicians, policy makers and researchers are highlighted. The findings from this review have informed the design of subsequent research within this thesis.

2.2 Introduction

As discussed in the previous chapter, an important element in managing the consequences of adverse events is disclosure to patients and/or their families (Kalra, Kalra & Baniak, 2013). Disclosure is imperative as healthcare professionals have a responsibility to be open about adverse events and patients have the right to know what has happened (CQC, 2015). Disclosure maintains trust between patients and healthcare professionals (Kim et al., 2017), and failure to disclose can result in increased litigation by patients (Wu et al., 2013; Gallagher et al., 2007). Frameworks have been developed in several countries (UK, Australia, Canada, and the USA) to guide adverse event disclosure (American Medical Association, 2019; Canadian Patient Safety Institute, 2011; Australian Commission on Safety and Quality in Health Care, 2013; CQC, 2015). Although transparency and openness are promoted in these policies, research suggests that disclosure does not always occur (Shannon, Foglia, Hardy & Gallagher, 2009; Gallagher et al., 2006; Kaldijan et al, 2007; Hobgood, Hevia, Tamayo-Sarver, Weiner & Riviello, 2005).

Research remains limited on the perspectives of patients and healthcare professionals on adverse event disclosure. A previous comprehensive review on disclosure has been conducted (O'Connor, Coates, Yardley & Wu, 2010) where the literature on adverse event disclosure was reviewed. This review found that there is a gap between the ideal disclosure practice and reality. The findings from this review suggest that disclosure practice can be improved by strengthening and policies and supporting healthcare professionals with the disclosure of adverse events (O'Connor et al., 2010). However, the questions still remain about how to best

disclose adverse events to patients and ways in which healthcare professionals can be supported to meet the needs of patients. Exploring both patients and healthcare professionals views on disclosure will help understand the expectations, barriers, and challenges faced by each group. This can help to generate interventions that are effective and practical for both patients and healthcare professionals.

This systematic review aimed to synthesize the views and experiences of patients and healthcare professionals on the disclosure of adverse events, and identify the barriers and facilitators to disclosure faced by healthcare professionals. This is the first review to synthesize the views of patients and healthcare professionals, using a qualitative synthesis approach. A meta-ethnographic synthesis approach developed by Noblit and Hare (1988) and adopted by Britten et al (2002) and Campbell et al (2003) was used. A meta-ethnographic synthesis was chosen as it offers a unique systematic analysis process to provide evidence on patients' and healthcare professionals' views and experiences on the disclosure of adverse events. Synthesizing qualitative studies using this approach can provide important theoretical and conceptual contributions to improve health-care policy and practice. The PhD student is referred to as the researcher throughout this thesis.

2.3 Methods

A systematic search of qualitative studies was conducted and data from included studies were synthesised using a meta-ethnographic approach. The review was reported according to the PRISMA guidelines (Moher, Liberati, Tetzlaff, Altman & Prisma Group, 2009). The eMERGE reporting guidance (France et al., 2019) was also followed to conduct and report this meta-ethnography.

2.3.1 Search strategy and data sources

Five electronic databases were systematically searched; MEDLINE, EMBASE, PUBMED, CINAHL, and PsycINFO (see Appendix 1 for the search strategy). The search strategy included a combination of free-text searching of the three main concepts being examined in this review (disclosure, incident, and experience) and was developed from an existing systematic review (O'Connor et al., 2010). A comprehensive set of search strategies were used to identify all available studies. Searches were conducted from inception to February 2017, updated to July 2018.

2.3.2 Eligibility criteria

Papers were included if they were in a healthcare setting, published in English, and involved

qualitative data collection and analysis. Studies focusing on breaking bad news were excluded. Grey literature was also excluded.

2.3.3 Study selection

Study selection followed PRISMA guidelines (see Appendix 2 for the PRISMA flow diagram). Two reviewers independently screened 10% of the abstracts (RS & JJ) and Cohen's kappa statistic was used to assess inter-rater reliability ($k \geq 0.7$). Once inter-rater reliability was confirmed, remaining abstracts were screened by one reviewer (RS). Full texts were screened by RS and all were double screened by JJ and RL. Disagreements were resolved through discussion between the three reviewers.

2.3.4 Critical appraisal

To assess study quality, the Critical Appraisal Skills Programme (CASP) qualitative research checklist was used (CASP, 2018). This tool has been previously used by published reviews of qualitative studies (Scott & Grant, 2018; Elmir & Schmied, 2016; Slade, Kent, Patel, Bucknall & Buchbinder, 2016; Slade, Patel, Underwood & Keating, 2015). All studies were critically appraised and each study was assigned a numerical score out of ten, where a higher score correlated to higher quality (Scott & Grant, 2015). The two highest-ranked studies were used as index studies and were the first studies from which concepts were translated into other studies, therefore shaping the analysis (Atkins et al., 2008). This process was carried out independently by two authors and scores were discussed to check for consistency (RS & JJ). Disagreements were resolved through discussion. No studies were excluded because of the quality of appraisal. None of the studies were rated as being 'very low' and a majority of the studies were rated as being of 'high quality'. Most studies reported on the methodological framework used and provided detailed descriptions of the data analysis methods. However, authors' across the studies consistently failed to report on whether the relationship between the researcher and participant was considered.

2.3.5 Data extraction

Two standardised data extraction forms were developed based on a published meta-ethnography (Slade et al., 2016). Descriptive data were extracted in one form by RS (study population, sample characteristics, country of origin, methods including data collection and data synthesis, and study conclusions). Key concepts or 'second-order constructs' (interpretations made by the primary authors), were extracted by RS and JJ into a table in Microsoft Word, alongside the illustrative quotations from study participants ('first-order constructs'). To preserve the primary authors' context and second-order construct meaning, the authors' own terminology and definitions were maintained. The completed forms were discussed and examined for consistency and items were assembled into common groups prior to analysis.

2.3.6 Data synthesis

A meta-ethnographic approach was used to synthesise the findings. Meta-ethnography provides an alternative to traditional aggregative methods of synthesis and supports the development of analytical rather than descriptive findings (Daker-white et al, 2015). Meta-ethnography relies on a process of 'translation' where key concepts from one study are introduced into another and assessed to the extent to which they can account for a particular phenomenon within a different context (Noblit & Hare, 1988; Scott & Grant, 2018). Key concepts also known as 'second-order' constructs are interpretations made by authors of the included studies. During this process of translation, new interpretations are developed which are known as 'third-order' constructs. These comprise of a new understanding of the phenomena under study (Scott & Grant, 2018). The synthesis involves deciding whether the studies are sufficiently similar in their focus to allow for a reciprocal translation or if the studies refute each other, a refutational synthesis is conducted.

Each of the seven phases to conduct a meta-ethnography as outlined by Noblit & Hare (1988) who first proposed this approach were followed as well as adaptations and developments from recent researchers. The method of conducting the meta-ethnography including each of the phases utilised to conduct this synthesis are described in Table 2.1. Data synthesis was an iterative process. Further in-depth detailed guidance for novice qualitative researchers, using illustrative examples to describe how to conduct a meta-ethnographic synthesis is displayed in appendix 4.

Table 2. 1: Method of conducting meta-ethnography

Phase 1: Getting started	This initial stage required identification of an area of interest (Noblit & Hare, 1988) and to consider if a synthesis of the topic is required and whether a qualitative synthesis fits with the research question (Toye et al., 2013).
Phase 2: Deciding what is relevant to the initial interest	Phase 2 involved the following steps: a) defining the focus of the synthesis, b) selecting studies for inclusion in the synthesis and locating relevant studies, c) developing inclusion and exclusion criteria and d) quality assessment of the included studies (Atkins et al., 2008).
Phase 3: Reading the studies	It is during this phase where the synthesis process began. This stage involved repeatedly reading the included studies and familiarisation with the key concepts and metaphors. It was important at this stage to become as familiar as possible with the content and detail of the included studies. A concept has been defined as 'having some analytical or conceptual power, unlike more descriptive themes (Britten et al., 2002). It is important to acknowledge that reading the studies was not a discrete phase; reading occurred throughout the synthesis process. The 'raw data' was extracted from each study including first-order constructs (participant quotations) and second-order constructs (primary author interpretations). Contextual information from each study was also extracted.
Phase 4: Determining how the studies are related	During this stage, the relationships between the key concepts from the different papers needed to be considered. In order to determine how the studies were related, a list of themes from each paper were listed. Common concepts from the studies were grouped. This was approached by gathering similar themes from studies into categories of shared meaning (France et al., 2019).
Phase 5: Translating the studies into one another	Translation was approached by organising the second-order constructs thematically, by grouping concepts with similar meanings. The studies within each grouping were then arranged chronologically (from the highest to lowest scoring paper based on quality appraisal). The concepts within each of the groupings were compared account by account in a process similar to the method of constant comparison (Cahill, Robinson, Pettigrew, Galvin & Stanley, 2018). During this

	phase, the table of study characteristics recorded earlier were used as a context for comparisons as well as the full papers. This process was supported by creating a translations table (see Appendix 3 for examples of translations tables) which is a useful way to display this level of synthesis (Coventry, Small, Panagioti, Adeyemi & Bee, 2015). Two separate translations were conducted; one for the views and experiences of patients and one for healthcare professionals.
Phase 6: Synthesising the translations	This phase is described by Noblit & Hare (1988) as 'making the whole into something more than the parts alone imply'. The synthesis process for this review consisted of three stages: (i) a reciprocal translation of the 'patient' studies to understand their views on the disclosure process of adverse events; (ii) two reciprocal translations of the 'healthcare professional' studies (1) to understand healthcare professionals views on the disclosure process of adverse events and (2) to understand the barriers to disclosure faced by healthcare professionals; and (iii) a line of argument synthesis of all the studies to outline how patients' and healthcare professionals views differ on disclosure and how the barriers faced by healthcare professionals may contribute towards this difference in disclosure views. A line of argument synthesis was chosen as it became apparent during the synthesis that the concepts from the 'patient' studies and 'healthcare professional' studies were not strictly contradictory in nature, rather described alternative perspectives of the same phenomenon.
Phase 7: Expressing the synthesis	This final phase involved writing up the synthesis by summarising the findings, discussing strengths and limitations, and providing recommendations and conclusions

2.4 Results

2.4.1 Study characteristics

15 studies were included (Table 2.2). 7 were with Healthcare professionals, 4 with patients (including family members/or the general public), and 4 included both patients (including family members/or the general public) and Healthcare professionals. These were published between 2003 and 2017 and involved 1205 participants. Participants were 376 patients and family members (including 18 members of the public) and 829 healthcare professionals. Healthcare professionals included doctors, nurses, surgeons, pediatric residents, and anaesthesiologists. Studies were from Canada (2 studies), USA (6 studies), UK (1 study), Australia (3 studies), Switzerland (1 study), Spain (1 study), and Korea (1 study).

Table 2. 2: Study characteristics

Author (s)	Year	Country	Participants	Data collection method	Method of data analysis
Gallagher et al	2003	USA	52 patients and 46 healthcare professionals (physicians)	Focus groups	Qualitative data analysis
Coffey et al	2010	Canada	24 healthcare professionals (paediatric residents)	Focus groups	Thematic analysis
Duclos et al	2005	USA	16 patients	Focus groups	A combined template & organising approach
Espin et al	2006	Canada	28 healthcare professionals (surgeons, nurses & anaesthesiologists) and 11 patients	Interviews	Iterative grounded theory approach
Fein et al	2007	USA	204 healthcare professionals (nurses, physicians &	Focus groups	A systematic approach to qualitative synthesis

			residents)		
Harrison et al	2017	UK	13 doctors and 22 nurses	Interviews	Framework analysis
Iedema et al	2011	Australia	119 patients and family members	Interviews	Discourse analysis
Iedema et al	2008b	Australia	131 healthcare staff and 23 patients	Interviews	Semantic discourse analysis
Iedema et al	2008a	Australia	23 patients and family members	Interviews	Thematic discourse analysis
Mazor et al	2013	USA	78 patients	interviews	Directed content analysis
McLennan et al	2016	Switzerland	18 healthcare professionals (nurses)	Interviews	Conventional content analysis
Mira et al	2016	Spain	27 healthcare professionals (15 physicians, 12 nurses)	Focus groups	Qualitative data analysis
Ock et al	2016	Korea	16 healthcare professionals (physicians) and 18 members of the public	Interviews and focus groups	Directed content analysis
Shannon et al	2009	USA	96 healthcare professionals (nurses)	Focus groups	Qualitative content analysis
Fein et al	2005	USA	204 healthcare professionals (nurses, residents, physicians, administrators) and 36 patients	Focus groups	Qualitative data analysis

The following sections show reciprocal translations of 'patient' and 'healthcare professional' studies, followed by a line of argument synthesis (see Table 2.3 for reciprocal translations for the 'patient' and 'healthcare professional' studies).

2.4.2 Reciprocal translation of the patient studies

Reciprocal translation of key concepts extracted from the 8 'patient' studies synthesised **3 third-order constructs: '*Need for information', 'Importance of sincere regret'*** and ***'Promise of improvement'***

Need for information

Patients felt that they were not provided with the information they needed (Duclos et al., 2005; Iedema et al., 2011; Iedema et al., 2008a; Espin, Levinson, Regehr, Baker & Linghard, 2006). This led to worries about what was going to happen to them next (Duclos et al., 2005). Patients consistently emphasised the importance of receiving relevant information. However, obtaining information was problematic, difficult, and time-consuming (Iedema et al., 2008b). Patients also believed they had a right to receive information and full disclosure (Espin et al., 2006). Patients wanted healthcare professionals to inform them comprehensively about the adverse event, the management plan, and the investigation. Patients did not want to have to ask numerous questions of their doctor. Patients threatened legal action to receive information and stated it was *refreshing* when they didn't have to battle with insurance companies to get information (Duclos et al., 2005). Only in one study were patients satisfied with the information provided to them during the disclosure process and still had confidence in their healthcare professional as a result of him being *honest*: *'he laid it on the line and gave me the facts'* (Duclos et al., 2005).

Importance of sincere regret

A predominant theme related to the need for accountability and an apology. Patients said they expected the healthcare professionals delivering the disclosure conversation to acknowledge what had happened and take responsibility for their actions (Duclos et al., 2005; Iedema et al., 2011; Gallagher et al., 2003; Mazor et al., 2013). The inability to admit a mistake by healthcare professionals and abnegating responsibility led to patient frustrations and disappointment (Duclos et al., 2005; Iedema et al., 2008a). When healthcare professionals took responsibility, the patient-professional relationship improved and there was an increased sense of trust from patients (Duclos et al., 2005; Iedema et al., 2008a). For some patients, assuming responsibility was seen as a pre-requisite for learning. Patients indicated they wanted healthcare professionals and institutions to regret what had happened:'*...it made me feel that I could trust my PCP [primary care physician] because I mean she took responsibility...had remorse about what*

happened' (Mazor et al., 2013). Patients responded positively to expressions of regret and apology, but only if these were perceived to be sincere. However, for some patients, an apology alone was not sufficient; they wanted to be informed of the steps taken to correct the incident (Mazor et al., 2013).

Promise of improvement

Patients and family members wanted to be assured that healthcare professionals and institutions were working to prevent recurrences (Gallagher et al., 2003; Mazor et al., 2013; Ock et al., 2016). Patients who had suffered due to the adverse event believed it was vital that the same error was not made with other patients (Mazor et al., 2013). An important element in preventing recurrences was that those involved had learned from the adverse event and the incident had resulted in institutional changes (Mazor et al., 2013). Patients specified that in disclosure conversations they would like their healthcare professional to state '*we assure you this problem will not happen again*' (Gallagher et al., 2003).

2.4.3 Reciprocal translation of the healthcare professional studies

Reciprocal translation of the key concepts extracted from the 11 'healthcare professional' studies synthesised **3 third-order constructs: *'sometimes economical with the truth', 'owning up without saying I'm sorry', 'To tell or to not tell?'*** which consisted of the following two sub-themes**: *'when honesty may cause unnecessary anxiety' and 'outcome determines disclosure'.***

Sometimes economical with the truth

A predominant theme across some of the studies related to excluding some facts or information when providing the explanation (Espin et al., 2006; Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2007; Mira et al., 2017). Healthcare professionals including nurses and physicians advocated the disclosure of adverse events to patients and their families, but sometimes provided only partial and selected information to patients/ family (Espin et al., 2006; Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2007; Mira et al., 2017). Many healthcare professionals described avoiding revealing too much truth to patients or families (Espin et al., 2006; Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2007; Mira et al., 2017). Errors which resulted in adverse events with a more serious outcome were disclosed in such a way that it would not be directly obvious to the patient/family that an adverse event had occurred and the fault of the healthcare professional(s) or the institution would be concealed (Espin et al., 2006; Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2007). This was achieved in different ways. At times the error and the adverse event were described '*in the most positive spin and in a positive light*' (Gallagher et al., 2003). Some healthcare professionals explained the

adverse event in clinical terms so that the patients/families would find it difficult to establish the connection between the error and the resulting adverse event (McLennan et al., 2016). Others described omitting certain information related to the adverse event (Espin et al., 2006; Gallagher et al., 2003; Fein et al., 2007).

Owning up without saying I'm sorry

Most Healthcare professionals believed an important element of disclosure was to acknowledge and accept responsibility for the adverse event (Gallagher et al., 2006; Iedema et al., 2008a; Iedema et al., 2008b; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). Disclosing the event and admitting fault was considered to be a moral, ethical and professional duty (Gallagher et al., 2006; Harrison et al., 2017; Fein et al., 2005). Healthcare professionals believed in ensuring the patient was made aware of this, even if the events leading up to the adverse event were not clear (Iedema et al., 2008b). In some situations healthcare professionals accepted responsibility for the adverse event, however, errors were often viewed as system faults rather than individual failures: *'it could have been made by anyone else in my shoes'* (Coffey et al., 2010). However, in one study doctors did not explicitly disclose responsibility or express regret in specific terms (Ock et al., 2016). This study was conducted with healthcare professionals from a non-westernised country (Korea) whereas healthcare professionals who believed it was important to vocalise this acknowledgement to patients were based in westernised countries. Unlike most western countries, open disclosure policies have not yet been implemented in Korea which may explain the difference in views.

The importance of an apology in the disclosure conversation was only cited by healthcare professionals in one study (Harrison et al., 2017) where there was a widespread belief that an apology was not an acceptance of liability and had no professional and legal implications. However, this group described the existence previously of a culture where apologising was considered to be an admission of liability (Harrison et al., 2017). This culture may still exist elsewhere, and this could explain why apologising was not discussed by healthcare professionals in other studies. Conversely, some doctors believed that it wasn't necessary to state an apology as '*you don't really need to say it through words*' (Ock et al., 2016).

To tell or to not tell?

Within this theme, the data was fractured into two subthemes: ***'when honesty may cause unnecessary anxiety'*** and ***'outcome determines disclosure'***.

When honesty may cause unnecessary anxiety

Healthcare professionals assumed in cases where the error was not obvious or evident, the

patient would rather not be informed (Espin et al., 2006; Gallagher et al., 2003; Ock et al., 2016; McLennan et al., 2016). Where it was felt the patient would be burdened by the disclosure, or it would cause unnecessary stress, the event was not disclosed: '*if a patient is 95 and bed-ridden- you might not want to tell them'* (Espin et al., 2006). As one healthcare professional related *'My job is to relieve anxiety, not to create it'* (Gallagher et al., 2003). Non-disclosure in such cases was rationalised as being in the patient's best interests.

Outcome determines disclosure

The impact of an error on the patient, whether it resulted in an adverse event, and the severity of the adverse event influenced whether disclosure occurred. When adverse events were minor or there was no substantial harm resulting from errors, disclosure was not believed to be of importance (Espin et al., 2006; Gallagher et al., 2003; Ock et al., 2016; McLennan et al., 2016; Fein et al., 2007; Fein et al., 2005) and was seen as impractical due to the frequent occurrence of these events (Gallagher et al., 2003). Lack of patient awareness of the error was also considered as a reason for non-disclosure (Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2005). Disclosure of medical errors resulting in minor or no adverse events was compared to aviation errors by suggesting that near misses occur frequently in aviation; however, people would only be informed if they became aware of these (Fein et al., 2005). Conversely, one healthcare professional endorsed the disclosure of errors which did not lead to adverse events and saw this as an opportunity to improve their trust with patients (Gallagher et al., 2003).

2.4.4 Reciprocal translation of the healthcare professional studies on barriers to disclosure

Reciprocal translation of the key concepts on the barriers to disclosure synthesised four third-order constructs: ***'difficulty of disclosure in a blame culture'***, ***'avoidance of litigation'***, ***'disclosure is a learned skill',*** and ***'inconsistent guidance'***. These barriers described by healthcare professionals may help to explain the differences between the two group's perspectives on disclosure.

Difficulty of disclosure in a blame culture

One of the commonly cited barriers to disclosing adverse events was a culture of blame, where these cultural barriers were either organisational (Gallagher et al., 2003; McLennan et al, 2016; Harrison et al., 2017; Fein et al., 2005) or professional in origin (McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). At times, it was difficult to distinguish between what constitutes as an organisational and professional/workplace barrier. Nurses, in particular,

described their healthcare organisations as having a closed culture that inhibited openness with patients in relation to adverse events (McLennan et al., 2016; Fein et al., 2005). Non-disclosure was attributed to the institutional culture in which the healthcare professionals were immersed (Fein et al., 2005). When adverse events occurred, blame was attributed towards individuals' errors rather than system errors, which resulted in healthcare professionals being apprehensive to disclose (Coffey et al., 2010). Changes to the institutional culture were suggested by nurses, doctors, and healthcare professionals as a strategy to promote disclosure practices. This included the removal of a blame culture and the development of a culture of openness and transparency (Fein et al., 2005).

Support and guidance from managers was described by nurses as a factor that either positively or negatively influenced disclosure practices (Fein et al., 2005; Gallagher et al., 2006). Supportive managers were described as never attributing blame to the individual but being empathetic and understanding as '*this could happen to anybody'* (Gallagher et al., 2006). On the other hand, healthcare professionals conveyed that they would be less likely to disclose future adverse events if they believed they had been unfairly blamed or shamed in the past. One nurse provided an account where a colleague was reprimanded for disclosing an adverse event to a patient, leading to the belief that they were being discouraged from carrying out their professional and moral duty to inform the patient (Gallagher et al., 2006). In this situation '*she felt like she did the right thing, but was told, 'don't do that again'* (Gallagher et al., 2006).

Worries and fear that a damaged reputation will accompany admittances of adverse events also hindered disclosure practices (Gallagher et al., 2003; McLennan et al., 2016; Coffey et al., 2010). Healthcare professionals described a fear of admitting and openly disclosing adverse events due to worries about how they would be perceived by colleagues and whether their mistakes would be discussed within the organisation (Fein et al., 2005). This was more so for the junior clinicians as they believed that there was an expectation to prove their competence (Coffey et al., 2010). Concerns about whether their mistakes would be discussed within the organisation were also voiced (Coffey et al., 2010). Fear of professional or workplace sanctions was also described as one of the reasons for concealing adverse events (McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). This included being fearful of disciplinary action which may be taken against them including losing their job (McLennan et al., 2016; Harrison et al., 2017), fear of being ostracised within their workplace (McLennan et al., 2016), and doctors, in particular, expressed fear of damaging career opportunities (Gallagher et al., 2003; Coffey et al., 2010). These sanctions which were put in place were found to be counterproductive in responding and disclosing future adverse events (McLennan et al., 2016).

Avoidance of litigation

A second category of barriers to disclosure comprised of fears about exposure to legal liability because of admitting and disclosing an adverse event to patients (Duclos et al., 2005; Espin et al., 2006; McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010). Healthcare professionals described worries that patient/family would take legal action against them if they took responsibility and were open and transparent about the adverse event (Gallagher et al., 2003; Harrison et al., 2017; Coffey et al, 2010; Fein et al., 2005). Healthcare professionals cited concerns that disclosure would result in patients/or family causing further issues if they felt that they had not received the best medical care (Coffey et al., 2010). Furthermore, healthcare professionals were apprehensive about including an apology in the disclosure conversation as there was the belief that it may be considered as an admission of legal liability (Gallagher et al., 2003). These healthcare professionals expressed a desire to be *'just straightforward'* (Gallagher et al., 2003) about the adverse incident and the events which led to it, however, believed that in reality, this would result in a lawsuit. Healthcare professionals from one UK study had contrasting views to this where they held the belief that patients/families would have a more '*generous and understanding view*' of the adverse event if they were honest and upfront about the situation (Harrison et al., 2017). These healthcare professionals advocated disclosure and transparency and described witnessing adverse events that resulted in harm to the patient, but legal action was not pursued due to open disclosure (Harrison et al., 2017). The differences in healthcare professional's views in this study may have been influenced by the recent Duty of Candour regulation which was implemented in the UK two years prior to this study. Some healthcare professionals acknowledged litigation fears as a barrier to disclosure, but regardless of these fears, they believed disclosure enhanced the patient-provider relationship and was therefore considered as valuable (Harrison et al., 2017).

Disclosure is a learned skill

Healthcare professionals described that a lack of training or absence of disclosure education led to a lack of confidence in skills, which resulted in hindered disclosure practices (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2015). The value of open disclosure education was recognised, however, one healthcare professional related '*I haven't had any personal training'* (Harrison et al., 2017). Similarly, other healthcare professionals reinforced the importance of training specific to disclosing adverse events but stated that they had only received training on how to break bad news to patients and had not received any training specific to adverse event disclosure (Ock et al., 2016; McLennan et al., 2016; Fein et al., 2015). Healthcare professionals believed that they lacked skills on how to communicate certain aspects of the adverse events. This lack of skills led to a lack of confidence when conducting the

disclosure (Fein et al., 2005). No training was provided from a legal perspective and healthcare professionals believed when it came to the legal aspects, they required more educational support (Fein et al., 2005). A situation was described where the healthcare professional was remorseful about what had happened, however, he *'just didn't know how to express or convey it'* (Ock et al., 2016). Regardless of which country healthcare professionals belonged to, a distinct need for education and training in this area was expressed by healthcare professionals (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005) suggesting that a lack of training is a universal issue.

Inconsistent guidance

Healthcare professionals described that there was a lack of clarity on what should be disclosed, when and how, as they were provided with varying guidance from seniors or management within their organisation (Gallagher et al., 2006; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005). Healthcare professionals were provided with contradictory views on whether they should disclose the adverse event. Instances were described where healthcare professionals were asked to refrain from disclosing the adverse event to colleagues or the patient/family (Gallagher et al., 2006; Harrison et al., 2017; Fein et al., 2005). Lack of awareness of organisational policies related to adverse event disclosure also made this process challenging (Gallagher et al., 2006; Fein et al., 2005). Some healthcare professionals were simply unaware of the existence of these policies, whereas others suggested the policy needed to be made known and enforced in the organisation as the existence of a policy alone did not ensure that appropriate disclosure practices would take place (Coffey et al., 2010). Furthermore, some healthcare professionals held the belief that awareness and implementation of organisational policies could promote openness if guidelines for disclosure were provided (Gallagher et al., 2006).

Table 2. 3: Examples of reciprocal translations

Third-order construct *Third-order constructs (higher order interpretations developed from a tertiary analysis of the first and second-order constructs)*	**Second-order constructs** *Second-order constructs (primary authors' interpretations of the primary data—metaphorical themes or concepts)*	**First-order constructs** *First-order constructs (primary data reported in each paper (participant quotations))*
Patient studies		
Need for information	Patient frustrations (Duclos et al., 2005)	'I wanted as much…whether I understood it or not. I wanted to hear it. I wanted details because then I could sort through it in my head, and then come to my own conclusions'(Duclos et al., 2005).
	Inadequate preparation for open disclosure (Iedema et al., 2011)	'We want to know what happened that day. Why was she moved from the room?... That could have contributed to her disorientation…They said oh well, we can't really give you that information' (Iedema et al., 2011).
	Full disclosure (Espin	Well, it's my body, it's not the surgeon's body, and so I would want to know all the details' (Espin et

	et al., 2006)	al., 2006).
Importance of sincere regret	Patient frustration (Duclos et al., 2005)	'As far as just the medical people involved. That was extremely frustrating for me because nobody was willing to say that they made a mistake' (Duclos et al., 2005); 'I just wanted him to take responsibility for it. 'Look I'm sorry I did this and I'll do whatever it takes to make things right'. Just own up to what happened' (Duclos et al., 2005)
	Was an apology offered and of what kind? (Iedema et al., 2008a)	'But it would have been nice if someone had had just acknowledged and said 'this is our fault' (Iedema et al., 2008a); 'I definitely didn't like the defensive nature of the people involved'…they were blaming the cancer' (Iedema et al., 2008a).
	Responsibility (Mazor et al., 2013)	'Taking responsibility, that's kind of what it's all about' (Mazor et al., 2013); '…it made me feel that I could trust my PCP because I mean she took responsibility…had remorse about what happened. She wasn't defensive about it…it goes a long way for me if a person can acknowledge 'I made a mistake' (Mazor et al., 2013).
	Importance of delivering an apology in open disclosure (Ock et al., 2016)	When a patient is harmed or dies, we want a wholehearted apology. Medical disputes come later on. Money and whatnot comes second… A good tongue is a good weapon, you know. With a heartfelt 'sorry'…(Ock et al., 2016).

Promise of improvement	Need to promise recurrence prevention in ambiguous medical errors (Ock et al., 2016)	'Well assuring recurrence prevention, this is a must, whatever the case….I'm sure when doctors say how sorry they are for what happened and reassure [the patients] that they'll make an effort to reduce possible complications, the patients will go back home feeling much better... No benefits whatsoever, but credibility will soar, I reckon' (Ock et al., 2016).
	Preventing recurrences (Mazor et al., 2013)	'The important thing is that it doesn't happen again'... 'The point that should be made is that she knew she made a mistake and will try harder not to do that again to anybody else' (Mazor et al., 2013).
	Insufficient integration of open disclosure with improvement of patient safety (Iedema et al., 2011)	'At the end of the day, you know when an unfortunate incident happens like that, that [inappropriate disclosure communication] could be avoided in the future…it would be good to know that my dad's death, you know, sort of prompted some changes in that area' (Iedema et al., 2011).
Healthcare professional studies		
Sometimes economical with the truth	How to disclose (Gallagher et al., 2003)	'I think you have to be a spin doctor all the time and put the right spin on it…I don't think you have to soft pedal the issue, but I think you have to try and put it in the best light. I think you have to be forthright with the patient to help them. And how

		you word it makes a big difference' (Gallagher et al., 2003).
	Partial disclosure (Espin et al., 2006)	'The patient's gonna be told, but what you say about how that injury occurs depends' (Espin et al., 2006).
	Attitudes and experiences concerning disclosing errors to patients (Ock et al., 2016)	'If I think it could have been a serious error that might have caused this damage to the patient, it will be explained differently or in a way the patient cannot realise' (Ock et al., 2016).
Owning up without saying I'm sorry	Responsibility (Coffey et al., 2010)	'I made an error. I discontinued a medication that I shouldn't have-by accident. You know, I picked up the error, presented it to the family. You know I tried to make it a system thing because the reason I did it was not because I'm a dummy. I'm sure it could have happened to the next guy in my shoes but I felt it was my responsibility to tell the family and I did' (Coffey et al., 2010).
	How should open disclosure be carried out (Ock et al., 2016)	'I don't literally bring up the word regrettable but I do it eventually…it's a Korean thing that you don't really need to put it into words to…the biggest problem is when you're about to discharge your patient after stitch removal, the last step of the surgery, the wound starts to open up. It'll drive you crazy and what can you say to the patient? Seems like you can't go home today…that's the Korean way of saying sorry…you don't really need to say it through words' (Ock et al., 2016).
	Support for open disclosure (Iedema et	

	al., 2008b)	'I really don't know what happened. I really can't explain what happened, but it shouldn't have happened, and I have to take the responsibility for it' (Iedema et al., 2008b)
To tell or to not tell? When honesty may cause unnecessary anxiety	When should open disclosure take place (Espin et al., 2006)	'If a patient is 95 and bed-ridden, you might not want to tell them…it could be upsetting, they will not understand this could happen to anyone with this case' (Espin et al., 2006).
	Attitudes and experiences concerning disclosing errors to patients (McLennan et al., 2016)	'You perceive this when dealing with patients; there are people who prefer not to know. And you need to somehow develop a sure instinct not to burden them' (McLennan et al., 2016).
	Whether to disclose near misses (Gallagher et al., 2003)	'My job is to relieve anxiety, not to create it. And to a certain extent when an error occurs that doesn't get to the patient, it's not their problem, it's my problem' (Gallagher et al., 2003).
Outcome determines disclosure	When should open disclosure take place (Ock et al., 2016)	'I suppose medical errors causing minor harm will be even more problematic…Hmm I'd rather not say. This is a matter of preference I think. The patient might not feel the need either. Telling the truth is the right thing to do but since nothing really happened, I guess doctors would be inclined not to do so' (Ock et al., 2016).
	Whether to disclose near misses	'I think if we were held to disclose all of those [near misses], I think that happens so often we wouldn't have the opportunity to practise

	(Gallagher et al., 2003) Attitudes and experiences concerning disclosing errors to patients (McLennan et al., 2016)	medicine' (Gallagher et al., 2003). 'In general, the patient clearly has the right [to be informed], whether it is a small or big error. But when errors happen that have no effect on the patient, when nothing happens- small errors that have no effect or the patient would not see the error as an error- then we would not tell' (McLennan et al., 2016).
Healthcare professional studies- barriers to disclosure		
Difficulty of disclosure in a blame culture	Institutional culture (Fein et al., 2005) Reputation risk (Coffey et al., 2010) Barriers to disclosure (McLennan et al., 2016)	'There needs to be a culture where individuals do not feel penalised for reporting errors. You should feel comfortable reporting to the chief of service of the head of nursing' (Fein et al., 2005). 'I think there's an openness about- we've caught that near miss. Give everybody a pat on the back whereas if something then bad happens, I think there's less of an openness and then you get more into looking at well-rather than what the system did, you look at the people in the system' (Coffey et al., 2010). 'The common working culture can be beneficial or also hindering. For example, if you have to fear reprisal once you disclose an error, that this falls back on a person who is then ostracised or even loses their job' (McLennan et al., 2016).

Avoidance of litigation	Understanding the repercussions (Harrison et al., 2017)	'I've learned that it's also quite a self-preserving thing to do…the worst thing…is if they [patients] get it into their heads that there's some sort of cover up going on, then they get the bit between their teeth and solicitors get involved and it's all very difficult' (Harrison et al., 2017).
	Reputation risk (Coffey et al., 2010)	'If families for whatever reason feel that they have not received the best medical care, they're going to make a big stink and go to the paper and feel hard done by and I think in the situations where the families are pressing and the families raising doubts- it may be more difficult to disclose' (Coffey et al., 2010).
	Provider factors (Fein et al., 2005)	'…two is fear of being sued and what is that going to do with your future' (Fein et al., 2005).
Disclosure is a learned skill	Absence of disclosure education (Ock et al., 2016)	I have never learned (open disclosure). Can't make facial expressions. Can't come up with words to say… 'I have never seen anyone do it, so I have no clue on how to do it' (Ock et al., 2016).
	Role models and guidance (Harrison et al., 2017)	'I haven't had any personal training. Certainly, the trust offers a sort of day if you like around breaking bad news, however I think that tends to be more related to breaking, you know, cancers and diagnoses type thing, rather than adverse events that happened (Harrison et al., 2017).

	Provider factors (Fein et al., 2005)	'As soon as it gets into the legal realm, suddenly as an attending physician, I feel like I need to be coached as to what can be said and how it can be said and so forth' (Fein et al., 2005).
Inconsistent guidance	It all depends on your nurse manager (Shannon et al., 2009)	'She actually got a big lecture saying 'you always run it by somebody before you disclose it to the families, because bedside nurses are not trained to discern litigiousness'…she felt like she did the right thing but was being told 'don't do that again' (Shannon et al., 2009).
	Provider factors (Fein et al., 2005)	'The emphasis at least in my training has been – don't talk about anything, keep quiet' (Fein et al., 2005).
	Institutional culture (Coffey et al., 2010)	I can say right now that I do not know what the policy is' (Coffey et al., 2010).

2.4.5 Line of argument synthesis

The syntheses of 'patient' and 'healthcare professional' studies in this review revealed that there was a disconnect between the perspectives of these two groups on how disclosure should be conducted and what the disclosure conversation should entail. These key differences are discussed in relation to the barriers to disclosure faced by healthcare professionals.

There was a difference between patients and healthcare professionals in their expectations and attitudes about what the disclosure conversation should include. Healthcare professionals of different clinical professions had similar perspectives regarding disclosure. Although only two studies included family members (Iedema et al., 2011; Iedema et al., 2008a), their views were in agreement with those of patients. Patients emphasised their right to receive all the relevant information related to the adverse event but described not receiving the information they needed from healthcare professionals (Duclos et al., 2005; Iedema et al., 2011; Iedema et al., 2008a; Espin et al., 2006). Healthcare professionals also acknowledged the importance of disclosure but said that often they would omit some information from the conversation (Espin et al., 2006; Gallagher et al., 2003; McLennan et al., 2016; Fein et al., 2007; Mira et al., 2017). A majority of the time, healthcare professionals did not provide patients with the breadth of information they required. This could be explained by the barriers healthcare professionals were faced with. They described worries that they would be exposed to litigation if they were open and transparent with patients (Gallagher et al., 2003; McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). Some expressed their desire to be *straightforward* but believed this would result in a lawsuit (Gallagher et al., 2003). There has recently been more awareness that open disclosure does not necessarily increase litigation risk, which was reflected by healthcare professionals in one of the later studies conducted in the UK (Harrison et al., 2017). Within this study, healthcare professionals acknowledged that the issue of litigation did exist, but believed that patients had a more *generous* and *understanding view* if they were honest and transparent. These professionals also described witnessing adverse events that resulted in harm, but which did not result in patients pursuing legal action due to the practice of open disclosure.

Apologising and taking responsibility was an element that many patients/family members considered to be an important aspect of disclosure (Duclos et al., 2005; Iedema et al., 2011; Iedema et al., 2008a). Many patients wanted an apology from the healthcare professionals as they felt this signified an expression of regret. However, healthcare professionals from only one study cited the importance of including an apology in the disclosure conversation. Some

professionals were worried that an apology would be interpreted as evidence that could be used to prove legal liability. There has been a previous existence of a culture where apologising was considered as an admission of legal liability and it is possible this culture still existed whilst most of these studies were conducted (between 2003-2017). Patients also wanted assurance that recurrences of the same adverse event would be prevented (Iedema et al., 2011; Gallagher et al., 2003; Mazor et al., 2013; Ock et al., 2016), however, the importance of this element was not acknowledged by healthcare professionals in the included studies.

Finally, a lack of certainty, skill, and confidence about how to disclose adverse events may have prevented many healthcare professionals from delivering a disclosure which included all the elements patients expressed a desire for. Regardless of clinical profession, many healthcare professionals had not received training on how to effectively communicate the adverse event to patients (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005) which could have contributed to the gap between the information patients felt they needed and the information healthcare professionals delivered in practice.

Altogether, this line of argument synthesis identified both the key elements of an ideal disclosure conversation desired by patients and the facilitators for healthcare professionals which can increase the likelihood of this taking place (Figure 2.1).

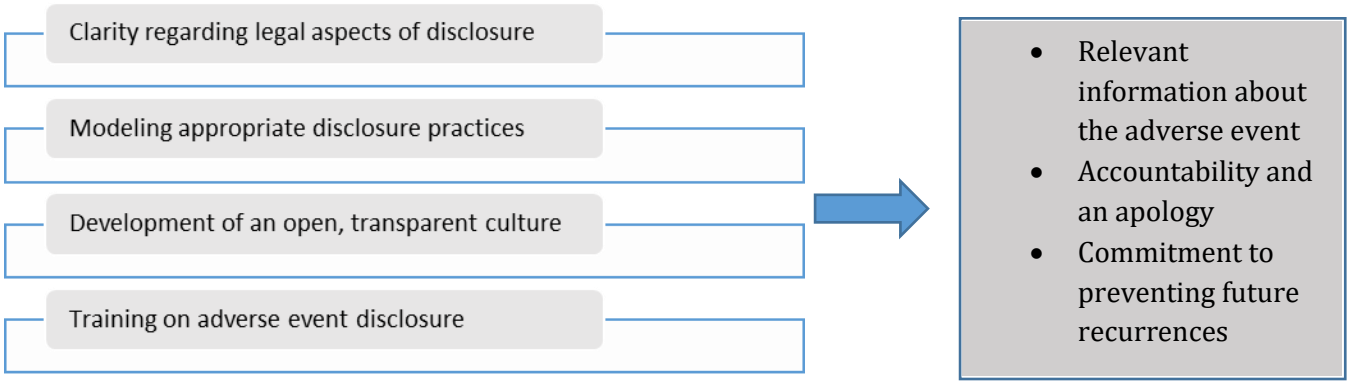


Figure 2. 1: Ideal disclosure practice and facilitators to effective and practicable disclosure for healthcare professionals

2.5 Discussion

2.5.1 Summary of results

This meta-ethnographic synthesis highlighted that there is a difference in attitudes and expectations between patients and healthcare professionals regarding the disclosure conversation. Fifteen studies were identified within this review and were diverse in terms of study location. Two studies were conducted in Canada, six in the USA, one in Switzerland, one in Spain, one in Korea, three in Australia, and one in the UK. Patients and families advocated disclosure following an adverse event. They expressed a need for certain information including accountability and an apology, and a commitment to prevent the same adverse event from occurring again. However, a majority of the time, patients did not feel satisfied with the disclosure or felt they were provided with partial disclosure which did not include all the elements they desired (Duclos et al., 2005; Iedema et al., 2011; Espin et al., 2006; McLennan et al., 2016; Mira et al., 2017). Healthcare professionals considered disclosure to be a moral and professional duty (Gallagher et al., 2006; Harrison et al., 2017; Fein et al., 2005); however multiple barriers prevented them from carrying out this disclosure. These include an organisational culture of blame, litigation fears, and a lack of skills and training on how to conduct disclosure. The findings of this review suggest that there is an evident gap between the expected communication practice and what is being done. These findings are similar to a previous narrative review conducted by O'Connor et al (2010) which also found that there is a gap between the ideal disclosure and what happens in reality.

The current review extends the findings of the review by O'Connor et al (2010) by using a meta-ethnographic synthesis approach to synthesise the studies, which allowed the re-interpretation of the conceptual data (key concepts) created by authors of each primary study, whilst taking into account the primary data (participant quotes) and used a unique translation synthesis method to transcend the findings of individual accounts and create third-order constructs. These third-order constructs enabled a new understanding of patient's and healthcare professional's views and experiences of adverse event disclosure. Using a meta-ethnographic approach allowed the preservation of the interpretative properties of the primary data from the included individual studies and provided a higher level of analysis. This systematic review also extends findings from the previous review, as a line of arguments synthesis was developed, which took into account the disconnect between patients and healthcare professional's perspectives on disclosure, and discussed why such differences may exist, whilst taking into

account the original study contexts. Based on the synthesis of patients' and healthcare professionals' views and experiences of disclosure, a model has been developed (figure X) to meet the needs of both of these groups. This model identifies both the key elements of an ideal disclosure conversation desired by patients and the facilitators for healthcare professionals which can increase the likelihood of this taking place. A further seven studies (Coffey et al., 2010; Iedema et al., 2011; Mazor et al., 2013; McLennan et al., 2016; Mira et al., 2016; Ock et al., 2016; Harrison et al., 2017) have also been identified since the last review focusing on the experiences of disclosure was published (O'Connor et al., 2010).

2.5.2 Strengths & limitations

Strengths of meta-ethnographic approaches include their preservation of the interpretative properties of the primary data (Dixen-Woods, Shaw, Agarwal & Smith, 2004) and their potential to provide higher levels of analysis (Atkins et al., 2008). Meta-ethnography is inevitably limited by the breadth and quality of studies (Scott & Grant, 2018); the articles included within this review were identified using a systematic approach, which enabled the identification of all relevant studies published within the area of disclosure. Although a comprehensive systematic search was undertaken, it is possible that not all the relevant studies were retrieved. The necessary inclusion of studies from different countries could be considered to be a further limitation as each country has a different healthcare system, therefore making the transferability of findings difficult. Also, due to the different healthcare systems represented in the literature, there is a lack of transferability of the legal aspects of disclosure. Therefore, the legal barriers to disclosure perceived by healthcare professionals may vary across countries. Also, a potential limitation is that all of the included patient studies were conducted in westernised countries including the USA, Australia, and Canada. Therefore, it can be argued that the literature represents the views and cultural expectations of a westernised culture. One of the reasons why a majority of the research may be conducted in western countries is that there are laws and policies in place in these countries, which require patients to be informed of all aspects of their care, including any unanticipated outcomes.

2.5.3 Implications for clinicians, policymakers, and researchers

This review has highlighted that there is a gap between what patients desire from disclosure and what healthcare professionals offer. The line of argument synthesis highlighted the following ways in which this gap can be reduced. At an organisational level, there is a need to develop consistent and transparent policies and promote and enforce these within organisations (Gallagher et al., 2006; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005). Also, shifting away from the existence of a blame culture and the development of an open and transparent culture can help facilitate effective disclosure practices (Gallagher et al., 2003;

McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). One of the frequently cited barriers to disclosure was the fear of litigation. However, patients described that they sought legal help when they did not receive appropriate disclosure (e.g. healthcare professionals failed to apologise or take responsibility for the adverse event). Patients did not desire to punish healthcare professionals or collect large sums of money. Therefore, it is imperative that healthcare professionals receive education regarding the legal aspects of disclosure, including the legal protections which are currently in place and reasons why patients seek legal support.

NICE (National Institute for Health and Care Excellence) which provides national guidance and advice to improve health and social care within the UK, highlights the importance of healthcare professionals being proficient in communication skills (NICE, 2012) and disclosure is a complex communication task. The findings of this review showed that healthcare professionals required more adverse event disclosure training (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005). A number of studies have developed and discussed adverse event disclosure educational programs which have used a variety of teaching methods (Bonnema, Gosman & Arnold, 2009; Sukalich, Elliott & Ruffner, 2014; Gunderson, Smith, Mayer, McDonald & Centomani, 2009; Kim et al., 2017; Langer et al., 2016; Kim et al., 2011). However, at an organisational level, these disclosure educational programs need to be integrated into training programmes for healthcare professionals.

Healthcare professionals also expressed worry and anxiety about disclosure. These worries stemmed from a blame culture which surrounded healthcare organisations, risk of damaging reputation and fear of litigation (Gallagher et al., 2003; McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). More clarity and guidance is needed on what constitutes relevant information that is provided during disclosure, as patients and healthcare professionals have different perceptions regarding this. Healthcare professionals also held inaccurate assumptions about what patients/family members would want to be disclosed (Espin et al., 2006; Gallagher et al., 2003; Ock et al., 2016; McLennan et al., 2016). Providing healthcare professionals with disclosure training which is specific to adverse events is one of the potential ways to improve this process. Training interventions should be informed by the elements patients' desire from disclosure and guidance from recent disclosure policies. Educating healthcare professionals on the benefits of taking a patient-centred approach when disclosing adverse events is one of the potential ways to meet patients' needs. This would include thinking beyond the healthcare professional's own beliefs and deem what is important

for patients. Involving patients/family members in the adverse event investigation is another one of the potential ways to meet the needs of this group.

2.6 Conclusion

This is the first qualitative meta-ethnography of patients' and healthcare professionals' experiences of adverse event disclosure. Our findings suggest that although patients and healthcare professionals both advocate disclosure, a number of barriers prevent healthcare professionals from carrying out disclosure effectively. Healthcare professionals also hold inaccurate beliefs about when and what patients want to be disclosed. To meet patients' needs for disclosure, training on disclosure for healthcare professionals and the development of an open, transparent culture within organisations are potential areas for intervention. Also, the responses of patients and relatives are not fully predictable and even the best of open disclosure practices may not resolve their problems or concerns. Therefore, it is important that guidance and training for healthcare professionals reflect these challenges.

2.7 Researcher reflections

Although meta-ethnography is a widely used qualitative literature synthesis method within healthcare research, it is poorly demarcated and there is a lack of clarity surrounding the description of the data analysis process. A number of reviews have used this approach (Scott & Grant, 2018; Elmir & Schmied, 2016; Cullinan, O'Mahony, Fleming & Byrne, 2014; Purc-Stephenson & Thrasher, 2010; Toye, Seers & Barker, 2017; Rubio-Valera et al., 2014) but fail to provide a fully rigorous description of the stages involved in the analysis process. Due to this lack of clarity available on the stages involved in meta-ethnography the researcher (PhD researcher) found this process to be difficult and challenging. Given the value of qualitative meta-ethnography in integrating the findings from multiple studies into a higher conceptual level, it is important to provide detailed guidance on each of the steps involved in conducting a meta-ethnography. Therefore, the researcher developed guidance for conducting a meta-ethnography, where a step-by-step method is outlined. Interpretations of each of the seven steps outlined by Noblit & Hare (1988) who first proposed this approach are described. Adaptations and developments by recent researchers have been incorporated. The systematic review described and discussed within this chapter is used as a worked example, and where applicable, illustrative examples from this review are provided alongside each phase to demonstrate the process. The detailed guidance for conducting a meta-ethnographic synthesis is presented in Appendix 4.

Chapter 3: Adverse event disclosure within the UK: A qualitative study exploring the experiences of maternity healthcare professionals

3.1 Chapter summary: *The previous chapter presented a systematic review on the views and experiences of patients and healthcare professionals on adverse event disclosure. This chapter reports on study 2, which is a qualitative interview study. This study aimed to explore the views and experiences of maternity healthcare professionals on adverse event disclosure within the UK. This chapter begins by providing a background and rationale for conducting this study, followed by the study methods. The qualitative method of thematic analysis was used to analyse the interview data. The findings of this study are presented and discussed, and key implications to support maternity healthcare professionals within the UK with disclosure are highlighted and discussed.*

3.2 Background and rationale

The importance of conducting disclosure has been highlighted in the previous two chapters. As discussed in chapter 1, in 2009 the National Patient Safety Agency (NPSA) launched its 'Being Open' framework within the UK (NPSA, 2009). This framework recommends that healthcare professionals must be open when communicating with patients and/or carers following an adverse event. Ten key principles are set out within this framework which underpin the successful facilitation of being open during disclosure. These include providing a genuine and timely apology for what has happened, keeping patients and/or their carers informed about the progress made with the incident investigation, reassuring patients and/or carers that the incident is being taken seriously, and ensuring that measures are taken to prevent the incident from happening again.

The Duty of Candour, which is a legal regulation, was introduced within the UK in 2015. This aims to support doctors, nurses, and midwives with the disclosure of adverse events in an open and transparent way, by providing guidance on the requirements of disclosure (CQC, 2015). This statutory duty states that individuals must offer information on what has happened, provide an apology, report these events to prevent them from occurring again and clinical leaders must encourage a culture of reporting and learning. Chapter 2 included a systematic review which focused on the views and experiences of patients and healthcare professionals on

the disclosure of adverse events. This systematic review revealed that most evidence to date originates from the USA, Australia, and Canada with a particular absence of UK data regarding experiences of adverse event disclosure. Surprisingly, only one study was conducted within the UK (Harrison et al., 2017) which explored the contributors to open disclosure of adverse events within the UK. This study found that factors which were important in supporting open disclosure included acceptance that disclosure was a moral and professional duty, positive past experiences, perceptions of reduced litigation, role models and guidance around disclosure, and clarity in relation to disclosure (Harrison et al., 2017).

Different countries have different healthcare systems. There is a unique model of healthcare provision within the UK, which is principally provided for by the National Health Service (NHS) and is free at the point of delivery. Disclosure within the UK may be different compared to other contexts (Roland et al., 2011). Limited evidence from survey research is available which suggests that doctors within the UK were more likely to agree that adverse events should always be disclosed to patients compared to doctors within the USA (Roland et al., 2011). A greater number of doctors from the USA also stated that they had not disclosed to patients, due to the fear of litigation (Roland et al., 2011). Legal frameworks and statutory requirements differ within different countries (Birks et al., 2014), and it is possible that the clinical negligence context within different countries may influence whether disclosure is conducted. At the start of this PhD, the Duty of Candour (CQC, 2015) had been a legal requirement for just a year and was becoming embedded as the studies within this PhD progressed. The study by Harrison et al (2017) was conducted a few years after the introduction of the Duty of Candour.

Adverse events occur in all areas of healthcare including maternity services. NHS Resolution is a body within the Department of Health and Social Care which supports the NHS by providing expertise on resolving concerns and disputes in a fair manner and sharing learning for improvement (NHS Resolution, 2020a). Statistics from the annual report and accounts in 2019/2020 suggest that maternity claims represent around 9% of the total number of clinical negligence claims received by NHS resolution each year, and represent 50% of the total value of new claims (NHS resolution, 2020b). This suggests that a significant number of adverse events occur within maternity services and can have an impact on both the affected patients and the NHS healthcare professionals involved. As discussed earlier, an important element in managing adverse events is the disclosure to patients and/or their families. Given the limited research available on disclosure within the UK, and no research being conducted within UK maternity

services, it was important to further explore the perspectives and experiences of healthcare professionals on adverse event disclosure within a UK context.

This chapter aimed to address this significant gap by conducting a qualitative study of maternity healthcare professionals within the UK. Understanding these views and experiences can help identify current disclosure practices within the UK, and how healthcare professionals can be supported through the process of disclosure.

3.3 Aims

The main aim of this qualitative study was to explore the views and experiences of maternity healthcare professionals in relation to the disclosure of adverse events. This study also aimed to explore how the disclosure process is perceived to affect the well-being of maternity healthcare professionals and understand perceptions of support and training available for adverse event disclosure.

3.4 Methods

3.4.1 Research design

A qualitative research design was chosen for this study. Qualitative methods use a person-centred holistic approach to gain knowledge and insight and are a useful means of answering questions related to healthcare practice (Holloway and Wheeler, 2010). Semi-structured interviews were conducted. These aim to examine the individual's beliefs and attitudes shaped by their own framework of meaning (Britten, 1995). Semi-structured interviews are typically based on a flexible topic guide developed by the study researchers. The topic guide provides a loose structure of open-ended questions to explore views and experiences. In-depth interviews provide the opportunity to gain an insight into the views and experiences of a specific group (Abadie, 2010) and obtain detail about a particular topic or experience.

Semi-structured telephone interviews were carried out as they were considered an appropriate method to gain insight into the individual experiences of participants (Fossey, Harvey, McDemott & Davidson, 2002). Such in-depth data cannot be fully captured by quantitative means, which ignores the subjective and contextual elements of the research (Holloway and Wheeler, 2010). The potential of in-depth telephone interviews as a viable option for qualitative research has been discussed within the literature where several methodological studies endorse the use of telephone interviews (Cachia and Millward, 2011; Sturges and Hanrahan, 2004; Shuy,

Holstein & Gubrium, 2003; Carr and Worth, 2001; Musselwhite, Cuff, McGreggor & King, 2007; Stephens, 2007). This is due to the logistical conveniences and other practical advantages which include enhanced access to geographically dispersed interviewees, lower costs for both the interviewer and interviewee, increased interviewer safety, and greater flexibility for scheduling (Cachia and Millward, 2011; Sturges and Hanrahan, 2004; Shuy et al., 2003; Carr and Worth, 2001; Musselwhite et al., 2007; Stephens, 2007). In addition to the convenience benefits related to the use of telephone interviews, the methodological strengths of using this method for conducting qualitative interviews have been emphasised. These include increased privacy for interviewees, perceived anonymity, and reduced distraction (for interviewees), or self-consciousness (for interviewers) when interviewers take notes during interviews (Cachia and Millward, 2011; Sweet, 2002; Stephens, 2007; Lechuga, 2012). Telephone interviews, compared to face-face interviews may be less intrusive and provide more power to interviewees in terms of negotiating interviews to suit their schedules as well as rescheduling the interview (Holt, 2010; Trier-Bieniek, 2012; Saura and Balsas, 2014). The limitations of using telephone interviews include the loss of visual cues and non-verbal information, and the opportunity to develop a researcher-participant relationship is reduced (Rubin and Rubin, 2012).

Also, as this study involved the recruitment of maternity healthcare professionals based in the UK, it was important to take into account the challenges associated with involving NHS healthcare professionals in research. The most prominent barriers faced by NHS healthcare professionals are the individual and organisational capacity to be involved in research (Marjanovic et al., 2019), which includes the lack of dedicated time available to take part in research (Marjanovic et al., 2019). Taking into account these challenges and benefits of telephone interviews, this form of data collection was decided to be the most appropriate.

3.4.2 Identification and sampling

The University of Leeds Research Ethics Committee, School of Psychology granted ethical approval for this study (ethics reference number: 17-0128). Research and development approval and Health Research Authority governance approval (ethics reference number: 229238) was obtained for both of the National Health Service (NHS) sites where potential participants would be recruited. The individual sites and services are not named in order to protect the anonymity of participants. Healthcare professionals were eligible to take part if they were doctors or midwives working within maternity services. Within this thesis, from here onwards, the term obstetrician (a doctor who specialises in the care of women during pregnancy, labour, and after birth) will be used when discussing doctors working within the maternity settings. Potential participants were identified in two ways; 1) by the trust

management where they were invited to take part via direct email from the research team to avoid coercion and 2) via the social media platform Twitter.

For this study, the relatively traditional methods of participant recruitment were combined with social media-based recruitment. Taking into account the challenges of taking part in research faced by healthcare professionals, the two recruitment methods were combined to maximise the reach and pace of recruitment. Social media platforms are increasingly popular for sharing and discussing content among diverse audiences (Arigo, Pagoto, Carter-Harris, Lillie & Nebeker, 2018). Given the high rate at which social media platforms are used daily for information exchange, social media is of increasing relevance to health-related research (Arigo et al., 2018). Within the context of health research, social media platforms such as Twitter offer unique and cost-effective opportunities for recruitment. Twitter which is a popular platform offers distinct advantages for recruitment, as Twitter feeds are public unless set otherwise therefore able to reach a larger audience. Twitter also provides the opportunity to post a recruitment tweet which includes selective information (including participant eligibility and a brief description of the study) and allows the tagging of users and organisations who would find the research relevant or interesting and may re-tweet the advertisement, resulting in a greater reach and increasing the chances of recruitment. Researchers have used the social media platforms Facebook and Twitter for recruitment and delivery of behavioural interventions (Cavallo et al., 2012; Napolitano et al., 2013; Frandsden et al., 2014; Pagoto et al., 2015).

A purposive sampling technique was used to recruit participants. This form of sampling method is typically used in qualitative research to identify and select the information-rich cases for the most proper utilisation of available resources (Suri, 2011). Purposive sampling involves identifying and selecting individuals that have relevant knowledge, expertise, and experience to address specific purposes related to the research question (Cresswekk & Plano Clark, 2011). Participants were purposively sampled to ensure that perspectives were captured from a range of midwives and obstetricians and degrees of experience of adverse event disclosure. The target sample size was fifteen to twenty participants. Due to this being an exploratory qualitative study, a formal sample size calculation was not required. The intention was to stop data collection once data saturation had been reached.

Potential participants who were interested in taking part in the study contacted the researcher directly via email. Potential participants were provided with a participant study information sheet that explained the purpose of the study and what the research would involve (see

Appendix 5 for participant information sheet). Potential participants were also provided with the study consent form (see Appendix 6 for participant consent form). Those who agreed to take part arranged a convenient time via email to conduct the telephone interview. It was ensured that the interviews were arranged for a convenient time for the participants, to minimise disruption to their clinical work.

3.4.3 Data collection

All interviews were by telephone. The interviewer was situated in a private room at the University of Leeds. Before the interview commenced, verbal consent was obtained from participants. Participants were provided with a unique code and were informed that they could withdraw from the study by providing this code. At the start of the interview, the researcher introduced themselves as a doctoral research student, reiterated the purpose of the interview, and explained the interview process. Each participant was provided with an opportunity to ask questions and was informed that they could stop the interview at any time. The interviews lasted between 30-40 minutes and were audio-recorded and transcribed verbatim. Transcripts were checked for accuracy and in order to protect confidentiality, all names of people and places were anonymised and pseudonyms were used.

3.4.4 Interview guide

The semi-structured interviews were based on an interview guide which is displayed in Figure 3. A discussion session with the supervisory team including a consultant obstetrician resulted in the generation of initial questions. These questions were designed in a way to elicit information from participants that would help to answer the research question. It also carefully considered that questions were asked in a sequence that ensured there was logical flow. Findings from the systematic review in chapter 2 informed the development of the interview guide in a number of ways. The systematic review revealed that there was a lack of research available on experiences of disclosure within the UK. Therefore, the interview guide focused on perspectives and experiences of disclosure within a UK context and guidelines available to support disclosure within the UK. The systematic review also revealed that one of the potential ways to support healthcare professionals with the disclosure process is by providing training. The interview therefore, explored the perception of support including training that is currently available for healthcare professionals within the UK. The interview guide also contained questions relating to the types of further support healthcare professionals believed would be useful. This included perceptions of peer support and organisational support such as receiving training related to adverse event disclosure and the types of training that may be useful.

Opening & introduction (including purpose and timeframe of interview)

1. **Can you tell me a little bit about yourself? How long have you been working in this profession?**
2. **Could you tell me whether you have ever had to disclose an adverse event to a patient? (If yes) Could you discuss this?**
   Prompts: *Does a particular incident/event come to mind? Could you describe the incident? What type of adverse event was it? How did you find this disclosure process? How did the patient take this news? How did it make them feel? Were there any guidelines that were useful in helping you through this disclosure process? How aware are you of the Duty of Candour regulation? Could you discuss your thoughts on this? Is this disclosure process more challenging when it is unclear whether it is an adverse event or a complication? Discuss complications in further detail.*

   If the participant has not been involved in disclosure, go to scenario and ask the participant to imagine they had to disclose this news to a patient.

   Scenario for Obstetricians: *You are called to see a woman on the labour ward. The baby has fetal bradycardia and requires immediate delivery. You perform an emergency caesarean section and the baby comes out in good condition. But unfortunately, the baby is accidentally cut during entry to the womb. It is not a severe scratch but the Duty of Candour states the parents must be informed.*

   Scenario for Midwives: *You are supporting a woman during the third stage of labour, and she has opted for active management. You are performing controlled cord traction. However, you realize that the cord snaps whilst you are pulling, with the placenta still in place. The patient will probably need to be taken into the theatre to remove the retained placenta. The Duty of Candour states that the patient must be informed.*

   Prompts*: What type of adverse event would you class this as? How did you think you would find this disclosure process? How do you think the patient take this news? How would it make them feel? Are you aware of any guidelines that may be useful in helping you through the disclosure process? Discuss in further detail. Would the disclosure process be more challenging when it is unclear whether it is an adverse event or a complication? Discuss complications in further detail*

3. **How did you feel after disclosing this adverse event to the patient and/or their family? (Slightly change this for those who have been presented with a scenario)**
   Prompts: *What types of emotions did you experience when you realised you had to tell the patient about this adverse event? What kinds of concerns did you have about disclosing this event? How confident were you when disclosing to patients? How did you feel once you had disclosed the adverse event to the patient? Are these effects different when you disclose complications? Why?*

4. **Can you talk to me about the type of support that was available to you after this adverse event took place? (Slightly change this for those who have been presented with a scenario)**
   Prompts**:** *How would you describe the support available after you disclosed this adverse event? How does this support differ to when you have to disclose a complication to a patient? What are your thoughts on receiving further support for disclosing adverse events? What types of support? What other additional types of support would you like to see in place?*

Closing – thank the participant; provide any further information and incentive details.

Figure 3. 1: Interview guide

3.4.5 Piloting of the interview

A pilot interview was conducted with an obstetrician. Discussions after the pilot session concluded that complications occur regularly within maternity and are routinely disclosed. Complications are defined as health problems that may occur that are associated with pregnancy (Burrow & Ferris, 1999). Therefore, it was perceived to be interesting to include some questions related to the disclosure of complications. The interview questions were categorised into the following three groups: experiences of disclosing an adverse event, the impact of disclosure, and support available for disclosure. For participants who had not previously been involved in the disclosure of an adverse event, hypothetical scenarios were developed with a consultant obstetrician, and the participant was asked to imagine that they had been involved in the adverse event. The interview guide was shared with a midwife after development, and minor changes were suggested which included changes to the wording of some questions. However, due to the tight timescales for piloting and the fact that midwives (unlike the obstetricians) did not have time for training and research activities, it was not possible to recruit a midwife during the piloting phase.

A number of prompts were included in the interview guide to assist the researcher in encouraging further detail from participants and exploring certain questions in more detail. The piloting allowed the testing of the interview and enabled refinement and modification of the questions. Piloting also allowed the researcher to practice their interviewing technique which greatly enhanced confidence before data collection. After initial data collection, reflection, and discussions with the supervisory team resulted in small further refinements to the interview guide. Within this chapter, the term healthcare professional encompasses midwives and obstetricians.

3.5 Analysis

The qualitative analytic method of thematic analysis was used to analyse the interview data. Thematic analysis is a method for identifying, analysing, and reporting themes (patterns) within the data. One of the benefits of thematic analysis is that it is viewed as a flexible approach that is essentially independent of theory and epistemology and can be applied across a range of theoretical and epistemological approaches. Thematic analysis was chosen as it is a useful and flexible research tool, which has the potential to provide rich, detailed, and a complex account of the data.

A number of decisions were involved when using thematic analysis. It was important to determine the type of thematic analysis to conduct in relation to the data set. Thematic analysis can be conducted to obtain a rich description of the entire data set or a detailed account of one particular aspect (Braun & Clarke, 2006). This analysis aimed to provide a rich thematic description of the entire data set to get a sense of the predominant and important themes. Therefore it was important to ensure the themes which were identified and analysed were an accurate reflection across the data set. Although some depth and complexity may be lost during this process, a rich overall description is maintained. This approach was used as it is particularly useful when investigating an under-researched area or working with participants whose views on the topic are unknown (Braun & Clarke, 2006). The themes within the data were identified using an inductive analysis approach, where the themes identified were strongly linked to the data (Braun & Clarke, 2006; Patton, 1990). This approach involved coding the interview data without trying to fit it into a pre-existing coding framework or the researcher's analytic preconceptions (Braun & Clarke, 2006), and therefore this form of thematic analysis is viewed as data-driven. However as suggested by Braun & Clarke (2006), it is important to note that researchers are unable to free themselves of their theoretical and epistemological commitments, and therefore, to some extent, the analysis will be influenced unintentionally by a researchers existing pre-conceptions.

Analytic rigour and transparency were promoted and enhanced within this study in a number of ways. The researcher and the supervisory team met frequently to discuss data collection and analysis. During the analysis, two transcripts were each independently analysed by two members of the supervisory team as well as the researcher to ensure rigour. The sets of analyses were discussed and common codes were agreed. Discussions also took place during the development of the themes and the final themes were agreed by the supervisory team.

Thematic analysis process

The thematic analysis process was based on the six-phase approach as described by Braun and Clarke (2006).

Phase 1: Familiarising yourself with the data

During this phase, the researcher became immersed in the data in order to understand the depth and breadth of each interview (Braun and Clarke, 2006). The first stage within this phase involved transcribing the data. All interviews were transcribed verbatim by the researcher. Although time-consuming, the process of transcription was important as it provided a useful

opportunity for the researcher to start familiarising themselves with the data. Each transcript was read and re-read, and initial ideas or points of interest were noted. The first three transcripts were read thoroughly in order to reflect on the interview process and review the data to refine the interview guide. This approach ensured that any interesting data within the initial interviews could be further explored with future participants.

Phase 2: Generating initial codes

This phase involved producing initial codes from the data. A code is defined as a *'feature of the data that appears interesting to the analyst and refers to the most basic segment, or element of the raw data or information that can be assessed in a meaningful way regarding the phenomenon'* (Boyatzis, 1998). The process of coding is an analytic process and was viewed as a way of organising the data into meaningful groups. Coding was approached in an inductive manner, where the codes were data-driven. The researcher worked systematically through the data set, identifying interesting aspects of the data that may form the basis of repeated patterns (themes) across the data set. An important aspect of the coding process involved retaining accounts that departed from the dominant story of the analysis. To increase rigour, the candidate's supervisors each double-coded two transcripts, resulting in four transcripts that were double-coded. Codes were discussed and compared between the supervisory team. The remaining content of the data set was coded by the researcher and coding was performed manually on Microsoft Word. This phase ended by collating all the codes and relevant data extracts.

Phase 3: Searching for themes

Within this phase, the different codes were sorted into potential theme categories, and all the relevant coded data extracts were collated within the identified themes. A theme is defined as a coherent and meaningful pattern in the data which is relevant to the research question (Braun and Clarke, 2013). During this phase, tables were used as visual representations to assist with sorting the different codes into themes. Searching for themes was an active process, where the themes were constructed by the candidate. Relationships between the codes, between themes, and between the different levels of themes were considered. This phase ended with a collection of candidate themes, sub-themes, and collated extracts of data that were coded in relation to them (Braun and Clarke, 2006) which were transferred to Excel.

Phase 4: Reviewing themes

At this stage, the candidate themes were reviewed and refined to represent a summary of the data. To reduce any potential bias, the themes were discussed in detail with the supervisory team at this stage. After discussions, some of the candidate themes collapsed into each other,

and others merged into one theme. Reviewing the original research question and aims of the study helped to focus the analysis during this phase. Reviewing the candidate themes helps to reflect the overall message portrayed by the data set and to check that this is in line with the original meaning intended by the participants (Braun and Clarke, 2006). Thematic maps were created which assisted in visualising the relationships between the codes, themes, and sub-themes.

Phase 5: Defining and naming themes

Each theme was defined according to the aspect of the data it represented and how it related to other themes and sub-themes. A concise and informative name was constructed for each theme which captured what each theme was about (Braun and Clarke, 2006; Braun and Clarke, 2013). The labels for each theme were shared and discussed with the supervisory team, and the final name for each theme was agreed within the team.

Phase 6: Producing the report

This was an integral element of the analytic process and involved telling a story of the data in relation to the original research question, evidenced by data extracts and contextualising it in relation to the existing literature.

3.6 Results

3.6.1 Participants

Participants were recruited via two NHS Trusts (*N=8*) and through the social media platform Twitter (*N=10*). Eighteen participants took part in total. The sample consisted of 10 obstetricians and 8 midwives. Table 3.1 provides information on participant characteristics. All participants except one midwife had been involved in disclosure and was the only participant who was provided with a hypothetical scenario.

Table 3. 1: Participant characteristics

Participant number	Profession	Number of years worked in profession	Gender	Method of recruitment
P1	Obstetrician	9	Male	NHS Trust
P2	Midwife	3	Female	NHS Trust
P3	Obstetrician	5	Male	Twitter
P4	Midwife	16	Female	Twitter
P5	Midwife	8	Female	NHS Trust
P6	Obstetrician	10	Male	Twitter
P7	Obstetrician	10	Female	Twitter
P8	Midwife	12	Female	NHS Trust
P9	Obstetrician	7	Male	NHS Trust
P10	Obstetrician	5	Male	Twitter
P11	Obstetrician	5	Female	Twitter
P12	Obstetrician	7	Female	NHS Trust
P13	Midwife *	13	Female	Twitter
P14	Midwife	3	Female	Twitter
P15	Midwife	13	Female	Twitter
P16	Consultant obstetrician	16	Male	NHS Trust
P17	Midwife	17	Female	Twitter
P18	Obstetrician	11	Male	NHS Trust

**Indicates that this participant had not previously been involved in disclosure and was provided with a hypothetical scenario.*

3.6.2 Thematic analysis of the interviews

5 main themes and several subthemes were developed which described and explored the experiences of adverse event disclosure within the UK. Each theme (and subthemes) is discussed below and the supporting quotations are identified by the unique participant numbers. The final thematic map illustrating the predominant themes that emerged from the data is presented in Figure 3.2 below.

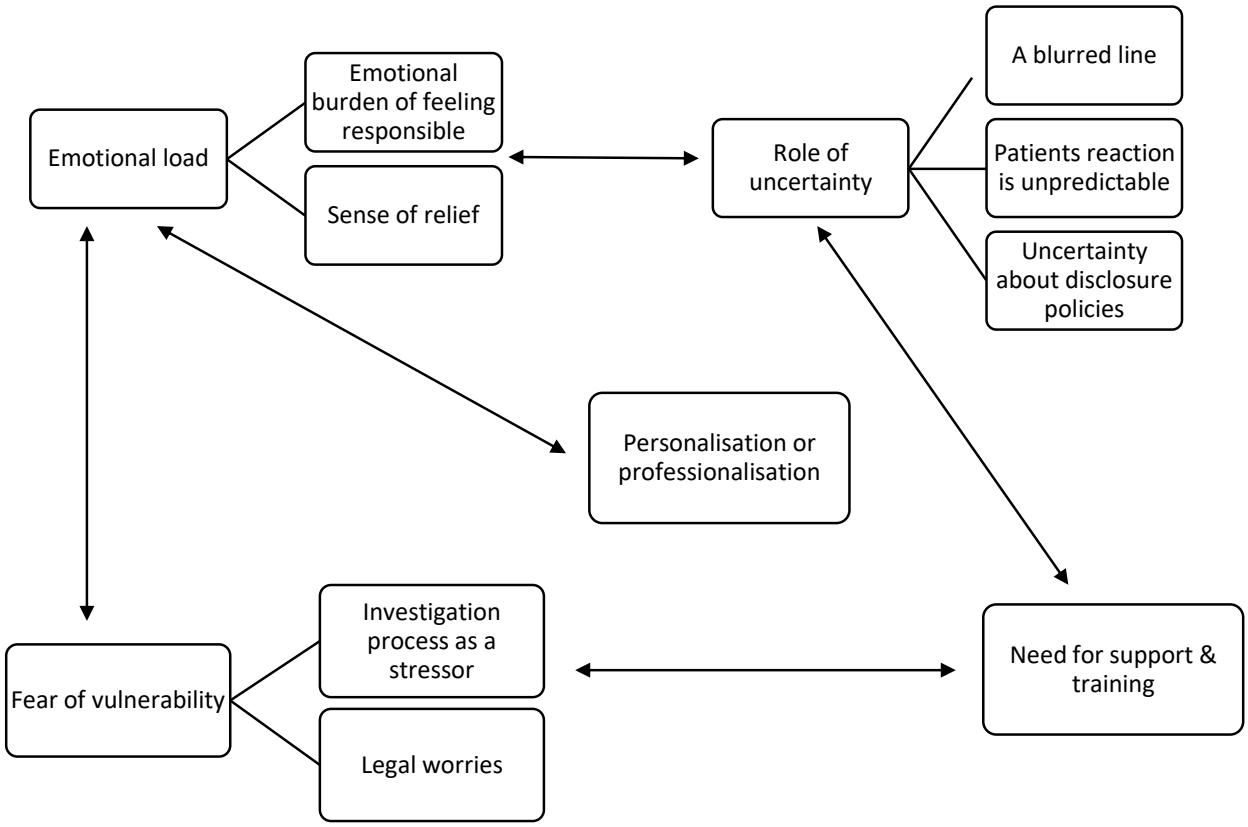


Figure 3. 2: Thematic map

Theme 1: Emotional load

Healthcare professionals faced a range of emotions after being involved in adverse event and feeling personally responsible intensified these emotional responses. Taking responsibility for the adverse event and conducting disclosure was viewed as an opportunity to ease this emotional load. Two sub-themes were developed within this theme; 'Emotional burden of feeling responsible' and 'A sense of relief'.

Emotional burden of feeling responsible

Healthcare professionals found the disclosure process to be more difficult and emotionally demanding when they felt personally responsible for causing avoidable harm to a patient. Healthcare professionals described that they faced a range of negative emotional responses after being involved in an adverse event. These manifested as psychological responses which included feelings of shame, anxiety, grief, and frustration. Healthcare professionals struggled with feelings of guilt, which were viewed as a burden that would have long-lasting effects on them. This included ruminating about an incident and repeatedly reassessing the situation with 'what if' questions. Feelings of embarrassment were linked to personal fault and lack of ability to prevent the adverse event from occurring.

'It felt almost embarrassing for me because it was our downfall really, we should have been responsible for preventing that…so I felt embarrassed and I felt really sorry. I felt sympathetic'. [Midwife 2].

Some healthcare professionals emphasised a personal need and desire to participate in the disclosure process when they were responsible. This reflected the need to accept responsibility for the incident, and there was a belief that patients may be more understanding and accepting if you were transparent and open.

'I wanted to be responsible, I wanted to make sure that, you know, people knew that I was taking responsibility for what I had done because I'm a really, really firm believer, that as long as you never lie and as long as you never cover up what you do, people will always try to find some understanding and usually there's a story behind that' [Midwife 8].

Healthcare professionals attempted to distinguish the difference between an adverse event and a complication. Although both conversations involved informing patients about an unfavourable outcome, due to the lack of personal responsibility associated with complications, the disclosure of these incidents were perceived as causing less emotional distress. Unlike adverse events, healthcare professionals believed that they were not to blame for complications as they had not contributed towards them, and could therefore have a relatively clear conscience about the incident. Healthcare professionals perceived that there was a justifiable explanation for complications which was related to the condition of pregnancy and this made disclosing these incidents less challenging. One participant differentiated between the two types of incidents by stating:

'Because I think it's all about giving you a rationale isn't it? So it's all about kind of saying, if it's a complication you can kind of say, it might be this or it might be that, you know your baby is not liking this environment or whatever, and you can look to rational explanations that aren't your fault. And you can kind of use the physiology to back up what you are saying to try and get people to understand' [Midwife 2].

There was a sense of control over adverse events, where healthcare professionals believed to some extent, they could have prevented the adverse event from occurring. However, healthcare professionals perceived they had no control over complications which made the disclosure conversation less difficult.

'*When it is a complication, it is outside of your control and then it's probably easier to discuss' [Midwife 4].*

Healthcare professionals described that the possibility or risk of a complication occurring was often discussed with patients or families beforehand. Due to the lack of accountability for complications, these conversations were conducted in a more confident manner. Complications were viewed as expected and, unlike adverse events, disclosure of these incidents would not result in naming and blaming those caring for the patient which made the process easier.

'And if conversations have been beforehand about the possibility then I think it's easier for people to accept than when things are unexpected. I think a natural reaction is to look for a reason and sometimes that can extend to a cause and somebody to blame when it's the unexpected' [Obstetrician 3].

However, a few healthcare professionals experienced similar emotions when disclosing complications and adverse events. These healthcare professionals experienced guilt even when there was no responsibility or blame associated. One participant reported that although it was easier to conduct the conversation about complications a sense of guilt was still present.

'You still don't really like doing it because especially if you've done the operation, you feel a bit responsible for it even though it's a known complication, so you do kind of feel a bit guilty then, but yeah all the same things (emotions)' [Obstetrician 12].

Sense of relief

Healthcare professionals felt that there was an element of relief after disclosure, as the conversation had been conducted and the process was over and done with. Disclosure was viewed as a job that needed to be done and there was relief when this task had been completed.

'I suppose it's a relief that you've…now that it was the morning that the patient was awake, you know the patient was informed and that job had been done' [Obstetrician 6].

Some healthcare professionals expressed relief at the way the patient had responded to the disclosure and were glad the patient had not reacted in a negative manner.

'I just felt relieved that she had taken it in quite a reasonable way' [Midwife 2]

Another healthcare professional stated that although there was some form of relief after having the disclosure conversation, there was always the worry the patient may be upset with you after disclosure. Healthcare professionals viewed disclosure as a way of unburdening, where disclosure allowed them to at least partially free themselves of the emotions which were related to being involved in the adverse event. Being open and transparent with the patient about what had happened was seen as a process for the healthcare professional to recover and move on from the adverse event.

'I felt relieved because then I was able to move on from that because of course, all the while you've got that in your mind of what you did' [Midwife 8].

There was a perception that it was important for patients and their families to understand what had happened and the events that led to the event, in order to help them recover and move past the traumatic experience of being involved in an adverse event. These healthcare professionals voiced their relief in having the disclosure conversation and providing patients with the information they needed to move on.

'I felt it was really important because I think when it comes to trauma especially after birth, it's really important they understand what had happened as that's part of the recovering process. It's when women don't get that honesty and openness, which is when they struggle afterwards. It's just sometimes as simple as knowing actually what had happened, and a part of women and their families overcoming adverse events is knowing about the events that led to that moment, that gives me relief to help them'. [Midwife 4].

Theme 2: Role of uncertainty

There was uncertainty regarding a number of factors which included whether an adverse event had occurred and how the patient may react, and this uncertainty made the disclosure process challenging for healthcare professionals. Healthcare professionals also lacked clarity about the Duty of Candour regulation. Three sub-themes were developed within this theme; 'A blurred line', 'Patients reaction is unpredictable' and 'Uncertainty about disclosure policies'.

A blurred line

Although healthcare professionals were able to differentiate between the definitions of an adverse event and a complication, in practice, trying to draw the line between which incidents would be classed as an adverse event or complication was problematic. The difficulty in determining which incidents would be classed as an adverse event or complication may be specific to the maternity settings and due to the complex processes involved in labour and birth.

'Obviously in our job, there's so many complications and so many things that are affected by the service and what's happening in the service, that it's then, it's difficult to tease out kind of what could be prevented or what is just part of the reality of having a baby in the NHS…I think trying to delineate between the two is extremely difficult' [Midwife 2].

When it was difficult to tease apart and define the event as an adverse event or a complication, healthcare professionals struggled with how to approach disclosure. This struggle was further exacerbated in certain situations where the patient had suffered from a complication but where a mistake was also made in the care that was provided. In such situations it was difficult to determine whether the mistake made by healthcare professionals contributed towards the complication that occurred.

'When you go to the theatre for forceps, there is a complication of having shoulder dystocia, which is what she had, and also a fourth-degree tear. But we did you know, we made a mistake in our examination findings and it's possible we wouldn't have…basically it's that situation of who knows? We don't know the degree to which that mistake increased the risk of…we know that increased the risk of the complication she suffered but we don't know whether it would have happened or not otherwise' [Obstetrician 9].

Patient's reaction is unpredictable

Some of the emotional distress that arose when anticipating disclosure of adverse events was attributed to an uncertainty of how the patient may react.

'I'm inherently a confident person, but I don't really like disappointing people and make people…I guess there's always the worry that people are going to get upset with you and lose their rag with you and that's never very pleasant' [Obstetrician 10].

Healthcare professionals were often plagued by fears of patients reacting negatively to the disclosure and would want to take further action. Other healthcare professionals feared that patients would lose faith in them and would no longer trust the care they provided, and wanted to conduct disclosure to see how the patient would react.

'I think it's going to be really really stressful because you don't know how the woman's going to react and there's always the worry that they are wanting to take it further in terms of court or whatever [Midwife 13].

'I really wanted to get it over with actually, I wanted to get it over with to see how the patient responded, whether she still wanted me to care for her because she might also think 'well what else might she [healthcare professional] do?' and therefore you know, you worry they are going to lose confidence in the care that you are giving' [Midwife 8].

Uncertainty about disclosure policies

Although the Duty of Candour was viewed as a fundamental principle for all those who were involved in patient care, there was variation in healthcare professionals knowledge of this regulation. A majority of healthcare professionals were merely aware of the existence of the Duty of Candour but were unfamiliar with the principles and disclosure requirements contained within it.

'With Duty of Candour, we know about it. It gets talked about in meetings and some Trust emails we get sent around. But I don't think we really know what it means, or how it helps with disclosing (adverse events). Or at least I don't know what exactly the Duty of Candour says' [Midwife 13].

Other healthcare professionals were simply not aware of the regulation.

'No, well I'm probably not aware of it myself [Duty of Candour]. No, no, nothing that's been reiterated to us within my Trust' [Midwife 5].

It was described that there was a disconnect between the emphasis on the importance of following the Duty of Candour in training and how disclosure was currently being carried out in practice.

'Well it does in terms of, you know, when we carry out mandatory training and e-learning packages it's quite clear but in terms of the practice I don't believe it really does actually happen...I don't believe it is, to be honest' [Midwife 4].

Theme 3: Fear of vulnerability

Healthcare professionals believed that at the heart of disclosure were the principles of accountability, honesty, and transparency. However, anticipating exposure to the investigation process and the potential of malpractice liability elicited feelings of worry and anxiousness. Two sub-themes were developed in this theme; 'Investigation process as a stressor' and 'Legal worries'.

Investigation process as a stressor

Although the interview did not address the formal process of investigating the adverse event, this process was discussed by participants. Healthcare professionals reported worries that once an initial disclosure had been carried out, an investigation process would be conducted for certain incidents. The inadequacies of the investigation process were discussed and poor routines in this process added to the emotional distress already faced by healthcare professionals. The management of the case and the investigation process were described as inappropriate and resulted in intense emotional reactions including sleep disturbances and feeling defenceless. The individual involved in managing the case played a role in whether the investigation was managed well. Healthcare professionals felt that the trust failed to provide emotional support during this difficult investigation process:

'So this was incredibly stressful, there was an internal investigation process that was handled badly, but it was incredibly stressful' [Obstetrician 6].

'They essentially invited the complainant to write their own response which says Dr X and his lack of insight is the sole cause of our trauma, and that made me feel incredibly vulnerable and I sort of felt that the trust had a duty of care towards me and it wasn't really fulfilling its duty of care…that

gave me real disturbed sleep, feelings of vulnerability. You've got letters going sent out on headed notepaper saying you know 'this DR X' is a cowboy in an attempt to pacify the complaint, which is actually wrong and very unhelpful' [Obstetrician 6].

When the investigation process was handled in a supportive manner by the organisation, it resulted in a positive learning experience. However, when it was handled incorrectly, it was a very stressful phase for those involved and the resulting physical implications included taking time off work due to the increased stress load. The course of the incident investigation process was very time-consuming and the long wait for a decision was distressing for those involved. The lengthy investigation time and the associated emotional distress increased the difficulty in recovering from the adverse event and reaching closure. Most healthcare professionals did not receive enough information on the steps involved in this process. Those responsible for the adverse event were not involved in the investigation process including investigation meetings, which was viewed as unreasonable and caused further anguish. Healthcare professionals believed that those involved in the adverse event could make useful contributions and assist with the case as they could provide facts about the incident. This lack of involvement often led to misinterpretations of the incident during the investigation:

'I don't think that's right, in that do we think they [healthcare professionals] won't tell us the truth, if we ask them, maybe they could fill in so many of the gaps that you have, just by asking them. So I don't know why they're not involved…and yet every time I saw a statement, every single time I saw it wasn't right, that did not happen. So I do worry that sometimes there can be some real misinterpretation and some I sit in them and I think, 'but you're inferring and you're suggesting, that's not the truth' [Midwife 8].

'The process takes a very, very long time and I would imagine that is quite stressful for healthcare professionals that are involved. And also for staff, I was at one [investigation meeting] yesterday where a colleague came said 'look you know, the staff are really worried and they're really worried you're having conversations in a room about them without them being there, and they're not part of the process' [Midwife 8].

For some healthcare professionals, the anticipation of what the investigation process would involve and how the organisation would respond was viewed to be more worrying than conducting the disclosure conversation itself with the patient. Healthcare professionals reported that they were not kept up to date with the investigation and had to chase the investigation team to understand the progress of the investigation:

'Actually, they weren't that good at keeping me informed, because it was a serious incident investigation, and they weren't that good at keeping me updated with how it was progressing and things like that. It was slightly…I felt I had to keep asking to see what was going on with it' [Obstetrician, 7].

Legal worries

Healthcare professionals' hesitancy to admit and disclose an adverse event often stemmed from a fear that it may make them vulnerable to malpractice liability. Feelings such as nervousness, anxiousness, and dread were commonly associated with the fear of legal repercussions. There was awareness surrounding the high litigation costs within maternity, and healthcare professionals reported that they were cautious when discussing adverse events with patients. It was perceived to be difficult to admit to causing harm to a patient which had resulted from inappropriate practice, however, despite this fear, disclosure was viewed as professional duty.

'This is a big barrier still and I think psychologically, it will remain a barrier for quite a while, while it takes sort of legislative changes to filter down to say that this shouldn't be a barrier. I think people throughout the NHS feel that things are becoming more defensive, more litigious. I know that costs for maternity, compensation is going up and up. And so you know, yes people are a bit scared to do it [disclosure], they do it because they know there's a duty of candour or whatever, but they feel like they have to be very, very careful before discussing things with patients, which is a shame really' [Obstetrician 9].

'You know it was dread, I was really kind of nervous and anxious…kind of nervous about making sure I said the right things and you know I'm aware as well that in maternity services, litigation is a significant issue' [Midwife 14].

Healthcare professionals described that there was a lack of support and guidance surrounding the legal aspects of disclosure and they were unsure about what could be disclosed to patients without accepting liability on behalf of the organisation. Further support in relation to the legal element of disclosure was needed. Worries about the GMC (General medical council) getting involved after disclosure were also discussed and the processes involved in this lacked clarity.

'I don't think there's a huge amount of information that comes from the Trust in terms of the legal side. I don't think the Trust always gives the most appropriate level of support and I think it's difficult bridging the gap between legal boundaries and medical training, I don't think that's

always clear and could do with a bit of work' [Obstetrician 11].

'I'd say the other thing is if it does go to things like GMC when they get involved and if the GMC contact the seniors here at the Trust, then you actually don't know the process, so these kinds of things need to be explained and also the process of litigation… it is difficult…so it would be nice to have more information' [Obstetrician 7].

One healthcare professional discussed the legal implications that disclosure would have on the organisation as well as the individual involved and believed it was important to take this into consideration when choosing what information to share with the patient. This healthcare professional also believed in situations where liability may be a potential issue, it was necessary to take into account how helpful the information you share with the patient will be.

Theme 5: Personalisation or professionalisation

Healthcare professionals viewed the adverse event and confronted disclosure in one of the following two ways. They adopted either a personalised or a professional approach and healthcare professionals experienced different emotional responses depending on which approach was used.

Personalisation

Those who adopted a personalised approach to the incident experienced a diverse range of negative emotions including feelings of shame, embarrassment, guilt, and feeling angry and frustrated at oneself. Healthcare professionals felt that they had let down the patient and expressed not feeling good enough about themselves. Being involved in an adverse event also resulted in a loss of self-confidence as they questioned their own actions and how they had contributed to the incident. These healthcare professionals described that anticipating disclosure evoked feelings of emotional distress. Disclosure was perceived to be important, however healthcare professionals
wanted to escape this disclosure process.

'I think there's a range of emotions there. I think one there is embarrassment about, you know, that you've made a mistake, it's about embarrassment, what will they think about you, there's some shame in that in terms of, you know, I should know better, you know, I'm supposed to be someone that they can trust and, you know, to be responsible and actually I've let them down. So I think for me there is that whole, you know, emotion of not being adequate enough, not being good enough, being angry with myself, you know. Why didn't you take that? Why didn't you do it better? You know, all those feelings of shame really' [Midwife 8].

‘You know we'd still done the wrong thing but a part of you wants to hide and not say anything [laughs] but you know obviously I knew that wasn't right’ [Midwife 14].

After conducting the disclosure, some healthcare professionals constantly reflected on the adverse event which involved self-criticism and were unable to escape this reflection process. This had an impact on work performance as healthcare professionals reported feeling distracted with these constant thoughts. Healthcare professionals ruminated on the incident and the disclosure conversation, where they experienced thoughts related to how the incident could have been better explained to the patient. The criticism and blame directed at oneself were still present after the disclosure, and some healthcare professionals reported feeling worse after disclosure as they still felt responsible. A coping strategy to deal with this was talking about the experience with family or friends.

'I would like to say that that's it done and dusted but I think, I think we're all human and I think we do ruminate on it, I mean afterward, and kind of think from a medical point of view, like could I have explained that adverse event a bit better? [Obstetrician 12].

'It takes me a little while to stop beating myself up, and I normally come home and need to debrief with a friend or family… probably more upset after I've told them cos I still feel just as responsible' [Midwife 5].

Professionalisation

Other healthcare professionals responded in their professional capacity. These healthcare professionals separated their personal-self from their healthcare professional-self. Adverse events were viewed as inevitable and although there was a sense of perfectionism within maternity, it was emphasised that human errors do occur. There was a belief that the way you viewed adverse events was dependant on your personality and accepting that as a human, you are fallible would help you move on from the adverse event. These healthcare professionals reported that they would conduct disclosure, but would not ruminate over the incident.

'But I suppose it does depend on personality, you know maybe you have to have this kind of personality to be in this specialty, but I also feel 'look I've done my very best and if something terrible happens I know that I didn't do it deliberately'. I'd hope that it wasn't because of a mistake that I had made, but even if it is a mistake, I'm only human so I will make mistakes, so I can sort of get over that' [Obstetrician 6].

'But I think within maternity there is this expectation that everything has to be done perfectly in a sense that it doesn't allow for human error and we are working in quite stressful situations where, you know, mistakes are going to happen and I think we have to be honest about this, you know [Midwife 4].

Those who adopted a 'professional' approach, viewed disclosure to be an important aspect of care and as part of the job and were confident to conduct disclosure. It was emphasised that a healthcare professional's role during this process was to provide support to the patient and not to bring their own emotions to the situation. Healthcare professionals described the importance of examining the adverse event situation rationally and believed this would help them manage their emotions. Although healthcare professionals did not like conducting disclosure, there were no strong feelings towards disclosure and it was described as a normal part of care.

'Although it's awful and you would never want that to happen to anybody it's all part of the job really and if you can do that in a way that is compassionate and give them time, you know help to support them, that's kind of why we're here, I see it as an important part of the job' [Obstetrician 3].

'But it's more kind of like yeah, no, I don't really like doing it but it's [disclosure] just part of the job' [Obstetrician 12].

Theme 5: Need for support & training

Healthcare professionals described that their main source of support for disclosure was debriefing with colleagues and peers. Only a few healthcare professionals believed that senior colleagues were readily available for support if it was required, however having an informal conversation after disclosure with immediate colleagues was preferred. Although peers colleagues offered support during these times, there was a lack of support from the organisation faced by both midwives and obstetricians.

'But from the Trust itself I got nothing, no-one offered to speak to me, no-one asked if I was okay, at least the staff on… the midwives and consultants did because they know me and they like me, but in terms of someone separate from the Trust I got nothing'. I actually got a letter from the kind of head of Obs and Gynae there, basically saying you're going to be part of this investigation, I think the letter word-for-word were if you feel you need support contact me, but that was it. And the tone of the letter didn't imply that you could readily contact them...But certainly, I was quite upset

but no-one offered me occupational health, for example, no-one offered me any sort of counselling services, nobody offered to kind of talk through the incident' [Obstetrician 1].

Midwives described that previously, their first line of support was the midwifery supervision. This is no longer available and midwives felt that it was devastating to lose this form of support.

'I think because we've lost supervision, so that was just such a longstanding thing and at the end of March, been taken away. I think that support was invaluable and that's, the kind of thing that was written down on paper, that's where you go to, if you need to talk about an event, you need to talk about disclosure, etc., supervision was amazing for that and just to be able to talk through things that happened if you'd been involved in something particularly upsetting, even if it's, it's nobody's fault and it happens, that mechanism was the absolute best, I thought. And to not have that anymore is disastrous' [Midwife 2].

Healthcare professionals reported that they had not received any specific training in relation to disclosure of adverse events to patients. Many had attended general communication training, however, this was more focused on breaking bad news to patients. Adverse event disclosure training was perceived as useful and a need for this was expressed by healthcare professionals. A preference for peer group training was voiced, as individuals would bring different experiences to the group and it would allow for collaborative discussions. A one-to-one session was believed to be appropriate when a healthcare professional required advice or support related to a specific incident.

'Oh, I think peer group is always quite helpful really because you can discuss cases together and collectively think of strategies to deal with these issues' [Obstetrician 6].

'And I think, you know, in a group you can then appreciate more than a one-to-one session, because, oh well this person had an event and I thought this person was really, really good, but they've had an event, and you kind of break down barriers, and one-to-one session tends to, I think can be very useful if a person is say very upset about a specific thing, or if you want to provide specific advice relating to a particular incident because you can then have a detailed in-depth look at what it is that the doctor is upset about' [Obstetrician 1].

Most healthcare professionals perceived that a framework to support them through the process of disclosure would be helpful. The use of a framework was associated with reduced stress and feelings of reassurance, as healthcare professionals would feel that disclosure has been conducted in the correct manner, following the appropriate steps. Frameworks were viewed as useful in aiding disclosure and providing structure to the disclosure process. Healthcare

professionals perceived that there was currently no formalised framework to assist with this process and the Duty of Candour was viewed as complicated and lacking clarity.

'But certainly, there's no formalised framework that would be..., so something like some form of a flowchart or some framework would be very useful and also at which points, you know, who you can engage with, because also is what I'm about to share going to, and I think there has to be some responsibility about that. So sometimes, so that I think is more challenging about what will this information do to the person? Because yes we have duty of candour, yes they have a right to the truth, but what if that truth, yeah, I think the whole thing is a bit of a minefield really' [Midwife 8].

However, one healthcare professional believed that a framework would not be useful as they were perceived to be used by healthcare professionals to cover inadequacies in communication skills. Disclosure was viewed as a one-one conversation on a human level and the use of a framework would reduce the empathy that should be involved in this conversation.

3.7 Discussion

This study is novel as it is the first study that has focused on maternity settings and has explored the experiences and perspectives of midwives and obstetricians on the disclosure of adverse events in the UK. Five main themes and several sub-themes were developed from the interview data. Surprisingly, overall, there was little difference in the experiences of disclosure between midwives and obstetricians within this study. This may be because both groups of professionals work in the same complex environment of maternity and disclosure itself is a challenging communication task, regardless of profession. There was also little difference in terms of levels of experience.

Some of the findings which emerged from this study are similar to those from previous disclosure studies. Healthcare professionals reported facing a range of negative emotional responses after being involved in an adverse event which includes feelings of shame, anxiety, grief, and frustration. Such emotional distress faced by healthcare professionals has been discussed extensively within the second victim literature (Aasland & Forde, 2005; Schelbred & Nord, 2007; Sirriyeh et al., 2010; Seys et al., 2013). The term second victim refers to healthcare professionals who are involved in an adverse event and become victimised in the sense that the provider is traumatised by the event (Scott et al., 2009). Interestingly, although healthcare professionals described suffering from negative emotions, they did not refer to themselves as a victim of the adverse event. This suggests that this may not be something that healthcare

professionals themselves identify with. However, when describing their experiences of the investigation process when handled badly, this was certainly something they might be perceived as being. When healthcare professionals were personally responsible for the adverse event, the disclosure process was perceived to be more difficult and emotionally demanding. When responsible for the adverse event, healthcare professionals described a personal need and desire to participate in disclosure to accept responsibility. This is concurrent with findings from the literature where participant's wanted to accept responsibility for their mistakes (Engel, Rosenthal & Sutcliffe, 2006; Goldberg, Kuhn, Andrew & Thomas, 2002; Penson, Svendsen, Chabner, Lynch & Levinson, 2001). These healthcare professionals had perceived that patients would be more accepting if they were open and transparent. This is in line with a previous study conducted within the UK (Harrison et al., 2017), where healthcare professionals experienced positive experiences of being honest with patients. Healthcare professionals generally felt that there was an element of relief after conducting the disclosure conversation for two main reasons. There was relief that the task of disclosure had been conducted and relief when the patient had provided a non-negative response. Healthcare professionals carried an emotional load after being involved in an adverse event. The disclosure conversation allowed healthcare professionals to unburden their emotions and move on from the adverse event.

The findings from this study revealed that healthcare professionals within maternity settings feared that they would be vulnerable to malpractice liability. Despite the differences in liability environments within different countries, a fear of legal repercussions has been consistently cited within the literature previously (McLennan et al., 2016; Gallagher et al., 2003; White et al., 2008; Coffey et al., 2010; Duclos et al., 2005). However, interestingly, compared to previous research which has identified that fear of litigation is a barrier to disclosure (Duclos et al., 2005; Espin et al., 2006; McLennan et al., 2016; Coffey et al., 2010), this study found that although healthcare professionals were hesitant to disclose due to legal worries, it was not viewed as a barrier to prevent them from conducting disclosure as this was viewed as a professional duty. There was also a lack of clarity and support in relation to the legal element of disclosure. A finding which was specific to the UK was concerns about the General medical council (GMC) getting involved when inappropriate practice had been identified. The GMC is a public body that maintains the official register of medical practitioners within the United Kingdom. The GMC's role is to protect patients and improve practice across the UK. This suggests a need for further transparency about the legal processes within the UK and information about procedures once the GMC are involved. Further education and training to reduce these fears and the associated emotional distress is necessary.

Previous research has found that investigations of adverse events cause emotional distress (Ullstrom, Sachs, Hansson, Ovretveit & Brommels, 2014). Within this study, although healthcare professionals emphasised that the principles of accountability, honesty, and transparency were at the heart of disclosure, there was hesitancy to disclose. Similar to previous findings, within maternity settings, the investigation process was viewed as a stressor. Healthcare professionals were hesitant to disclose due to worries that an investigation process may follow. The investigation process that followed disclosure was more worrying than the disclosure conversation itself. The poor routines involved in this process, inappropriate management of the case, lengthy wait for a decision, and lack of support from the organisation during this time resulted in further emotional distress. These findings are similar to a previous study which has also found that investigations of adverse events caused doctors and nurses distress (Ullstrom, Sachs, Hansson, Ovretveit & Brommels, 2014). Although the impact of adverse events on healthcare professionals is well documented within the literature (Aasland & Forde, 2005; Schelbred & Nord, 2007; Sirriyeh et al., 2010; Seys et al., 2013), the notion that the investigation process has the potential to cause further damage to healthcare professionals is less well recognised. Investigations are important in determining the root cause of adverse events, and to help prevent the recurrence of these incidents in the future. However, such processes should support rather than isolate those who are involved.

There is a need for organisations to provide healthcare professionals with support throughout this process. This includes providing information on the steps involved in the investigation, being informed on the progress of the case, and where appropriate, be included in investigation meetings to avoid any misinterpretations of the incident. The Patient Safety Incident Response framework (NHS England & NHS Improvement, 2020) which has very recently been introduced within the UK states that when there is an investigation of an incident such as an adverse event, healthcare professionals should be fully informed in person and in writing about what will happen. However, although this framework suggests that healthcare professionals should have the opportunity to contribute to other responses that allow learning from the incident; it does not advocate the inclusion of healthcare professionals in investigation meetings. The findings from this study suggest that involving healthcare professionals in the investigation meetings could reduce some of the emotional distress that they experience during this process. This framework has not yet been implemented within the NHS, as a phased approach to implementation is being taken.

Midwives and obstetricians described they did not receive training specific to adverse events and expressed a need for this. These findings in relation to the absence of training specific to adverse event disclosure map onto existing literature from several different countries including

the USA, UK, Switzerland, and Korea (Ock et al., 2016; McLennan et al., 2016; Harrison et al., 2017; Fein et al., 2005), indicating that a lack of training within this area is a universal problem. The lack of support, training and maternity specific guidance highlighted by both midwives and obstetricians may help explain the similarities in perceptions and experiences of disclosure. Healthcare professionals describe experiencing strong negative emotions throughout the process of disclosure. A lack of support from their organisations during this time can make healthcare professionals feel further emotionally damaged. Midwives described that previously, their main avenue of support for discussing adverse events and disclosure was midwifery supervision. Midwives utilised this support to discuss aspects related to disclosure. This support is no longer available and losing this support was devastating. Disclosure is a challenging and emotionally charged conversation that requires advanced communication skills. It is imperative that healthcare professionals are provided with training on these non-technical skills to ensure that they are prepared to conduct disclosure when an adverse event occurs. Healthcare professionals also discussed the value of a framework to aid them with the disclosure process.

Other findings which emerged from this study may be specific to the UK maternity setting. A novel finding from this study was that midwives and obstetricians tended to adopt a personalised or professionalised approach to disclosure, and each resulted in different emotional responses, as shown in the theme 'personalisation or professionalisation'. Those who adopted a personalised approach experienced intense negative emotions compared to those who had a professional approach towards the adverse event and disclosure. These findings indicate that adopting a more professional outlook towards disclosure may be a better coping mechanism and an adaptive way to deal with disclosure than a personalised approach. It is possible that the use of a professionalised approach may be used as a coping mechanism by some healthcare staff working in the complex and challenging environment of maternity. There is a need to raise awareness among healthcare professionals of the different ways of viewing and approaching disclosure.

A second novel finding which emerged from this study was the comparison made between adverse events and complications in relation to disclosure by healthcare professionals. Complications occurred regularly within maternity and also required disclosure. Healthcare professionals associated the term adverse event with incidents that occurred due to the care provided, whereas a complication was described as an incident that healthcare professionals did not contribute towards and had no control over. For most midwives and obstetricians, disclosure of complications was perceived to be easier and less emotional than adverse event disclosure as healthcare professionals could have a relatively clear conscience about a

complication.

Another novel finding which may be specific to the environment of maternity is that healthcare professionals struggled to draw the line between adverse events and complications which resulted in difficulties on how to approach disclosure. Although healthcare professionals were able to define the two different types of incidents, in practice they struggled to draw the line between which incidents would be classed as an adverse event and a complication which led to difficulties to decide how to disclose the incident. In some situations, an adverse event had led to a complication and it was difficult to determine how this would be disclosed. These findings may be unique to the speciality of maternity and this uncertainty may be due to the complex environment of maternity and medical complexities during pregnancy. It is important that national guidance or policies are developed which is specific to maternity settings and assists healthcare professionals in determining which incidents can be classed as adverse events or complications. Guidance also needs to take into situations where it is not possible to distinguish between the two and provide assistance on how to best approach disclosure in such circumstances.

There is a lack of literature discussing adverse events and complications. Previous literature has focused either on adverse events or complications independently. The link between the two types of incidents is an interesting line of inquiry that requires much further research. However, this can be linked to the general literature in patient safety which suggests that there is difficulty in defining inevitable and preventable harm within healthcare (Pronovost & Goeschel, 2010). Despite the need to disentangle the two types of harm, the methods to make this distinction require development (Pronovost & Goeschel, 2010). This can be linked to the challenges of distinguishing between preventable adverse events (which can be classed as preventable harm) and complications (which can be classed as inevitable harm) described by healthcare professionals in the current study.

This study has also highlighted the need to raise awareness of the Duty of Candour due to the lack of familiarity of this amongst healthcare professionals. This is important to ensure that disclosure is conducted in a transparent and respectful manner. This is also a novel finding, specific to a UK healthcare context and may have emerged as the legal duty of Candour came into place only a few years before this study was conducted. Due to the lack of research conducted on adverse event disclosure within the UK, there is limited focus on the Duty of Candour regulation. Midwives and obstetricians within this study had mixed feelings towards the Duty of Candour. Some were familiar with the disclosure principles whereas others were only aware of its existence. Some organisations raised more awareness of this regulation than

others. However, healthcare professionals reported that although there was an emphasis on the Duty of Candour, the principles were not always implemented in practice. This is similar to findings by Harrison et al (2017) which suggested that there was a need for senior healthcare professionals and managers to encourage the uptake of the Duty of Candour in practice. Given that the Duty of Candour (2015) is a statutory regulation within the UK, has now been in place for a few years, and sets out specific requirements that healthcare professionals must follow when disclosing an adverse event, it is surprising that there was a lack of familiarity of this by some healthcare professionals.

3.8 Key implications

A number of different areas for clarity and support during the disclosure process were identified by both midwives and obstetricians.

- There is a need for national maternity-specific guidance or policies which provide assistance in determining which incidents can be classed as adverse events and which can be classed as complications. Such guidance also needs to provide support for instances when it is unclear which category the incident would fall into and how to best approach disclosure.
- A support mechanism for the investigation process also needs to be developed. This involves providing information on the stages involved in the investigation, being kept up to date with the investigation, and where deemed appropriate, to include healthcare professionals in this process. Providing this support may help to alleviate some of the distress associated with the investigation process. Organisations need to ensure transparency about the legal processes and the current malpractice laws within the UK. Procedural clarity surrounding the involvement of the General Medical Council is also required.
- Although the Duty of Candour is implemented at a policy level within the UK, further awareness of this regulation and the requirements needs to be raised by individual organisations. The development of a structured framework that incorporates the Duty of Candour principles may be one of the ways in which healthcare professionals can be educated about this regulation, as well as providing a structural aid to assist with disclosure.
- Non-technical performance has only been recognised as an important component of healthcare professional's training recently. Accreditation Council for Graduate Medical Education (ACGME) has published 6 core patient safety competencies in 2007. These include patient care, medical knowledge, interpersonal and communication skills,

professionalism, practice-based learning and improvement, and systems-based practice. Disclosure is classed as a non-technical skill and a complex communication task. Training programmes for adverse event disclosure need to be developed and delivered from an organisational level. In addition to providing healthcare professionals with factual guidance on disclosure, findings from this study illuminated the need to be transparent and aware of the emotional consequences of being involved in an adverse event and disclosure. This needs to be brought to the forefront and training initiatives need to help healthcare professionals to consider how they would deal with the emotional implications of disclosure.

- Given the significant emotional burden of being involved in the disclosure process, an alternative support system to the midwifery supervision is needed not only for midwives but should also for obstetricians. This could be in the form of debriefing sessions with colleagues or on a one-to-one basis, depending on the needs of the healthcare professional involved.

3.9 Limitations & further research

This study has several limitations. Within the maternity setting, obstetricians and midwives are the key healthcare professionals who disclose adverse events to patients. However, this study may not reflect the experiences of other professional groups. Due to the differences between healthcare systems, all the findings within this study may not be relevant internationally. Data was collected from two NHS sites and Twitter and therefore, the sample may not be geographically diverse.

This study has focused on the experiences of disclosure in secondary care and a majority of previous research has also focused on this context. There is notably a lack of research conducted within the UK which has focused on primary care such as the area of general practice. Further research may be directed to these areas. Further research can also focus on the effectiveness of training programmes and guidance intended to increase disclosure within the UK.

3.10 Conclusion

This is the first study to focus on the experiences of disclosure within a UK maternity setting, an area which has previously lacked research. This study suggests that although healthcare professionals believed that honesty, transparency, and openness were important principles of disclosure, they struggled with this process. Within the UK, there is currently a lack of clarity and support surrounding the disclosure process. There is a need for support and guidance from an organisational level in terms of the investigation process, current legal processes within the UK, how to approach disclosure when there is uncertainty about whether an adverse event or

complication has occurred, and the Duty of Candour regulation. Training programmes which take into account these factors need to be developed. It is important to recognise that support packages and guidance need to be developed and disseminated at a national level to promote consistency and maximise usage. Educational training on adverse event disclosure and one-to-one support should both be provided to meet the individual needs of the involved healthcare professionals.

Chapter 4: Developing a training communication intervention to enhance maternity healthcare professional's skills for disclosing adverse events

4.1 Chapter summary: *The previous chapter has presented primary data relating to the experiences of midwives and obstetricians on adverse event disclosure within the UK. This chapter describes the process of designing and developing a training intervention to support maternity healthcare professionals with the disclosure of adverse events within the UK, based upon existing evidence. The rationale for the choice of theoretical approaches and the selection of intervention components are discussed, and an outline of the intervention is presented.*

4.2 Background & rationale

The previous chapters have identified the need to develop evidence-based training interventions to support healthcare professionals with the disclosure of adverse events to patients. Chapter 2 provided a systematic literature synthesis of the views and experiences of patients and healthcare professionals on the disclosure of adverse events. As discussed in depth in chapter 2, the findings of this review revealed that patients expressed a need for information relevant to the adverse event, an apology, and wanted to be assured that the same mistake would not happen in the future. Patients were also more likely to seek legal help when this information was not proactively made available to them or if they struggled to obtain the relevant information from the clinicians involved. Clinicians, on the other hand, acknowledged the importance of disclosure and considered it to be a moral and professional duty, however, multiple barriers were identified which prevented them from carrying out effective disclosure. These included: The fear of honest disclosure in a blame culture, a wish to avoid litigation, a lack of skills and training in conducting disclosure conversations and inconsistent practical guidance. Chapter 3 presented primary qualitative data relating to midwives and obstetricians views and experiences on the disclosure of adverse events in the NHS, and the current support and training which exists in maternity services for disclosure. As discussed in chapter 3, the key findings were:

1. Healthcare professionals highly valued honesty and transparency with patients; however, they found disclosure to be an emotionally and psychologically strenuous task, with little perceived support from their organisations.

2. The majority of healthcare professionals were aware that a Duty of Candour regulation existed but were not familiar with the specific legal requirements contained within it.
3. Most healthcare professionals described having received general training in breaking bad news but felt that this was not sufficient for disclosing AEs and expressed a need for specific training.
4. When asked about how the training should be structured, healthcare professionals expressed a preference for peer group training sessions based around a simplified guideline/framework designed to assist with the disclosure process.

The findings from these two chapters confirmed the necessity to deliver training which is specific for disclosing adverse events to support healthcare professionals with this process. This chapter details the process of designing and developing an intervention to support healthcare professionals with the process of disclosing adverse events, based on existing research evidence and theoretical approaches. The selection of different intervention components are also discussed and justified. An outline of the training intervention is presented.

Interventions are often made up of several interacting components (Medical Research Council [MRC], 2008). The MRC guidelines have been developed to assist researchers with the development of an intervention by helping them to choose and implement appropriate methods, given the state of existing knowledge and nature of their target intervention. The MRC guidelines propose that the following steps are considered when developing an intervention: 1) identifying the relevant, existing evidence base, usually by carrying out a systematic review; 2) identifying or developing relevant theory as this is more likely to result in an effective intervention than a purely empirical or pragmatic approach. This can also be supplemented with new primary research e.g. interviews with stakeholders (those who will be involved in the development or delivery of the intervention and those who will be targeted by the intervention). The MRC guidelines also outline key considerations which include the desired outcome, how the change will be achieved, a coherent theoretical basis to the intervention and the systematic use of theory (MRC, 2008). These guidelines have been used when developing this training intervention and will be discussed in further detail later in the chapter.

4.3 Identifying the relevant existing evidence on adverse event disclosure interventions

Whilst reviewing the literature on adverse event disclosure interventions, a systematic review was identified which examined previous disclosure interventions had already been conducted. This systematic review was conducted as part of the following report '*An exploration of the implementation of open disclosure of adverse events in the UK: a scoping review and qualitative exploration'* (Birks et al., 2014). This systematic review aimed to identify, assess & summarise the effectiveness of open disclosure strategies/interventions that had been used to promote or support open disclosure of patient safety incidents within a healthcare context. This review defined the term 'patient safety incident' as any unintended or unexpected incident which could have, or did lead to harm to a patient. As this definition is in equivalent to our definition of an adverse event, we will use the term adverse event when describing this systematic review to ensure consistent terminology is used throughout the thesis. Open disclosure is defined by the review authors as informing patients and/or family members when a patient safety incident has occurred using an honest and consistent approach. As this definition also corresponds to the definition of disclosure used within the thesis, for consistency throughout the thesis, the term disclosure will be used when discussing and describing this systematic review.

In this systematic review, studies of interventions using actual events (real cases) or hypothetical scenarios were included. Studies, where the intervention aimed to promote or improve communication of illness (breaking bad or sad news), were excluded. Interventions which were related to deliberate acts of harm were also excluded (Birks et al., 2014). In total, eight studies were included in which the interventions aimed to promote disclosure. One study included a comparison group (Paxton & Rubinfeld, 2010) and seven used an uncontrolled before and after study design (Gunderson, Smith, Mayer, McDonald & Centomani, 2009; Halbach & Sullivan, 2005; Kiersma, Darbishire, Plake, Oswald & Walters, 2009; Madigosky, Headrick, Nelson, Cox & Anderson, 2010; Moskowitz, Veloski, Fields & Nash, 2010; Posner & Nakajima, 2011; Wayman et al, 2007). As the review by Birks et al. was conducted in 2014, a literature search was conducted in late 2017 to identify whether any new studies on interventions or training for disclosure had been published since this review had been conducted. It was identified that since 2014, four new intervention studies on disclosure had been published (Sukalich, Elliott & Ruffner, 2014; Langer et al., 2016; Kim, Myung, Eo & Chang, 2017; White, Brock, McCotter, Shannon & Gallagher, 2017). This literature search also revealed that there was one intervention study (Bonnema, Gosman & Arnold, 2009) conducted before 2014 which had not been identified by the previous systematic review. Detailed descriptions of each of the

studies including participants, intervention and components, outcome measures and main findings are displayed in Appendix 7.

Description of the intervention studies

Setting

Thus, at the point of intervention development in late 2017, thirteen studies were identified from both the review by Birks et al. (2014) and the subsequent searches. Eleven of the intervention studies were conducted in the USA (Gunderson et al., 2009; Halbach & Sullivan, 2005; Kiersma et al., 2009; Madigosky et al., 2006; Moskowitz et al., 2007; Paxton & Rubinfeld, 2010; Wayman et al., 2007; Sukalich et al., 2014; Langer et al., 2017; White et al., 2017; Bonnema et al., 2009), one in Canada (Posner & Nakajima, 2011) and one in South Korea (Kim et al., 2017). Most of the studies took place in educational establishments; seven in training schools/colleges or universities, one took place in healthcare organisations, one took place in a specialised simulation-based training centre and in four studies, it was not clear where the intervention took place.

Participants

Most participants were students from health-related disciplines including medicine, nursing, pharmacy and dentistry (Gunderson et al, 2008 & 2009; Halbach et al, 2005; Kiersma et al, 2009; Madigosky et al, 2006; Moskowitz et al, 2011; Paxton et al, 2012; Sukalich et al, 2014; Kim et al, 2017; Bonnema et al, 2009). Four of the studies recruited qualified healthcare professionals as participants (Posner & Nakajima, 2011; Wayman et al, 2007; Langer et al, 2017; White et al, 2017).

Interventions

In the thirteen included studies, the interventions were intended to support or promote disclosure. In all of the included studies, the interventions were delivered as educational or curricular modules and workshops. These were delivered either exclusively about disclosure or incorporated into a broader theme of patient safety. These interventions included the following components: didactic lecture sessions, pre-reading materials, DVD materials, observation, small group work and discussions and role-play or simulated training to practise disclosure, often including feedback sessions.

Outcome measures

A range of outcomes was assessed which were related to knowledge about safety and disclosure, perceived self-efficacy to perform disclosure and confidence in dealing with disclosure. These outcomes included perceived self-efficacy to understand and conduct full disclosure, self-awareness about patient safety, student knowledge of medication safety,

knowledge of medical errors/adverse events and perceived self-efficacy in communication. Seven studies also carried out descriptive evaluations of the intervention provided. Outcome measures included questionnaires (true/false or multiple choice), rating scales including Likert scale of self-assessment, subjective evaluation for role plays where participants enacted disclosure and checklists of performed tasks.

Nine studies compared pre with post-test scores (Gunderson et al., 2009; Halbach & Sullivan, 2005; Kiersma et al., 2009; Madigosky et al., 2006; Moskowitz et al., 2007; Posner & Nakajima, 2011; Wayman et al., 2007; Sukalich et al., 2014; Langer et al., 2017). These evaluated outcomes such as perceived self-efficacy, knowledge and confidence as well as evaluating the curriculum. One study included a comparator group, however, results were only provided for within-groups analyses and intervention and comparator group outcomes were not compared (Paxton & Rubinfeld, 2010). Three studies only examined scores after taking part in the interventions (Kim et al., 2017; White et al., 2017; Bonnema et al., 2009). One of these studies evaluated confidence after taking part in the intervention (Kim et al., 2017) and one examined attitudes and self-efficacy after taking part in the intervention (White et al., 2017).

Identification of intervention components

The following intervention components have been identified from previous disclosure interventions that have been discussed above:

- Pre-reading/background reading materials
- Didactic lectures- to provide an overview and background to the topic area
- Simulation- these either involved practising disclosure techniques using standardised actors as patients or through the use of role plays. These often included feedback sessions.
- Group discussions- these included the opportunity to describe and discuss experiences

4.4 Theoretical basis

It was important to identify the relevant theories which could contribute towards the development of the intervention as this is more likely to result in an effective intervention than a purely empirical or pragmatic approach alone (MRC, 2008). The MRC guidelines also propose that an intervention needs to have a coherent theoretical basis and these theories should be used systematically to develop the intervention (MRC, 2008). Emphasis is placed on the use of theory for developing interventions as theoretically-informed interventions lead to better outcomes (Michie & Prestwich, 2010). However, when examining previous adverse event

disclosure interventions, it became apparent that the theoretical backgrounds underpinning these interventions were not obvious. Based on the research evidence from the systematic review (chapter 2) and interview study (chapter 3) the key elements that needed to be addressed for an adverse event disclosure intervention were considered in great detail.

During this stage, it became apparent that no one particular theory would underpin the training intervention, and different theories would be relevant for developing different aspects of the intervention. It is important to note the limitations of using a number of different theoretical approaches to develop the training intervention. One of the weaknesses with this approach is that as all the constructs specified within the Social Cognitive Theory were not explicitly targeted, and therefore, only parts of the theory may have been tested rather than the theory as a whole (Prestwich et al., 2015) and this has the potential to hinder the effectiveness of the intervention. Research also suggests that the number of theories applied by an intervention is unrelated to the effectiveness of the intervention (Diep et al., 2014) and combining multiple theories may reduce the effectiveness of the intervention compared to interventions which are based on single theories (Prestwich et al., 2014). Therefore, careful integration of theories was required (Prestwich et al., 2014).

Discussed below are the identified key elements. Each of the theories needed to address these elements are mentioned and are discussed in greater detail further on in the chapter. The research evidence (from chapter 2 and 3) identified that the training intervention would need to address the following elements:

1. *Knowledge related to adverse event disclosure within the UK:* The evidence from the systematic review (chapter 2) and interview study (chapter 3) revealed that healthcare professionals required clarity on the process of adverse event disclosure and the current disclosure policies within the UK. The findings also suggested that it was important to raise awareness of what patient's desire from the disclosure process and how healthcare professionals can meet their needs.

2. *Confidence to disclose adverse events to patients and or/their family and encourage disclosure:* The findings from the systematic review (chapter 2) and interview study (chapter 3) suggested that although healthcare professionals advocated disclosure and considered it to be a moral and professional duty, at times there was hesitancy to disclose due to several barriers. One of these barriers was a lack of confidence and skills on how to conduct disclosure. Therefore it was important to include a component which focused on encouraging and increasing confidence to disclose adverse events.

3. The emotional consequences of being involved in an adverse event & disclosure, and ways to manage one's emotional responses: The findings from the previous two chapters (2 and 3) identified those training initiatives which are developed, need to help healthcare professionals understand and consider how they might deal with the emotional implications of adverse events and disclosure.

A number of different psychological (Cognitive Behavioural Therapy Model and the Social Cognitive Theory), educational and learning theories (Bloom's Taxonomy) underpinned the communication training interventions. Below, the relevant theories are described and how they informed the development of this training intervention is discussed.

Learning knowledge and skills of disclosure

Bloom's taxonomy (1956)

This is a learning and educational theory which aims to promote higher forms of thinking in education such as analysing and evaluating concepts, processes, procedures and principles rather than just remembering facts (Adams, 2015). Bloom's taxonomy uses a multi-tiered scale to express the level of expertise required to achieve certain measurable outcomes. Within this model, there are three core elements of the taxonomy which are the cognitive domain (knowledge), the affective domain (attitudes) and the psychomotor domain (skills). Research suggests that the most common use of Bloom's taxonomy focuses on the cognitive domain, rather than the affective and psychomotor domains. The latter two domains are thought to be important in learning skills and abilities (Adams, 2015).

How can Bloom's taxonomy inform this intervention?

This taxonomy was useful in assisting with the structuring the training intervention to promote learning. Based on this taxonomy, the intervention was structured in a way which would address each of the three domains. The training intervention included knowledge about adverse event disclosure, (*cognitive domain*), the intervention provided evidence-based information on the perceived benefits of conducting disclosure and consequences of non-disclosure (*affective domain*), and role-plays to practice disclosure skills (*psychomotor domain*).

Changing thought processes in an emotional context

Cognitive Behavioural Therapy Model (Beck, 1967)

The cognitive behavioural therapy (CBT) model explores the links between thoughts, emotions and behaviour. CBT is a structured approach that is used to treat a variety of mental health

disorders and is the most widely researched and empirically supported psychotherapeutic method (Fenn & Byrne, 2013). The CBT model aims to alleviate mental distress by helping patients to develop more adaptive cognitions and behaviours. In its simplest form, the cognitive model hypothesises that people's emotions and behaviours are influenced by their perception of events. *'It is not a situation in and of itself that determines what people feel, but rather the way in which they construe a situation'* (Beck, 1964). Therefore, how people feel is determined by the way in which they interpret situations rather than by the actual situation (Fenn & Byrne, 2013). The CBT model aims to help individuals understand their current ways of thinking and behaving, and encourage them to challenge unhelpful thoughts into more realistic and practical thoughts. Through this model, individuals are encouraged to develop practical strategies to promote positive thinking and achievement of their goals. The rationale behind CBT is that negative thoughts and beliefs can lead to cycles of negative mood and physiological sensations. These are maintained by avoidant behaviour. This cycle is broken by challenging negative thoughts, changing behaviours and engaging in exercises which boost these thoughts into more rationale thoughts (Tarrier & Johnson, 2015).

How can the Cognitive Behavioural Therapy Model inform this intervention?

Findings from the primary interview study (chapter 3) revealed that given the significant emotional burden of being involved in an adverse event, there is a need to highlight and discuss the emotional consequences of being involved in adverse events and disclosure. As well as providing factual guidance on disclosure, healthcare professionals need to be provided with support related to the emotional implications of adverse events and disclosure. The effective disclosure of an adverse event to a patient and their family relies upon being in the correct frame of mind and mentally prepared. However, for many healthcare professionals, being involved in a significant event triggers an intense emotional stress response (Sirriyeh et al., 2010). Distress, panic, self-doubt, fear, guilt and shame are all commonly experienced in the aftermath of an adverse event (Sirriyeh et al., 2010; Schwappach & Boluarte, 2008). Whilst in the grip of such strong reactions, composing and preparing oneself for a disclosure conversation with the patient and their family involved can be incredibly difficult.

The CBT model can help to increase awareness of the emotional consequences of being involved in an adverse event, as it can help explain how particular cognitive appraisals healthcare professionals may construct about the adverse event can trigger intense emotional and physiological responses. As a result of being involved in an adverse event, healthcare professionals may have negative, threat orientated thoughts e.g. 'I can't believe I did that to the patient, I'm totally incompetent and I'm going to lose my job'. These thoughts will then trigger

the fight-flight-freeze response (a physiological reaction that occurs in response to a perceived harmful event). This results in emotions such as 'worries about losing a job, self-doubt and reduced confidence' which then impedes functioning (e.g. trouble concentrating at work, more likely to make future mistakes) and this cycle continues. Based on this awareness, strategies to reduce negative emotions to facilitate effective disclosure (including reducing threat-oriented thoughts, forming adaptive self-statements and behavioural experiments such as breathing exercises) can be discussed.

Encouraging behaviour change

Social Cognitive Theory (Bandura et al, 1986)

The Social Cognitive Theory (SCT) posits that learning occurs in a social context with a dynamic and reciprocal interaction of the person, environment and behaviour (Bandura et al., 1986). The unique feature of SCT is the emphasis on social influence and external and internal social reinforcement. The SCT considers the unique way in which individuals acquire and maintain behaviour, while also considering the social environment in which individuals perform that behaviour. SCT takes into account an individual's past experiences which factor into whether behavioural action will occur. These past experiences influence reinforcements, expectations and expectancies, all of which shape whether an individual will engage in a specific behaviour and the reasons why a person engages in that behaviour (Bandura et al., 1986).

The SCT model suggests that human functioning can be explained by a triadic interaction of behaviour, personal and environmental factors (Burney, 2008). This theory suggests that confidence, intention to carry out a behaviour and the belief that carrying out the behaviour has more benefits than costs are critical to achieving behaviour change. This model proposes that several constructs underlie the process of learning and behaviour change and these variables may also intervene in the process of learning and behaviour change. These include modelling, self-efficacy, outcome expectations and emotional coping (Nabavi, 2012). The constructs which are relevant to the development of this training intervention are self-efficacy, outcome expectations and emotional coping. Self-efficacy is the judgement of one's ability to perform a particular behaviour. Outcome expectations is a judgement of the likely consequences a behaviour will produce. Emotional coping is described as the ability of an individual to cope with emotional stimuli.

How does Social Cognitive Theory inform this intervention?

Research evidence suggests that healthcare professionals often did not meet the patient's expectations for disclosure. Whilst patients expected information about the adverse event, an apology and a commitment to preventing recurrences, at times, healthcare professionals were

economical with the truth, did not include an apology when disclosing and would not conduct disclosure in certain situations (chapter 2). A number of barriers have been reported to disclosure which could prevent or make healthcare professionals hesitant to conduct disclosure. This includes a lack of confidence and skills on how to conduct disclosure (chapter 2 & 3).

One of the important constructs in SCT relevant in the context of developing a disclosure intervention is self-efficacy. An individuals' level of self-efficacy can be increased by providing resources and support to raise an individuals' confidence when conducting disclosure. Bandura (1986) states that even when individuals have a strong sense of efficacy, they may not perform that behaviour if they have no incentive. This suggests that to promote disclosure to patients, it may be important to provide incentives and rewards to healthcare professionals for conducting disclosure. In the context of this training intervention, the rewards may not be concrete but rather in the form of highlighting the advantages and benefits of disclosing adverse events to patients. Shaping the environment may also encourage behaviour change. This can include providing opportunities for behavioural change, assisting with those changes and offering social support (Perry, Baranowski & Parcel, 1990). One of these opportunities for behavioural change is providing healthcare professionals with training on adverse event disclosure and providing assistance through this process.

4.5 Disclosing adverse events to patients: Enhancing your skills training workshop

4.5.1 Developing session plans and support materials

The theory-informed content was combined with existing evidence from previous interventions and primary qualitative research from maternity healthcare professionals, taking into account practical issues to produce an initial draft for a 3-hour training intervention. The decision to develop and deliver a 3-hour training workshop was based on a number of factors. The findings from the systematic review (chapter 2) and interview study (chapter 3) highlighted that support for disclosing adverse events needed to include the following: an opportunity to improve confidence and skills to disclose, knowledge and information related to disclosure including recent policies and legal aspects, and information and discussions surrounding the emotional implications of disclosure and coping strategies. In order to incorporate these elements into a form of support for disclosure, it was decided that a training intervention which would cover these key elements, using a mixture of interactive-lecture teaching components with facilitated group discussions and exercises would be appropriate. The literature suggests

that understanding what colleagues have experienced after an adverse event can help healthcare professionals to cope with their own feelings of fear, guilt, shame and loss of confidence (Schelbred & Nord, 2007).Therefore, it was believed to be important to bring healthcare professionals together in a face-face intervention to discuss and share experiences of disclosing adverse events. This may help to normalise feelings and discomfort associated with adverse events and disclosure. It was anticipated that this would have an impact beyond the training, and lead to an ability to understand, empathise and share experiences with colleagues.

During discussions with obstetricians and midwives during the initial development of the support sessions, it was voiced that a training workshop which is similar in format and timing to the annual training which healthcare professionals already receive would be useful as this type of disclosure training could be implemented into programme of annual training for healthcare professionals. Therefore, it terms of practicality of being able to deliver the intervention, and healthcare professionals being able to attend, a three-hour face-face workshop was chosen. A web-based intervention was considered where all components of the intervention would be delivered online. This was initially considered to be an appropriate approach as it would allow healthcare professionals to complete the training in their own time and would not require a group of healthcare professionals to be available at the same time. However, this approach was discounted as developing an online intervention would require specialist software, and would be expensive in terms of cost and time. Using an online approach also limited the interactions and group discussions that could take place. Instead of a 3-hour educational training workshop, there are alternative approaches to support healthcare professionals with adverse events and disclosure. This includes trained peer supporters or support individuals who are able to provide one-to-one intervention to help with the disclosure process, peer support mentoring or team debriefings (Scott et al., 2010) where the topic of adverse events and disclosure can be discussed. The supervision team reviewed the draft intervention plan and accompanying support materials. In-depth discussions were held between members of the supervisory team to ensure the content and materials were readable, comprehensive and useful. Comments provided by the supervisory team were used to amend and refine the intervention.

4.5.2 Collaborating with midwives and obstetricians

Midwives and obstetricians were involved in the entirety of this research project and made valuable contributions at every stage of the research process including the development & piloting of the training intervention. Findings from existing research evidence (systematic review) and primary research (interview study) were shared with these healthcare professionals. Initially, a meeting was held with three midwives and three obstetricians

including a consultant obstetrician to discuss the idea of developing a training intervention to support maternity healthcare professionals with the disclosure of adverse events. This was received positively and these healthcare professionals expressed an interest in supporting the development of the intervention.

A second meeting was held where the researcher discussed possibilities of what content might be included in the intervention and the healthcare professionals provided feedback. A draft of the intervention was then developed and, in a third meeting, this was presented to 3 midwives and 3 obstetricians who shared their thoughts and suggested changes which were predominantly related to the structure of the session and timings of each component. The consultant obstetrician supporting this research provided instrumental support in developing the case studies and ensuring they were applicable to maternity, that the correct medical terminology was used throughout and in making final changes to the intervention. Collaborations with these healthcare professionals were key to further development of the intervention. As these midwives and obstetricians had the first-hand experience of adverse events and disclosure they had much to offer. Discussions with them aided understanding of the types of training workshops which would be the most useful and practical. Further decisions about who should deliver the intervention, intervention format and setting, session frequency duration and fidelity were discussed with this group, and decisions were made accordingly. Arranging sessions for delivery of the training also involved working closely with a consultant obstetrician from the Trust where the intervention was being delivered. This provided invaluable support particularly during the development and recruitment for the delivery of the training, which otherwise would have proven to be very challenging due to the limited time available for training and shift patterns of maternity healthcare professionals.

The final version of the training intervention and schedule was piloted with midwives and obstetricians and suggested changes to the layout of the training session (such as beginning the session by a group discussion of what constitutes an adverse event and incorporating the role-play element at the end of the session) were made. The training intervention aimed to enhance maternity healthcare professional's skills with the disclosure of adverse events within the UK. The objectives of the training intervention were to:

1. To improve knowledge of adverse event disclosure, which includes the legal obligations within the Duty of Candour guidance that healthcare professionals are expected to adhere to when disclosing adverse events, and how to deliver this using a patient-centred approach.
2. To increase confidence to disclose adverse events to patients and/or their family.

3. To increase awareness of the emotional responses that healthcare professionals may encounter after being involved in an adverse event and understand some of the psychological strategies that can be used to manage with these.

4.5.3 Curriculum content

The training intervention was designed as a 3-hour training workshop for obstetricians and midwives working within maternity. Based on the above-mentioned theories and research evidence discussed in previous chapters, the training included a mixture of interactive lecture-based components with facilitated group discussions and exercises. The group discussions provided healthcare professionals with the opportunity to share experiences and thoughts. A number of different aspects of the workshop are dedicated to providing participants with the opportunity to review anonymised, real-life clinical case studies and have group discussions based on these. This also allows participants to share their own experiences. The case studies were developed with the assistance of consultants to ensure these were clinically relevant. The training intervention consisted of the following components:

(1) Defining adverse events, the principles of the Duty of Candour, patient's expectations of disclosure and research evidence on adverse event disclosure.

(2) Exploring the emotional impact of involvement in an adverse event.

(3) Psychological self-management strategies to feel calmer and more confident to disclose to the patient and/or family.

Defining adverse events, the principles of Duty of Candour, and research evidence on adverse event disclosure

This first component is interactive and lecture-based. Participants are encouraged to share their ideas as to what constitutes an adverse event and the definition of an adverse event within a clinical context is then outlined. Participants are then encouraged to discuss and feedback to the rest of the group, their current understanding of the Duty of Candour regulation and what it means to them. The principles of Duty of Candour and the importance of adhering to this legal requirement is then discussed. The statutory Duty of Candour introduced in 2015 within the UK, now applies to all NHS organisations and all other CQC registered providers. The statutory Duty of Candour states that when patients are exposed to moderate harm (or worse), healthcare professionals have a legal duty to offer timely information on what has happened and to provide an apology whether or not a complaint has been made. These events must also be reported for investigation to avoid similar incidents in future, and leaders must encourage a culture of reporting and learning. Following on recent research and evidence from the literature on

adverse event disclosure are discussed. This includes the importance of disclosure, the benefits of conducting disclosure, consequences of non-disclosure, and barriers to disclosure faced by healthcare professionals, and patient's expectations of disclosure and how their needs can be met during disclosure. The research evidence discussed in this section is taken from findings from the systematic review conducted in chapter 2, and the interview study conducted in chapter 3.

Development of an adverse event guidance document

As part of the training, an A4 educational guidance document (figure 4.1) was developed which outlines a structured approach to disclosing adverse events to patients.

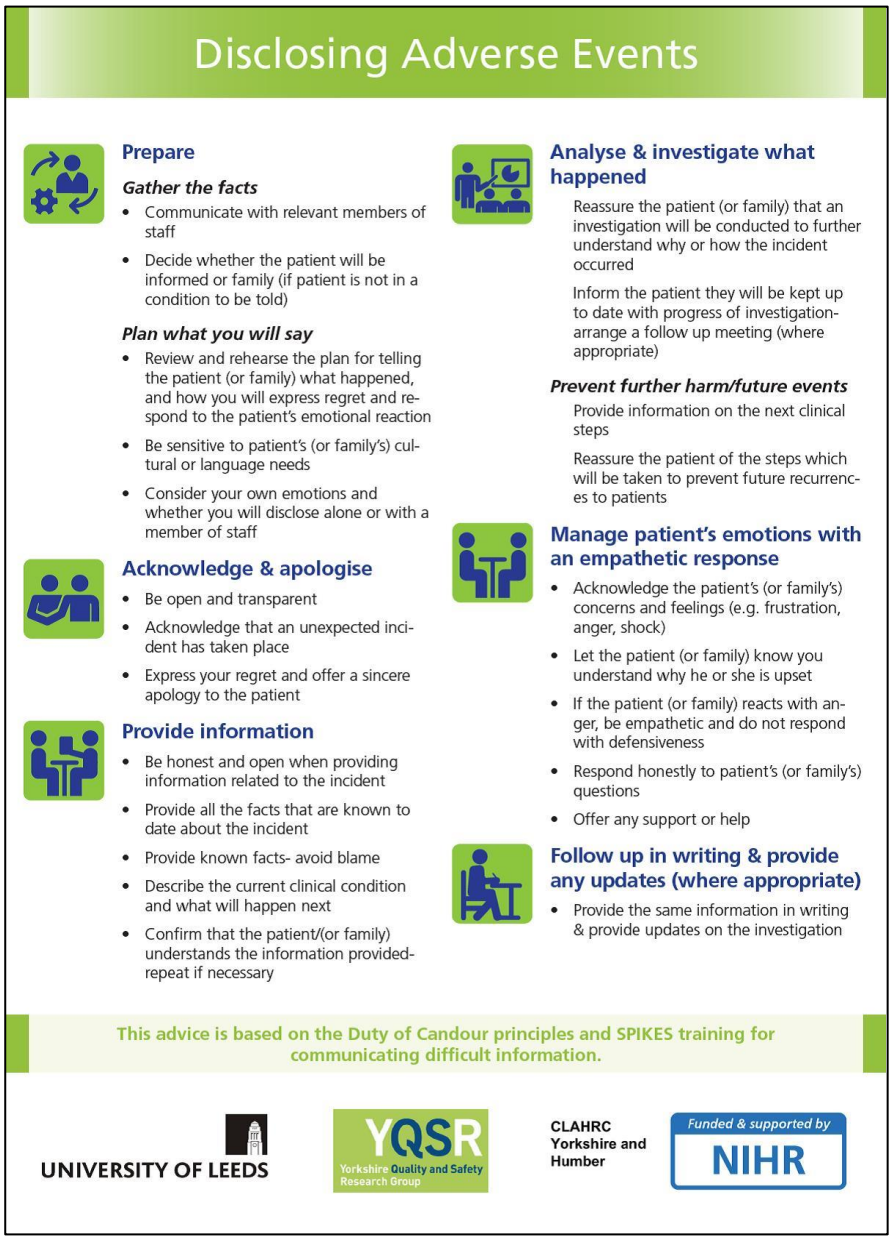


Figure 4. 1: Educational guidance document

This guidance combines the legal principles of Duty of Candour (CQC, 2015) with the 'SPIKES' framework (figure 4.2) for breaking bad news, which currently exists within the literature. SPIKES is a 6 step protocol where the goal is to enable the healthcare professional to fulfil and cover the most important objectives of the conversation when disclosing bad news to a patient or their family, whilst being sensitive to the needs of the patient (Baile et al., 2000).

The SPIKES protocol is a common template for breaking bad news that healthcare professionals can utilise as a starting point if they are unsure of how to proceed (Baile et al., 2000; Buckman, 2005; McFarlane, Riggins & Smith, 2008). Breaking bad news is a task that often must be

completed in the context of a busy clinical scenario, with less than optimal time and conditions.

Although not all communication involving breaking bad news can follow an exact protocol, the considerations of the SPIKES protocol can be helpful (Eggly et al, 2006). Research has suggested that there are a number of benefits of using a protocol to aid difficult conversations. The SPIKES has been shown to improve the confidence of healthcare professionals who use it when breaking bad news to patients (Bailie et al., 2000). Evidence from the literature also suggests that having a plan of action is useful for providing structure for difficult conversations (Kaplan, 2010). Understanding the processes involved in disclosure and approaching it as a stepwise procedure can help to improve the task of disclosing an adverse event (Bailie et al., 2000). Following an evidence based-protocol while integrating empathetic communication can assist in making the difficult task of breaking bad news more comfortable for the healthcare professional and helps to improve the communication between the patient and family (Rosenzweig, 2012).

SPIKES: A six-step protocol for delivering bad news

SPIKES (Baile et al., 2000) is widely used by healthcare professionals to communicate difficult news to patients in a *clear, supportive* and *compassionate* manner. The following six steps are included in this protocol:

1. **S – SETTING** up the interview
2. **P** – Assessing the patient's **PERCEPTION**
3. **I** - Obtaining the patient's INVITATION
4. **K –** Giving **KNOWLEDGE** and information to the patient
5. **E**- Addressing the patient's **EMOTIONS** with empathetic responses
6. **S**- **STRATEGY** and **SUMMARY**

Figure 4. 2: SPIKES framework

There is an evident difference between breaking bad news and disclosing an adverse event. Breaking bad news involves disclosing unfavourable medical information related to the patient's medical condition to the patient or their families. On the other hand, adverse events disclosure involves disclosing an unexpected or unintended incident which occurred as a result of the care or the services provided rather than the underlying condition. However, breaking bad news and disclosing adverse events both fall under the category of disclosing unfavourable information to a patient and/or their families. Disclosure is an important skill and similar to breaking bad news, disclosing an adverse event to a patient and/or their family is a complex communication task. Therefore, as part of the training intervention, a checklist to assist with the disclosure process was developed.

The aim of combining the legal principles of Duty of Candour (CQC, 2015) with the 'SPIKES' framework for breaking bad news is to help ensure that information related to the adverse event is delivered in a comprehensive and compassionate manner, whilst also adhering to the legal requirements of disclosure. The aim of this flexible guidance document is to support and aid healthcare professionals with the adverse event disclosure process. This component ends by providing an example and general instructions of how a disclosure conversation can be conducted using a patient-centred approach, whilst using the Duty of Candour principles.

Exploring the emotional impact of involvement in an adverse event

The effective disclosure of an adverse event to a patient and their family relies upon being in the correct frame of mind and mentally prepared. However, for many healthcare professionals, being involved in a significant event triggers an intense emotional stress response (Sirriyeh et al., 2010). Distress, panic, self-doubt, fear, guilt and shame are all commonly experienced in the aftermath of an adverse event (Sirriyeh et al., 2010; Schwappach & Boluarte, 2008). Whilst in the grip of such strong reactions, composing and preparing oneself for a disclosure conversation with the patient and their family involved can be incredibly difficult. Therefore, a core aspect of the intervention acknowledges these difficulties and supports healthcare staff with psychological strategies to manage their own emotions after being involved in an adverse event. It draws upon existing extensive work surrounding the 'Second Victim' phenomenon (e.g. Harrison, Lawton & Stewart, 2014; Stewart, Lawton & Harrison, 2015; Sirriyeh et al., 2010; Seys et al., 2013; Johnson, Panagioti, Bass, Ramsey & Harrison, 2017; Harrison et al., 2015).

This part of the intervention focuses on 'preparing yourself' for a disclosure conversation, and provides participants with:

Information on the potential impact of being involved in an adverse event, both personally and professionally.

This section aims to increase participants' awareness of the personal and professional impact of being involved in an adverse event. A group case study is used as a platform to encourage discussions and personal reflections of being involved in such events, in a supportive, confidential setting. In doing this, the goals are to reassure participants that there is a well-documented, natural human response to being involved in such incidents, to help prepare them for what to expect and also reduce feelings of isolation.

Psychological self-management strategies to feel calmer and more confident to disclose to the patient or family

This section provides further reassurance that the strong, natural responses experienced after an event can be attenuated by using simple strategies. The Cognitive Behavioural Therapy (CBT) model (figure 4.3) is introduced, positioning it as a useful personal self-management tool. The CBT model is populated with clinically relevant examples to illustrate how particular cognitive appraisals or narratives individuals construct about the adverse event can trigger intense emotional and physiological responses. For example, harsh thoughts (e.g. 'I can't believe I did that to the patient. I'm totally incompetent. I'm going to lose my job!'), are threat-oriented, therefore they trigger the fight-flight-freeze response. Corresponding physiological changes then impede functioning (e.g. we have difficulty concentrating, are forgetful, are avoidant, make more mistakes) and this cycle continues.

The different strategies that can be used to interrupt this 'fight-flight-freeze' response are examined and practised throughout the session. These strategies are broadly based around (a) reducing threat oriented thoughts and (b) switching off threat-based physiology.

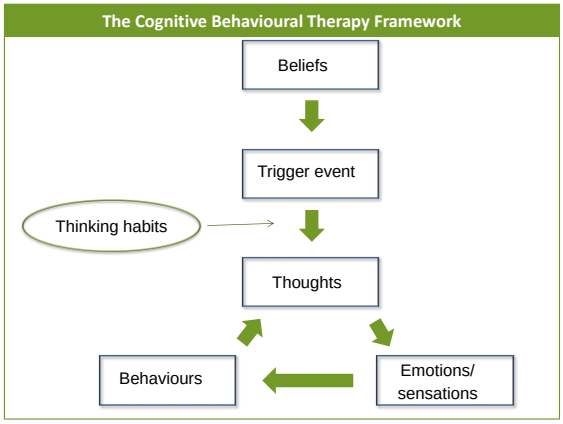


Figure 4. 3: The cognitive Behavioural Therapy Model

Reducing threat-oriented thoughts involves firstly recognising a toxic thought (e.g. *"I'm a terrible doctor! Why am I doing this job?. I can't face the family"*) and formulating a more adaptive, compassionate statement to counteract it (e.g. *"I'm not terrible, I've done loads of these procedures well and helped many families. I'm human. The family will be upset but I can draw on my training to guide me through this."*) There is strong evidence that engaging in this more compassionate, cognitive reappraisal of situations increases self-esteem (Amritsu & Hofman, 2017), decreases depression (Philpot & Bamburg, 1996) and is superior to anti-depressants,

light therapy, counselling or yoga for reducing repetitive, negative thinking (Spinhoven et al, 2018). This element also focuses on reinforcing that participants are able to successfully conduct disclosure and that they can and will succeed with disclosure. Participants are provided with a few minutes to practice self-encouragement to support them with the disclosure.

A simple controlled breathing technique is introduced and practised, which **switches off threat-based physiology** by stimulating the 'rest and digest (parasympathetic) nervous system. Just a few minutes of slow, measured breathing has been found to have an immediate effect on reducing blood pressure and heart rate (Pramanik, Pudasaini & Prajapati, 2010). With more regular practice, there is evidence that it reduces anxiety (Chen, Huang, Chien & Cheng, 2017), depression (Valenza et al, 2014) and even procedural pain and anxiety in burns patients whilst having their dressings changed (Park, Oh & Kim, 2013). This element of the session ends by providing an opportunity to practice disclosure skills through the use of role-plays, using a case study.

Signposting for further support with adverse events

This element of the workshop concludes by signposting healthcare professionals to further support on adverse events. One type of support participants are signposted to includes a second victim website (https://secondvictim.co.uk/) which provides additional support for coping with adverse events. As discussed in further detail in previous chapters, the term second victim is used to describe the emotional suffering that is experienced by healthcare professionals when they are involved in adverse events (Wu & Steckleberg, 2012). This website has been recently developed by researchers in collaboration with stakeholders including the Royal College of Physicians as well as second victims. This is a particularly useful resource which provides key information and signposting for second victims, colleagues and managers who wish to help an individual in this situation and those who are seeking to develop more strategic, organisational and system-level support.

A logic model is displayed below (figure 4.4) which presents a summary of how the training intervention to enhance maternity healthcare professional's skills with disclosure is intended to work and describes the relationships between resources, activities and results.

The problem *(Why is there a need for change?)*	**Inputs** *(Materials used by the intervention)*	**Activities** *(What the intervention does with the resources to direct change)*	**Outcomes** *(Expected results of taking part in the intervention)*		
			Short-term outcome	Intermediate outcome	Long-term outcome
Guidance& training on how to conduct disclosure not available. A need to develop skills on how to conduct an effective disclosure. Lack of familiarity with Duty of Candour. Need to understand emotional consequences of disclosure & strategies to manage negative emotions.	3 x 3 hour face-face training intervention workshops. Will be delivered by three facilitators. (Including two health psychologists with a research background in adverse event disclosure and patient safety, and a consultant obstetrician to provide clinical	Provide information about disclosure. Provide information on the benefits of disclosure and the consequences of non-disclosure. Provide instructions on how to conduct disclosure using a patient centred approach.	Improved knowledge of adverse event disclosure. Improved confidence to disclose adverse events. Increased awareness of the emotional consequences of being involved in an	Increased disclosure rates. Improved quality of disclosure. Reduced negative emotional consequences for healthcare professionals.	Improved patient ratings of disclosure. Decreased litigation rates.

	context.). A training presentation. Disclosure guidance document. Case studies for the 2 group discussions.	Provide verbal persuasion about capability. Encourage and provide opportunity to practice self-talk/self-encouragement (silently) to support disclosure. Provide opportunity to practice disclosure with colleagues with feedback *(in the form of role plays, using case studies).* Provide the links between being involved in an adverse event and the emotional consequences that may occur. Provide explanation for these emotional	adverse event. Awareness of strategies to manage negative emotions.		

		consequences using the CBT model framework. Advise ways to reduce negative emotions to facilitate effective disclosure *(including reducing threat-oriented thoughts, forming adaptive self-statements and behavioural experiments such as breathing exercises).*			

Figure 4. 4: A logic model presenting a summary of the training intervention

4.6 Delivery of intervention

Selecting mode and style of delivery

The intervention was designed to be delivered as a face-face group intervention. This mode of delivery was selected following considerations of the evidence, practical issues identified, analysis of qualitative interviews with maternity healthcare professionals (chapter 3), and discussions with obstetricians and midwives during the intervention development and planning stages. It was decided that an interactive delivery style should be utilised, to encourage healthcare professionals to reflect on and discuss their own experiences. The training combines traditional lecture style learning approaches with group exercises, discussions and reviewing of case studies to maximise effectiveness. Three facilitators will conduct the workshop; two health psychologists with a research background in adverse event disclosure and patient safety, and a consultant obstetrician to provide clinical context. The intervention was developed to be delivered to small groups of healthcare professionals. The optimal group size was set between 8-12 healthcare professionals. This was felt appropriate to enable sufficient individual attention and support, particularly during the practical aspects of the training. An outline of the intervention is presented in Table 3 which includes timings, activities and materials included within the intervention.

Table 4. 1: Schedule of training intervention session

Timings (minutes)	Activities	Materials
00:00 –10:00	*Welcome & confidentiality-contracting* *Welcome the group and discuss who we are and briefly outline what the session will cover.* *Explain that this workshop can be viewed as a useful space where people can feel safe to discuss experiences.* *Ask everyone if they are happy to keep confidential what is discussed in the room.* *Explain that this is part of a PhD project and whether the group would be happy to complete some anonymous questionnaires.*	Slide one: Introduction and welcome Slide two: Plan for the session Slide 3: PhD work and data collection
10:00 – 15:00	Background to disclosure Provide a background to adverse events and disclosure and the importance of training in this area.	Slide 4: Adverse events – background

15:00- 25:00 25:00-40:00	Defining adverse events & Duty of Candour principles Group exercise 1: The group are encouraged to share their ideas of what constitutes an adverse event. Definition of an adverse event is then provided. The group are encouraged to share their current understanding of Duty of Candour regulation. The Duty of Candour principles are then discussed and the importance of this regulation is discussed.	Slide 5: Group exercise 1 Slide 6: Disclosure of adverse events
40:00 -50:00	Research evidence on current adverse event disclosure practices Barriers to adverse event disclosure faced by healthcare professionals. Discussions with the group surrounding the barrier 'lack of training available/absence of disclosure education'.	Slide 8: Barriers to disclosure
50:00-55:00	Overview of the different elements of the workshop	Slide 9 & 10: Overview

	The workshop will include the following three elements: -'Preparing yourself' - 'Preparing your approach' -'Do it' -Optional reflection exercise	of workshop
55:00-65:00 65:00-80:00	'PREPARING YOURSELF' The emotional impact of involvement in an adverse event Information and research evidence on the personal and professional impact of being involved in an adverse event are discussed. Group case study 1 Used to encourage discussion and personal reflection of being involved in an adverse event. Group are encouraged to consider what thoughts might be triggered by the adverse event and how they might feel in the aftermath of the event.	Slides 10, 11 & 12: Emotional impact of involvement in an adverse event Slide 13 & 14: Group case study Post-it notes to write down reflections
80:00-95:00	BREAK	
95:00-125:00	Psychological self- management strategies to feel calmer and more confident to disclose adverse events Managing your thoughts – psychological perspective	Slides 15 & 16: Psychological

	Cognitive behavioural therapy (CBT) framework is introduced and explained in relation to adverse events. CBT framework is positioned as a useful personal self-management tool. Two psychological self-management strategies are examined, demonstrated and practised: 1. Ways to reduce threat-oriented thoughts – practised for 5 minutes. 2. Breathing techniques – practised for 2 minutes.	perspectives on the impact of thinking Slides 17, 18 & 19: Cognitive behavioural therapy framework model Slides 20, 21 & 22: Psychological self-management strategies
125:00-130:00	Signposting for further support with adverse events Group are encouraged to share the types of support they are currently aware of. Group are then signposted to a particular source of support; www.secondvictim.co.uk	Slide 23: A new national resource – Second victim support
130:00-140:00	'PREPARING YOUR APPROACH' Background knowledge Discuss the importance of disclosure	Slide 24: The importance of disclosure

	Research evidence discussing patients expectations after an adverse event	Slide 25: Patient expectations after an adverse event
140:00-145:00	Guidance checklist The group are each provided with the Duty of Candour guidance checklist (figure 1). The development and aims of the checklist are explained.	Slide 26: Guidance checklist Duty of Candor checklist handout
145:00-155:00	Applying knowledge into practice Group case study 2 The group are provided with a clinical case study to role play in pairs. They are reminded to provide feedback to each other. They are also asked to consider the following questions and be prepared to feedback to the rest of the group: *-Think about disclosure from your point of view – how would you be feeling?* *-Think about disclosure from the patient/family's point of view- how would they be feeling?* *-How would you approach disclosure? What exactly would you say to the patient/family?*	Slides 27-28: Group case study 2 Post-it notes to write down any thoughts
155:00-165:00	Rounding up: Reviewing learning outcomes	

	Wind the session down by recapping the learning outcomes for the session. Ask the group the following: What for them has been the most significant aspect we've covered today? Is there a particular "take-home message" for them personally?	

4.7 Requirements for implementation

Access to suitable premises is required for the implementation of the intervention. These must-have PowerPoint facilities and allow for a group of 8-12 maternity healthcare professionals to be seated comfortably. It is also important to arrange flexible workshop sessions at a time where maternity healthcare professionals will be not be restricted to attend due to their working hours. In-depth discussions with a consultant obstetrician revealed that the most practical time to deliver these sessions would be during a day where healthcare professionals had protected learning time. At the main intervention delivery site, obstetricians and midwives had two days a month which contributed towards protected training time.

4.8 Conclusion

This chapter has described the design and development of an intervention to support midwives and obstetricians within the UK with the disclosure of adverse events. The intervention was developed based on the MRC guidelines (MRC, 2008) and aimed to enhance midwives and obstetricians skills with the disclosure of adverse events. A number of theoretical approaches were combined with existing research evidence, and incorporated evidence from the recent Duty of Candour disclosure policy within the UK. The training intervention which was designed was a 3-hour training workshop, and included a mixture of interactive lecture-based components with facilitated group discussions and exercises.

Chapter 5: The acceptability and feasibility of a training intervention to support maternity healthcare professionals with the disclosure of adverse events

5.1 Chapter summary: *The previous chapter described the development of a training intervention to enhance maternity healthcare professional's skills with the disclosure of adverse events. This chapter presents a feasibility study that was conducted to explore the acceptability and feasibility of this intervention. The results of this study are presented and implications for future development are discussed.*

5.2 Background

The findings from previous research on adverse event disclosure have identified that a priority for supporting healthcare professionals with the disclosure process is to provide training on adverse event disclosure (chapters 2 and 5). A systematic review and meta-ethnography were conducted to synthesise the qualitative literature on the views and experiences of patients/family members and healthcare professionals on the disclosure of adverse events (chapter 2). The findings from this revealed that although healthcare professionals advocated the disclosure of adverse events, they faced several barriers that hindered appropriate disclosure practices. One of these barriers was a lack of skills and training available on conducting adverse event disclosure. A qualitative interview study with midwives and obstetricians within the UK revealed that although healthcare professionals believed that honesty, transparency, and openness were important principles of disclosure, they struggled with this process (chapter 4). Within the UK, there is currently a lack of clarity and support surrounding the disclosure process. There is a need for support and guidance from an organisational level for factors such as the Duty of Candour regulation. Maternity healthcare professionals expressed a need for educational training specific to adverse event disclosure. A distinct need for training that is specific to adverse event disclosure was expressed by both midwives and obstetricians and they reported that they had not previously received this type of training. The relevant existing evidence on adverse event disclosure interventions was identified and previous intervention studies to improve or promote adverse event disclosure were conducted in the USA (Gunderson et al., 2009; Halbach & Sullivan, 2005; Kiersma et al., 2009; Madigosky et al., 2006; Moskowitz et al., 2007; Paxton & Rubinfeld, 2010; Wayman et al., 2007; Sukalich et al., 2014; Langer et al., 2016; White et al., 2017; Bonnema et al., 2009),

Canada (Posner & Nakajima, 2011) and South Korea (Kim et al., 2017) with no intervention studies identified within the UK.

Disclosure is imperative as healthcare professionals have a responsibility and duty to be open and honest with patients when things go wrong within their care. Disclosure is important for both patients and healthcare professionals. Patients have the right to know what has happened to them, providing an ethical imperative to disclose adverse events (O'Connor et al, 2010). It maintains trust between patients and healthcare professionals, and failure to disclose can result in increased litigation by patients (Wu et al., 2013; Gallagher et al., 2007). It has also been argued that disclosure provides an outlet for the emotional consequences that healthcare professionals experience during involvement in an adverse event (Hall & Scott, 2012;). As a result of the detailed preliminary work discussed above, taking into account healthcare professional's needs and preferences, and informed by theoretical frameworks, a training intervention to enhance maternity healthcare professional's skills with the disclosure of adverse events within the UK was developed. The development of this intervention is described in great detail in chapter 5. The purpose of the training intervention was to enhance participant's skills for disclosing adverse events. After developing this training intervention, it was necessary to explore the feasibility and acceptability of this intervention.

Feasibility studies are pieces of research carried out before the main study and answer the question, 'Can this be done?' (Cope, 2015) and are intended to guide the planning of larger-scale studies. Feasibility studies focus on the process of developing and implementing interventions and results in the preliminary examination of participants responses to the intervention (Orsmond & Kohn, 2015). These types of studies are used to estimate important parameters that are needed to design the main study. These can include the willingness of healthcare professionals to recruit participants, follow up rates, response rates to questionnaires, the time needed to collect and analyse data (National Institute for Health Research, 2019), intervention acceptability, the suitability of the study procedures, and evaluation and refinement of data collection procedures and outcome measures (Orsmond & Cohn, 2015). Feasibility studies can help to identify any modifications regarding the intervention before a larger trial as well as the research methodology (Thabane et al., 2010). Based on the definition mentioned above, the current study is a described as a feasibility study which is conducted in preparation for a future, larger randomised wait-list control trial to assess the effect of the training intervention (Elridge et al., 2016).

5.3 Aims

5.3.1 Primary aims:

1. To explore the acceptability of a training intervention to enhance maternity healthcare professionals' skills with the disclosure of adverse events.
2. To explore the feasibility of delivering this intervention and feasibility of collecting research data.

5.3.2 Secondary aim:

To assess the extent to which the training intervention has the potential to enhance knowledge of adverse event disclosure and self-efficacy (confidence) to disclose.

5.4 Objectives

1. To explore the acceptability of the format and content of the training intervention and the perceived usefulness of the intervention.
2. To explore the feasibility of delivering the intervention *(including participant uptake (which includes all participants approached and eligible for the intervention, and those who were successfully recruited for the intervention) and feasibility of delivering the intervention within the allocated time).*
3. To explore the feasibility and appropriateness of the data collection procedures (*including the feasibility of completing baseline and follow-up questionnaires, and follow-up response rates, and retention rates).*
4. To explore the magnitude of change on knowledge and self-efficacy outcomes to inform the parameters of a subsequent randomised wait-list control trial. The feasibility of the full trial design was not assessed in this study.

5.5 Methods

5.5.1 Study design

A mixed-methods approach was used to assess the acceptability and feasibility of the training intervention, and the feasibility and appropriateness of the data collection methods, where both quantitative and qualitative data were collected and analysed. The quantitative element of this study involved a pre-post study design to explore the magnitude of change in knowledge and self-efficacy outcomes. The quantitative element

also involved exploring participant's feedback on the training workshop through the use of a feedback questionnaire. The qualitative element involved the use of follow-up semi-structured interviews to understand participant's experiences and perceptions of taking part in the training intervention and obtain feedback to improve the intervention in the future. This is consistent with the MRC guidelines for complex interventions which suggest that a mixture of qualitative and quantitative methods are likely to be needed to assess feasibility (MRC, 2008). Evaluation of a training program is an effort to determine whether the training program objectives have been achieved, by gathering information to assess the efficiency of the program (Musal et al., 2008). As well as exploring the feasibility of delivering the training, the training programme was also evaluated with regard to its acceptability and impact. The outcome measures for this study were informed by the Kirkpatrick model (Smidt, Balandin, Sigafoos & Reed, 2009) for assessing training interventions. This model suggests that evaluations should collect data at the following four levels:

(1) Reaction

This level of evaluation typically involves participants completing a post-course evaluation of their impressions of the training. This level of evaluation does not measure what participants have learnt but aims to understand participant's opinions and reactions to the training (Smidt et al., 2009).

(2) Learning

The second level of evaluation involves measuring what participants have learnt in terms of knowledge and skills. This level of evaluation allows participants to demonstrate their understanding of specific skills or knowledge within the learning programme (Smidt et al., 2009)

(3) Behaviour

The third level of evaluation is behaviour or performance and involves assessment of the trainee's ability to use their newly learned knowledge or skills in the workplace. This level of evaluation aims to determine whether participants use their newly acquired skills when they return to their work environment (Smidt et al., 2009).

(4) Results

The fourth level is a measure of the long term impact that the training has had overall, including financial and morale impacts (Smidt et al., 2009).

For Level 1, feedback was collected from participants regarding the perceptions of the intervention immediately following the workshop, using a feedback questionnaire. Qualitative telephone interviews were also conducted up until two weeks after taking part in the training intervention to further understand participant's perceptions of the training and to obtain feedback to improve the intervention in the future. For Level 2, participants completed a multiple-choice questionnaire (knowledge questionnaire) and a self-efficacy questionnaire which were related to adverse event disclosure to explore whether there was any change in knowledge and self-efficacy. Both questionnaires were completed before and after taking part in the training. Whilst data which directly pertained to Level 3 (behaviour) was not collected, within the follow-up interviews, participants were asked what they had learnt in terms of knowledge and skills, and how they would apply these skills or knowledge within their healthcare organisation. Due to the time restrictions of this PhD research, it was not possible to measure Level 4 (results) as this would require a long term follow up of participants to measure the long term impact of the training (this is discussed in further detail in the discussion chapter).

5.5.2 Identification, sampling, and procedure

5.5.3 Ethical and Governance approvals

This study received ethical approval from the University of Leeds Research Ethics Committee, School of Psychology (ethics reference number: PSC-415). Research and Development approval and Health Research Authority governance approval was not required for this study as there was only one recruitment site and research at this Trust was classed as service development.

5.5.4 Sampling

Participants were eligible to take part in the training intervention if they were a midwife or an obstetrician working at the NHS recruitment trust. Participants were only excluded if they did not meet these criteria. Based on existing recommendations which suggest that sample sizes between 24 and 50 are reasonable for feasibility studies (Sim & Lewis, 2012; Julious, 2005), this study aimed to recruit 36 participants in total (18 obstetricians and 18 midwives). It was planned that 3 workshops would be run with 12 participants in each workshop (each with 6 midwives and 6 obstetricians).

5.5.5 Procedure

Potential participants were sent the recruitment email by the designated contact within the Trust who had agreed to help support the research. Potential participants were also made aware of this training intervention study in their scheduled teaching sessions by the designated contact. Those participants who expressed an interest in the study contacted the researcher by email, who was able to answer any questions. The researcher confirmed that the potential participant was eligible to take part in the study. These potential participants were provided with a study pack, which contained the participant information sheet (see Appendix 8), participant consent form (see Appendix 9), and information regarding the session dates, location, time, and duration. These were provided at least 24 hours in advance of taking part in the training intervention. Participants were sent an email reminder a week before the workshops were due. Upon arrival, to ensure that participants felt welcome, they were provided with refreshments including tea, coffee, and biscuits. At the beginning of the session, before the workshop session began, participants were asked to complete a multiple-choice questionnaire assessing knowledge of adverse event disclosure (see Appendix 10) and a questionnaire measuring self-efficacy to disclose (see Appendix 11). Once the training intervention was completed, participants were asked to complete the same multiple-choice and self-efficacy questionnaire as well as a feedback questionnaire (see Appendix 12 for feedback questionnaire).

At the end of the training intervention, participants were provided with the opportunity to sign up to take part in a follow-up telephone interview lasting approximately 30 minutes. This was to gain a further in-depth understanding of participant's experiences and perceptions of taking part in the training intervention and to obtain feedback to improve the intervention in the future.

Those participants who had not initially signed up to take part in the follow-up interviews were sent a reminder email by the researcher after the training. A mutually convenient time was arranged with those who expressed an interest. Participants were able to take part in the follow-up interviews anytime up until two weeks after the training intervention. It was made clear to participants that taking part in the follow-up interviews was optional. Participants were informed that this was an opportunity for them to provide their views and feedback on the training workshop they had taken part in. Participants received an incentive in the form of a £25 amazon voucher for taking part in the follow-up interview. The researcher interviewing ensured that all follow-up interviews were conducted and recorded in a confidential room where only the researcher was present.

5.6 Intervention

5.6.1 Setting

All three of the training intervention sessions were delivered at the NHS recruitment site for the convenience of participants. Each of the intervention sessions were delivered in a multipurpose room, which had PowerPoint facilities, chairs, and plenty of space to move around. These rooms were booked in advance by the designated contact at the Trust where the intervention was being delivered.

5.6.2 Format and delivery

The intervention compromised of a three-hour training session for midwives and obstetricians. All participants received a group intervention that aimed to support them with the disclosure of adverse events. Each training session was delivered by the candidate (a psychologist by background), and an occupational psychologist with the support of a consultant obstetrician. The candidate and occupational psychologist will be referred to as the course leaders from here onwards. The course leaders delivered all aspects of the training intervention sessions. The consultant obstetrician provided support throughout the session and in particular, was able to answer any obstetrics and gynaecology specific questions participants had. The consultant obstetrician provided instrumental support in discussing the case studies (more information provided in chapter 4) with participants. Each session was delivered using the same format and content and lasted approximately three hours including a tea/coffee break.

5.6.3 Content

The training intervention included a mixture of interactive lecture-based components with facilitated group discussions and exercises. The training intervention consisted of the following components:

(1) Defining adverse events and principles of Duty of Candour

(2) Exploring the emotional impact of involvement in an adverse event

(3) Psychological self-management strategies to feel calmer and more confident to disclose to the patient and/or family

Detailed information about the intervention development, content, format, structure, and delivery has been described in chapter 4.

5.6.4 Development of session plans and support materials

Detailed session plans were developed to aid delivery and facilitate learning. These have been described in more detail in chapter 4. The training intervention and all materials including questionnaires were piloted with a group of 4 midwives and 5 obstetricians. Minor changes and refinements were made before delivering the first training intervention session. These included changes to some terminology within the training and slightly altering the format of the training.

5.7 Measures

1. Acceptability and perceived usefulness of the training intervention

To assess acceptability and perceived usefulness of the training intervention, study participants completed an anonymised feedback questionnaire at the end of the training workshop, which consisted of eight items. Participants were asked to rate the following eight items on a five-point Likert scale which ranged from 'strongly disagree' to 'strongly agree': *'The training was effective in its delivery', 'The training was an effective use of time', 'The training provided an adequate time to learn the concepts and skills', 'The training described skills which will be applicable in my hospital', 'The background information on adverse event disclosure was useful', 'The case-based group discussions were useful', 'The guidance document for adverse event disclosure was useful'* and *'The awareness of psychological strategies to reduce emotional distress faced after an adverse event was useful'*.

Participants were asked a further open-ended question: 'Do you have any comments related to this training? (E.g. were there any aspects of the training that you did not find useful? Is there anything else that you would have liked to see included in the training?)? Participants were asked to complete the questionnaire and to ensure anonymity, they were asked to leave them at the front desk before leaving, rather than hand them to the course leaders. Once all participants left, these were then collected by the course leaders.

2. Feasibility of delivering the intervention

To assess the feasibility of delivering the training intervention, the following feasibility indicators were included: **1).** Participant uptake *(includes all participants approached and eligible for the intervention, and those who were successfully recruited for the intervention)* and **2).** Feasibility of delivering the intervention within the allocated time.

3. Feasibility and appropriateness of the data collection procedures

To assess the feasibility and appropriateness of the data collection procedures, the following indicators were included: **1).** Feasibility of completing the questionnaires which were determined by the number of questionnaires completed, missing items on questionnaires, and the time taken to complete the questionnaires and **2).** Follow-up response rates which were determined by the number of individuals who chose to take part in the follow-up interviews and **3).** Recording retention rates of participants from the beginning of the training intervention until the end of the training intervention, including the number of people who initially signed up to take part but did not end up attending.

4. Knowledge of adverse event disclosure

As there was no tool available to assess knowledge of adverse event disclosure based on UK disclosure practices, a 6-item multiple-choice questionnaire was developed, where one answer was correct and three incorrect. Participants were instructed to tick one response which they believed was correct for each of the 6 questions. Each participant's knowledge score was calculated by adding up the number of correct answers. Each participant had a pre-intervention and post-intervention knowledge score. The questionnaire was designed to assess participant's knowledge of the current adverse event disclosure practices within the UK. The questions developed were based on the current Duty of Candour regulation (CQC, 2015) and discussions with a consultant obstetrician and a senior midwife. The questionnaire was piloted with two midwives and two obstetricians and refinements were made. Copies of the multiple-choice questionnaire with the correct answers highlighted, were available for participants to collect from the researcher once they had completed and handed in their completed knowledge and self-efficacy questionnaires.

5. Self-efficacy (confidence) in disclosure skills

Domain-based assessments of perceived self-efficacy (confidence) are strong predictors of performance (Bandura, 1997). Self-efficacy theory is a subset of a well-established social cognitive theory (Bandura, 1986) which has previously been used in assessments of adverse event disclosure (Bonnema et al., 2009). An 8-item instrument to assess healthcare professionals ' perceived disclosure self-efficacy was developed based on a published existing instrument (Bonnema et al., 2009), where modifications were made to ensure it was applicable for the current study. The items were designed to assess healthcare professionals' self-efficacy in their (a) understanding of the importance of disclosure, (b) understanding of the steps that should be included in the disclosure conversation, (c) knowledge of the professional Duty of Candour, (d) ability to

communicate a statement that an unexpected adverse event has occurred, (e) ability to provide an expression of regret/empathy to the patient (or family), (f) ability to answer questions posed by the patient (or family) about the adverse event, (g) ability to manage emotions that patients (or family) may exhibit when they are informed of the adverse event, (h) ability to manage own emotions when disclosing an adverse event to a patient (or family). The training intervention covered all the above-mentioned elements related to disclosure. Healthcare professionals rated their confidence for each of the questions on a four-point Likert scale (1= not confident at all, 2 = a little confident, 3= confident, 4= very confident). A total self-efficacy score was calculated for each participant by adding up Likert scores for each question. Each participant had a pre-intervention and post-intervention self-efficacy score. Internal consistency describes the extent to which all the items in a questionnaire measure the same concept or construct, and is therefore connected to the inter-relatedness of the items within the questionnaire. Internal consistency was determined before this study took place by pilot testing the questionnaire and was measured using Cronbach's alpha. A co-efficient value of 0.80 was produced, indicating that the items within the questionnaire had relatively high internal consistency.

5.8. Data collection

Both the information sheet and consent form highlighted that data would be collected from participants for research purposes. Participants were provided with the opportunity to ask any questions related to this before the sessions took place and any issues were clarified. Written informed consent was also obtained before each session commenced.

5.8.1 Demographic information

Basic demographic information was collected from each participant, which included gender, age, and work-specific demographics including profession and number of years worked in their profession.

5.8.2 Quantitative data analysis approach

All quantitative data was entered into IBM SPSS statistics (version 26). Quantitative data from the feedback questionnaire was analysed using descriptive statistics, where each of the Likert-type scale responses was reported in the form of frequencies, displayed in a graph. Paired samples t-tests were used to compare participant's pre and post-intervention knowledge assessment total scores and self-efficacy total scores. Participants had to complete all assessments to be included in the data analysis of each session. In order to determine which aspects of disclosure participant's self-efficacy improved, a non-

parametric test was chosen as the data was ordinal. The non-parametric test chosen was the Wilcoxon signed-rank test. A Bonferroni correction was applied to account for multiple comparisons resulting in a $p<0.006$ needed for statistical significance. Where participants had left before the session ended, the data for that participant was deleted from the analysis.

5.8.3 Qualitative data analysis approach

Semi-structured follow-up telephone interviews were conducted to understand participant's experiences and perceptions of taking part in the training intervention and obtain feedback to improve the intervention in the future. These interviews were based on an interview guide developed in discussion with the supervisory team and consultant obstetrician (see Appendix 13 for interview guide). Participants were asked questions related to their overall thoughts and perceptions of the training session including the different components if they perceived that they had learnt anything from the training, what they perceived as useful within the training, what did not go well, and what future improvements could be made.

The qualitative data were analysed using Thematic Analysis. This is a method for identifying, analysing, and reporting themes (patterns) within the data. One of the benefits of thematic analysis is that it is viewed as a flexible approach that is essentially independent of theory and epistemology and can be applied across a range of theoretical and epistemological approaches. The themes within the data were identified using an inductive analysis approach, where the themes identified were strongly linked to the data (Braun & Clarke, 2006; Patton, 1990). This approach involved coding the interview data without trying to fit it into a pre-existing coding framework or the researcher's analytic preconceptions (Braun & Clarke, 2006), and therefore this form of thematic analysis is viewed as data-driven. The thematic analysis process was based on the following six-phase approach as described by Braun and Clarke (2006); Familiarising yourself with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the report. The process of thematic analysis that was followed is previously discussed in detail within chapter 3. In qualitative research, as a concept, rigour can be thought of in terms of the quality of the research process. The more rigorous the process, the more trustworthy the findings are considered to be (Given, 2008). Analytic rigour and transparency were promoted and enhanced in several ways. The researcher and the supervisory team met frequently to discuss data collection and analysis. During the analysis, two transcripts were each independently analysed by two

members of the supervisory team as well as the researcher to ensure rigour. The sets of analyses were discussed and common codes were agreed upon.

5.9 Results

5.9.1 Participant characteristics

A total of 31 maternity healthcare professionals enrolled and took part in the training intervention (20 females and 11 males). Participants' ages ranged from 25 to 56 years and participants were recruited from the participating trust. All participants reported that they had not previously received training on adverse event disclosure *(n=31)*. In total, 3 training workshops took place. Workshop 1 (*n=8*) and workshop 2 (*n=11*) included only obstetricians, and workshop 3 (*n=12*) included both midwives (*n6*) and obstetricians *(n=6).* Participant demographic information is displayed in Table 5.1 below.

Table 5. 1: Participant demographic information

Workshop	Number of participants	Gender	Grade	Years worked in the profession	Age range
Workshop 1 *(Obstetricians only)*	8	*Females:* 37% *Males:* 63%	ST1: 25% ST2: 12% ST5: 25% ST7: 38%	*Ranged between:* 3 -15 years	26-40 years
Workshop 2 *(Obstetricians only)*	11	*Females:* 64% *Males:* 36%	ST7: 82% ST6: 18%	*Ranged between:* 7-15 years	35-45 years
Workshop 3 *(Obstetricians & midwives)*	12 *(6 midwives & 6 obstetricians)*	*Females:* 83% *Males:*	ST1: 17% ST2: 8% ST3: 8% ST7: 17%	*Obstetricians ranged between:* 1-10 years	*Obstetricians:* 25-38 years *Midwives:*

		17%	Band 6 (*midwives):* 42% Band 7 *(midwives)*: 12%	*Midwives ranged between:* 3-33 years	28-56 years

5.9.2 Objective 1: The acceptability of the format and content of the training intervention and the perceived usefulness of the intervention.

All 31 participants completed the feedback questionnaire, where they responded to a number of statements about the training. Figure 5.1 displays a visual representation of the feedback statements and participant ratings. The preliminary data available from 31 participants showed that overall, the training was rated as effective in its delivery (M=4.26, SD = 0.44), an effective use of time (M=4.32, SD= 0.47), provided adequate time to learn the skills and concepts (M= 4.26, SD=0.44), described skills applicable in their hospital (M= 4.22, SD= 0.56), role play/case studies were useful (M= 3.83, SD= 0.52), guidance document for adverse event disclosure was useful (M= 4.13, SD= 0.67) and awareness of psychological strategies was useful (M=4.19, SD=0.75).

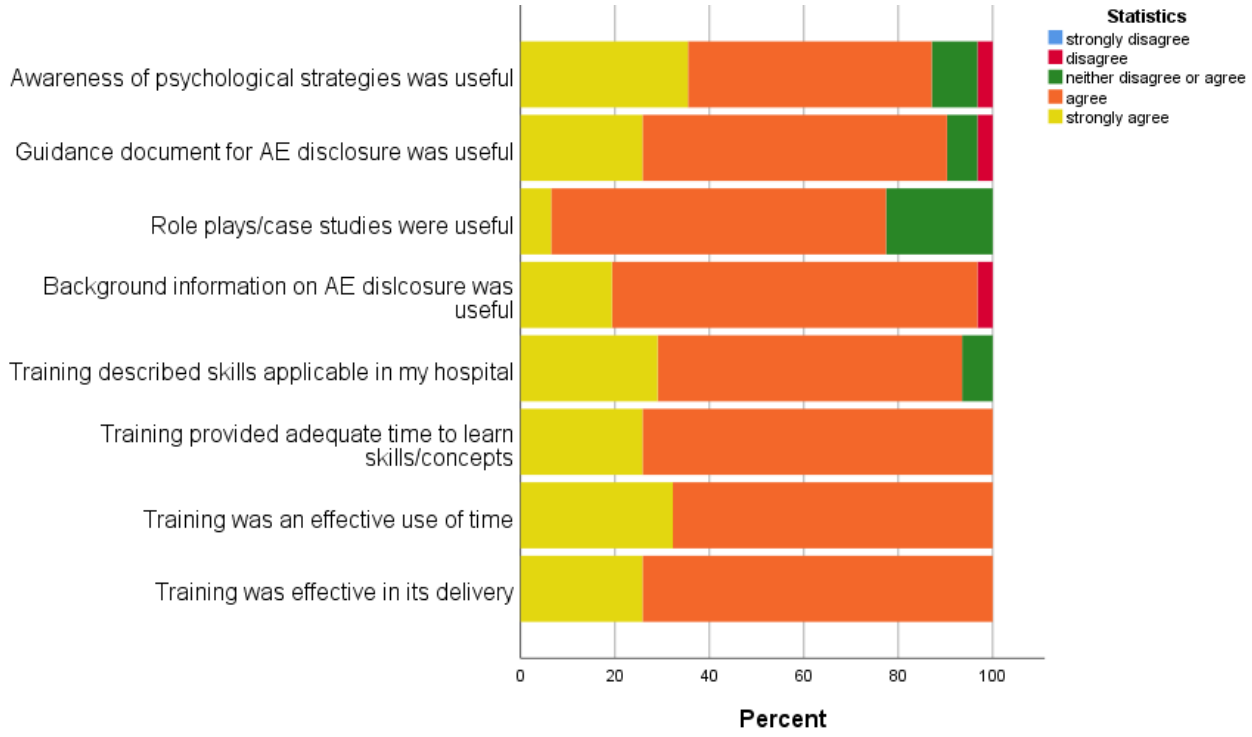


Figure 5. 1: Feedback – Likert ratings for the training intervention

On the feedback questionnaire, participants also provided additional comments about the training. These were related to overall thoughts of the training intervention, what was learnt, and suggested improvements. To summarise, participants had a positive attitude towards the training workshop, believed it was relevant, and useful to discuss the Duty of Candour and the impact of adverse events and disclosure on healthcare professionals. In terms of learning, participants described that they learnt about what patient's desire from disclosure as well as ways to reduce their own emotional distress. Improvements to the training included increasing the amount of time for discussions, providing less detail on the CBT model as some participants were already familiar with this, and including more scenarios. A detailed table of all the comments provided by participants on the feedback questionnaire is available in Appendix 14.

5.9.3 Objective 2: The feasibility of delivering the intervention

1). Participant uptake (includes all participants approached and eligible for the intervention, and those who were successfully recruited for the intervention)

In total, 31 participants were recruited for this taking part in the intervention. This included 6 midwives and 25 obstetricians. There were three intervention sessions in total;

only obstetricians took part in two of the workshops and the third workshop was interdisciplinary in nature and included both midwives and obstetricians. It was made clear in the workshop information document in which the session dates were presented, that only obstetricians may sign up for the first two workshops and both midwives and obstetricians for the final workshops. Participants were clearly informed in the workshop information document that they may only sign up for one of the workshops. This was ensured by the researcher as the registers for each of the workshops were checked to confirm no participant had taken part in the previous workshops.

Several efforts were made to try and arrange a workshop session for midwives only. Although a few preliminary dates for sessions were arranged in collaboration with the Head of Midwifery, each session was cancelled due to the lack of availability of midwives. The reasons for this included short staffing and the lack of allocated training time available for midwives. Obstetricians, on the other hand, were allocated protected training time, one afternoon per month. The intervention sessions were delivered during this training time. Arranging the training sessions for obstetricians was also a challenging and time-consuming process, however, and four prior sessions were booked and later cancelled due to the obstetricians having to attend clinical duties. Due to four of the preliminary booked intervention sessions being cancelled, it took a period of eight months to arrange and deliver the training intervention sessions.

2). Feasibility of delivering the intervention within the allocated time

The intervention was planned to be delivered within 3 hours. Each of the three training intervention sessions were delivered within the allocated 3 hours. This time frame enabled the delivery of all the content within the training session with sufficient time for discussions and exercises.

5.9.4 Objective 3: Feasibility and appropriateness of the data collection procedures

1). Feasibility of completing the questionnaires

All participants (except the two who left halfway through the intervention) completed the pre-training, post-training, and feedback questionnaires. 10 minutes were allocated at the beginning of the training and 10 minutes after the training to complete the questionnaires. No missing data was identified within the questionnaires. However, only 15 participants provided responses for the open-ended item on the feedback questionnaire which was

related to providing additional comments about the training intervention.

2). Follow-up response rates which was determined by the number of individuals who chose to take part in the follow-up interviews

From the 31 participants, 12 from the three intervention sessions (9 obstetricians and 3 midwives) chose to take part in the follow-up interviews. All participants who had signed up for the follow-up interviews took part.

3). Recording retention rates of participants from the beginning of the training intervention till the end of the intervention

Initially, 39 participants had signed up for the training intervention, however, due to clinical duties or a change in work rotas, 8 participants were unable to attend (4 midwives and 4 obstetricians). 2 participants (both obstetricians from training session 1) left halfway through the intervention. One of the participants left due to clinical duties, and the second left due to personal reasons. The data of these participants who left partway through the training was excluded from the final analysis. In addition to these 39, an additional 10 participants were recruited for the initial intervention sessions that were cancelled and did not end up attending the final sessions. Therefore in total, 49 participants had signed up for the sessions, including for those sessions that were later cancelled.

5.9.5 Objective 4: The magnitude of change on knowledge and self-efficacy outcomes

Knowledge of adverse event disclosure

There was a significant difference between knowledge scores before (mean =4.74, SD= 0.99) and after (mean =5.13, SD=0.92) taking part in the training workshop; t (30) = -3.23, $p < 0.05$. Healthcare professionals' knowledge of adverse event disclosure increased after taking part in the training workshop.

Self-efficacy (confidence) in disclosure skills

There was a significant difference between self-efficacy scores before (mean =20.45, SD= 3.17) and after (mean=25.19, SD=3.41) taking part in the training workshop; t (30) = -8.24, $p<0.05$. Healthcare professionals' self-efficacy in disclosure skills increased after taking part in the training workshop. To determine which aspects of disclosure

participant's self-efficacy had improved, eight Wilcoxon signed-rank tests were conducted. A Bonferroni correction was applied to account for multiple comparisons, to reduce the chances of a type 1 error occurring. This resulted in a significance level set at $p<0.006$. The findings from these tests indicated that there was a significant difference in each of the eight aspects of disclosure. Table 5.2 below displays each of the aspects of disclosure measured in the self-efficacy questionnaire, the associated means, standard deviations, Z values, and significance levels. From this table, it can be seen that the greatest change in self-efficacy was in items 2 and 5, confidence in the understanding of steps that should be included in the disclosure conversation, and confidence in the ability to provide an expression of regret/empathy to the patient and/or their family.

Table 5. 2: Each aspect of disclosure measured in self-efficacy questionnaire and the associated means, standard deviations, Z-values and significance levels

Aspects of disclosure	Mean		Standard deviation		Z -value	Significance levels
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention		
Item 1: Confidence in the understanding of the importance of disclosure	2.93	3.45	0.63	0.51	*Z= -2.996*	*p=0.003*
Item 2: Confidence in the understanding of steps that should be included in the disclosure conversation	2.13	3.19	0.72	0.60	*Z= -4.456*	*p=0.000*
Item 3: Confidence in the knowledge of the professional Duty of Candour	2.45	3.22	0.62	0.49	*Z= -4.021*	*p=0.000*
Item 4: Confidence in the ability to communicate a statement that an unexpected adverse event	2.55	3.32	0.62	0.59	*Z= -4.179*	*p=0.000*

has occurred						
Item 5: Confidence in the ability to provide an expression of regret/empathy to the patient and/or family	2.87	3.35	0.67	0.61	*Z= -3.273*	*p=0.003*
Item 6: Confidence in the ability to answer questions posed by the patients/and or families about the adverse event	2.55	3.22	0.72	0.49	*Z= -3.722*	*p=0.000*
Item 7: Confidence in the ability to manage emotions that patients and/or families may exhibit during disclosure	2.51	3.29	0.62	0.59	*Z= -3.086*	*p=0.000*
Item 8: Confidence in the ability to manage own emotions when disclosing to patients and/or families	2.68	3.39	0.65	0.56	*Z= -3.720*	*p=0.000*

**A Bonferroni correction to account for multiple comparisons was applied resulting in p<0.006.*

Objective 1: **To explore the acceptability of the format and content of the training intervention and the perceived usefulness of the intervention**

5.10 Qualitative analysis

A total of 12 participants took part in the semi-structured follow-up interviews, including nine obstetricians (three males and six females) and three midwives (all female). All interviews were completed within two weeks of taking part in the training workshop. The possibility of bias within this sample was explored and the feedback intervention scores were compared for those who took part in the follow-up interviews compared to those who did not, to assess whether those who took part in interviews had provided high rating scores for the intervention. However, there was very little difference in scores between the two groups, suggesting there was little bias in those who responded to take part in the follow-up interviews. Five main themes were developed which described and explored participants' perceptions and experiences of taking part in the training workshop for adverse event disclosure. Each theme is discussed below and the supporting quotations are identified by the unique participant numbers. The final thematic map illustrating the predominant themes that emerged from the data is presented in Figure 5.2 below.

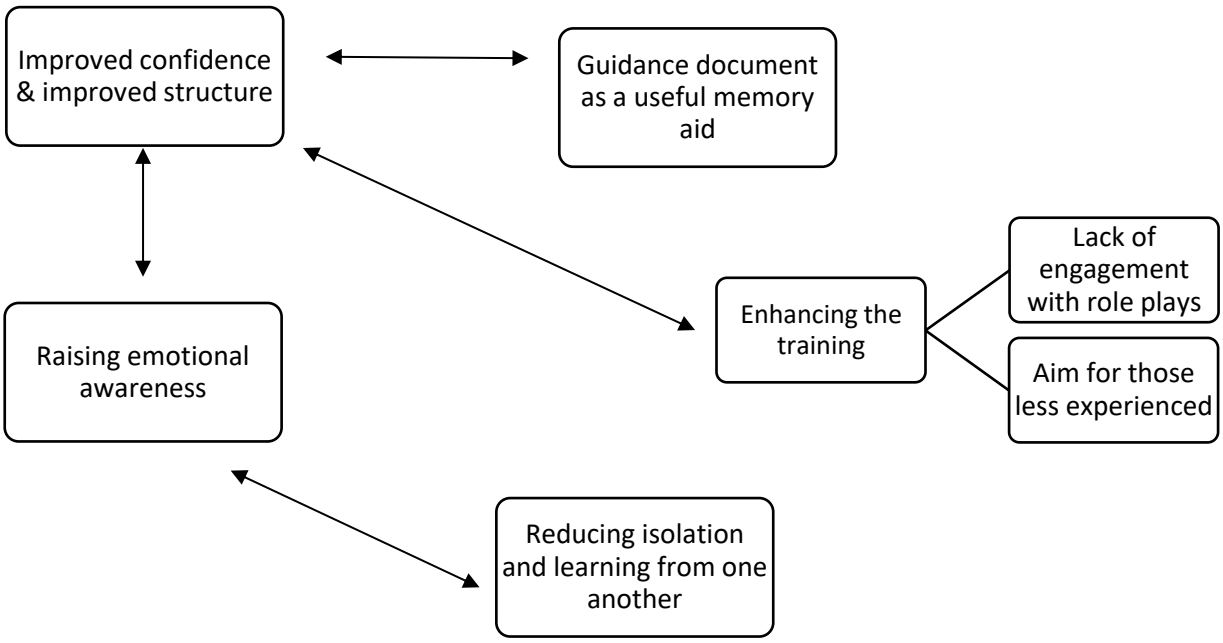


Figure 5. 2: Thematic map

Theme 1: Increased confidence and improved structure

Healthcare professionals described that they felt that their disclosure skills had improved after taking part in the training workshop. They were more confident in conducting disclosure, as they better understood how to approach the patient and disclose adverse events:

'I think probably just more confident in disclosing, I know better about what and how to disclose' Participant 2 Obstetrician

'I feel happier now knowing what to say and how to approach disclosing the incident with the patient. I think I know better on how and when to conduct disclosure' – Participant 7 Midwife

The training workshop increased clarity of the disclosure processes and the steps involved in disclosure. Healthcare professionals were also more aware of the legal requirements of disclosure including the Duty of Candour regulation. Increased knowledge of these processes made healthcare professionals less hesitant to disclose, as they were confident that they could inform the patient of the adverse event and apologise without the worry that they would be blamed. Before taking part in the workshop, healthcare professionals were unclear about what steps would be taken after conducting the disclosure conversation with the patient. Following up with patients after disclosure was also described as one of the things learnt from the workshop.

'I think I'd probably feel more confident just because I think I'm probably more aware of the specific steps and like the steps in Duty of Candour. So for example, I now know I'm allowed to apologise without feeling like I'll be blamed and I didn't really know before about the letters that the patient would get and how exactly it would all be followed up. So I think I'm more aware now of the kind of steps that you would take sort of beyond just telling the patient that there has been an incident'

'I feel a bit more confident than before, because like I say it was always a grey area as to what situation we need to offer this duty of candour and things like that, that's always a grey area, but I think having this discussion and this workshop at least gave me some information

and like a little bit of insight into what exactly to do in a certain area. Yeah, it has changed, and I feel like more confident in doing so now' – Participant 6 Obstetrician

A number of healthcare professionals reported that they viewed disclosure in a more structured manner after taking part in the training workshop. Using a stepwise approach to disclosure was believed to assist with structuring the conversation with patients, and would provide patients with a better understanding of what had happened.

'Yeah, I think there's more structure to it (disclosure) now. I think it's important to have a more structured approach to these things, I think it gives the patient a better understanding as well. I mean like the different steps involved and in terms of coming up with how and when disclosing and what needs to be disclosed' – Participant 4 Obstetrician

One participant did not perceive any changes in how they felt about conducting disclosure as they were already confident with conducting disclosure. This was attributed to the fact that the participant had previously been involved in disclosure.

'I mean that I already felt comfortable with it, having had to do it previously, so it probably hasn't particularly changed my comfort level, because it's something we have to do anyway'– Participant 5 Obstetrician

Theme 2: Guidance document as a useful memory aid

The guidance document provided to participants during the workshop, which summarised the Duty of Candour principles was received positively by participants. This was viewed as a useful reminder or a revision tool to look over before conducting the disclosure conversation with patients. Although many healthcare professionals were familiar with the Duty of Candour, the guidance document was perceived to be a useful way to remind oneself of the steps and requirements involved in disclosure.

'You know the little handout that you gave us (Duty of Candour guidance document) I've actually kept it in my work bag so I think I would just sort of look over that and revise that before I went and had a chat with them. I think that was really helpful' – Participant 1 Obstetrician

'I think that framework was helpful, it's nice just to be able to have something to refer back to and just remind you of the steps. In principle, I knew what Duty of Candour was, but it was a nice refresher as you forget these things'– Participant 4 Obstetrician

For some participants, the guidance document was viewed as a tool that provided reassurance, for others it boosted confidence to disclose, as following it ensured that the requirements of the Duty of Candour were covered.

'That you can just, kind of like a quick revision sheet before you go and talk to somebody so everything's fresh in your mind, you're less likely to mess it up or miss something. It just gives you some sense of peace that you've followed the Duty of Candour guidance so you can't get in trouble for that at least' – Participant 10 Obstetrician

'I mean I do like the laminated guide, and I did take a photo of that for reference, I think that's definitely useful. I will be using that in the future. Yeah, I think that's really good, it's kind of a reminder, or something people can just quickly read when they're in those situations to use it as a tool, probably help their own confidence of what they're going to do' – Participant 5 Obstetrician

Both midwives and doctors thought that the guidance document was simple and easy to follow and were interested in sharing the guidance document with their colleagues either in the form of an educational resource or in an office as a visual prompt so that others could also benefit from it.

'I really liked the framework, and one of the things I'm planning on doing with other colleagues is to put together some educational resources for doctors, and I'll be including this in there too, I think it's really important thing to put in there. It's quite straight forward and easy to follow, it's simple and easy to follow and I like that' - Participant 7 Midwife

Theme 3: Reducing isolation and learning from one another

Being involved in an adverse event was described as lonesome. The group discussions in the training workshop led to the realisation that others had been through similar experiences and understood the impact of being involved in an adverse event and that healthcare professionals could turn to their colleagues for support during these times.

'I think the group discussions are particularly useful. I think that when something does happen one of the big problems that we have is that it's a very lonely place to be and traditionally medicine is very much stiff upper lip and you carry on. But it's actually really useful to know that you don't have to keep a brave face in front of your colleagues, everyone has been involved in these, and that you have got support, you have got friends. So I think the

discussion bit was absolutely key, being able to talk to your colleagues about things' – Participant 10 Obstetrician

Discussions around experiences of adverse event disclosure are usually neglected within maternity. Healthcare professionals described that although the adverse incident and ways to improve future practice are discussed within their Trusts, the experience of the individual involved is not heard. The group discussions in the training workshop provided healthcare professionals with an opportunity to share their experiences of adverse events and disclosure with the rest of the group. This was viewed as a rare opportunity. Healthcare professionals described a sense of feeling less alone and reassured after hearing what other colleagues had experienced, particularly after realising that most colleagues had been involved in an adverse event.

'I just think everybody sort of discussing adverse events and just by discussing them it makes you realise that everybody has had them, so sometimes I think adverse events can make you feel quite isolated and alone but actually you're not because everybody has them' – Participant 2 Obstetrician

'It (training) was quite useful. To be honest, I found the most useful bit was actually where people were actually sharing their own experiences of things. And that is a very useful sort of hearing, the realism of the fact that most people have been through most things by the time they're a senior registrar. I think just to say that I think it's really useful stuff and really relevant to our speciality as well' – Participant 3 Obstetrician

Participants, who attended the multi-disciplinary workshop where both midwives and obstetricians took part, perceived that there was a sense of togetherness during these discussions. Sharing experiences helped midwives and obstetricians realise that they would deal with adverse event situations similarly. Including healthcare professionals from other disciplines was also recommended.

'I think what your course does is, and I think it's really important to keep doing this is making the midwife and doctors come together on that course. So that we see their point of view and they see ours. It was very interesting listening to the doctors take on different scenarios and their experiences, but I think midwives need to come onto these types of joint courses more. It was good to see that we (doctors and midwives) were in agreement about how to tackle adverse event situations. It was nice to see we were all singing from the same hymn book' – Participant 9 Midwife

Healthcare professionals believed that an element of learning emerged from the group discussions with colleagues. It was perceived that there was a lot to learn from hearing about colleagues good and bad experiences, as well as ways that they managed and coped with adverse event situations

'You know, listening to other people's experiences is always useful, because you think, oh well, you know, that's something to avoid or something I could try, so I think that is definitely helpful. The discussions were good to share and hear others experiences, things that were good and things that didn't go so well and how they dealt with it' – Participant 5 Obstetrician

Theme 4: Raising emotional awareness

A lack of emotional support from Trusts after being involved in an adverse event was described by a number of participants. Midwives and obstetricians felt that their emotional distress after being involved in an adverse event was not acknowledged and they were left to deal with their emotions by themselves. The element surrounding the emotional impact of adverse events on healthcare professionals within the training was viewed as important and greatly valued by participants.

'I think the whole awareness of mainly the emotional side really of how we feel was useful, because we all know the principals of adverse events at least to a certain extent, but I think we have particularly been neglected for a long time, and continue to be neglected, and neglect ourselves in terms of emotional health. So, that awareness was really useful, and I think needs to be more so' – Participant 3 Obstetrician

This element of the training was also described as useful for raising awareness of avenues of support available for healthcare professionals after being involved in an adverse event.

'The training taught me about the sort of the support that might be available to you as the healthcare professional after being involved in an AE like that 2nd victim website. That's important and something that all healthcare professionals should be made aware of really' – Participant 4 Obstetrician

Awareness of the psychological strategies for healthcare professionals to manage their own emotions was viewed as valuable knowledge that needed to be disseminated more widely so others could make use of them. These were thought to be useful coping strategies to help yourself feel in control of your own thoughts and feelings after being

involved in an adverse event. There was a perception that different strategies may be used in different situations.

'Sometimes we tend to think, we'll deal with this in our own ways but I think you just need someone to stand there and say these are some of the things you can do, try this. And that will get you thinking 'oh maybe I should try this next time' or 'this might be helpful for me'. I might use breathing strategies in one instance, or write down my feelings the next. More of us need to be made aware of this' – Participant 7 Midwife

'When you were showing kind of the spider diagram of all the different things, you think, oh, yeah, I do all of those things, like the kind of catastrophizing and thinking this is, this is it, like every time I do something it's going to go wrong now. So I think it was, I found that bit useful to kind of, because it means that, when you know those things it kind of helps you sort of yourself up, and say, actually, I'm doing this and I'm kind of getting thoughts out of control that I try and like rationalise a bit more. That will help me feel calmer and in control of my feelings' - Participant 4 obstetrician

One participant described the link between being in control of their emotions and conducting a more effective disclosure:

'It was good to hear the different ways, simple ways we can manage how we feel at the time, which will then make us feel calmer and allow us to conduct a better disclosure' – Participant 9 Midwife

A few healthcare professionals already had their own personal strategies to help them manage their emotions and were comfortable to continue using these:

'I mean I think these things are very individual and I over time I guess have built up what I feel comfortable with, so I don't think, I'm pretty happy with my own personal strategy in general, so I probably wouldn't use anything new' – Participant 2 Obstetrician

Theme 5: Enhancing the training

Participants discussed the weaknesses of the training and suggested ways to improve the training intervention. This theme has the following two sub-themes; 'Lack of engagement with role plays' and 'Aim for those less experienced'.

Lack of engagement with role plays

The role-playing element was believed to be important for learning, however, participants suggested that the role plays could be enhanced by the use of actors to play the role of the patient. The use of actors would ensure that the role-play was more realistic, and would be taken more seriously by healthcare professionals. Role-playing with colleagues made it difficult for healthcare professionals to immerse themselves within the scenario, resulting in a lack of engagement with this element.

'I think role play's important in general, you do learn from role plays, but sometimes when you're role-playing with colleagues, it's not taken as seriously as it should be and you lose focus, and actors are just better at coming up with actual things that patients might feel' – Participant 2 Obstetrician

'I always find a bit difficult with role-playing, is if you're doing it with your colleagues, acting as the patient. I think sometimes it's sometimes a bit hard to kind of fully get into the role, because, partly because I'm thinking, oh, are they judging my approach to it? It's, yeah, but I think the principle of it, I think, is really useful' – Participant 4 Obstetrician

Aim for those less experienced

Although the training was perceived to be useful by most participants, some obstetricians suggested that future training sessions should be aimed at those who are earlier in their career. Senior obstetricians had learnt how to conduct disclosure through experience, whereas disclosure would be new to those early in their career.

'I enjoyed it and thought it was quite good, yeah. I think it's definitely worth doing. I did discuss it with your colleague and it's something that more senior trainees I suspect some of the lessons we've learnt the hard way already, so I do think, do wonder whether it's something that maybe would be useful to be aimed at kind of ST1s, ST2s, people kind of earlier in their career' – Participant 5 Obstetrician

Teaching junior obstetricians the skills and coping strategies related to disclosure before they are faced with an adverse event was viewed as an important strategy by another obstetrician.

Yeah, I think it's one of these things that you need to be thinking about, particularly for us,

you know, earlier in the career and kind of between ST1 and ST3, because as you become a registrar and you're dealing with these situations you are then exposed, so it'd be better if people had those kind of coping strategies or thoughts before they are in fact exposed to being in these situations – Participant 5 Obstetrician

Organising the training by levels of seniority was also a suggested improvement by other participants. Feedback from obstetricians suggested that it would be more appropriate to have separate training sessions for junior and senior obstetricians as each group faced different issues, and separating the training in this way would allow the training sessions to be tailored to each group.

'So I think if we had these workshops at different, like ST1 to 3, together, then ST3 to 5 together, I think because the problems faced by each healthcare professional at that level are much different and if we help at all organise the workshops, in a certain way, even the case studies at an ST3 to 5 level, will be different than what ST1 to 3 will go through' – Participant 8 Obstetrician

5.11

This study explored the acceptability and feasibility of a training intervention to enhance maternity healthcare professionals' skills with the disclosure of adverse events and the feasibility and appropriateness of the data collection methods. It also assessed the extent to which the training intervention had the potential to enhance knowledge of adverse event disclosure and self-efficacy (confidence) to disclose. This training intervention was novel in the sense that it was the first intervention that was focused on disclosure within the UK and integrated the current UK policies and requirements of disclosure.

5.11.1 Acceptability of the training intervention

The feedback for the workshop was overwhelmingly positive and some areas of improvement were also identified. The high rating scores recorded by participants on the feedback questionnaire suggested the acceptability of the training workshop in terms of content and format. Overall, the training was rated as effective in its delivery and an effective use of time. In terms of content, the training was rated as having provided adequate time to learn skills and concepts, described skills applicable to the healthcare professional's hospital, the role play and case study elements were useful, the guidance document for adverse event disclosure was useful and awareness of the psychological

strategies was also useful. Additional comments by participants on the feedback questionnaire suggested that the training was viewed positively. Participants commented that they had learnt how to structure disclosure and manage their own emotions.

The follow-up interviews provided rich data on healthcare professional's experiences of taking part in the workshop including suggestions for future improvements. Although only three midwives took part in the follow-up interviews compared to nine obstetricians, there was little difference in the experiences of taking part in the training intervention between the two professional groups. Amongst midwives and obstetricians, there was a perceived sense of improvement after taking part in the intervention. Participants were confident to disclose due to clarity of disclosure processes including the Duty of Candour (CQC, 2015). The Duty of Candour guidance document provided to participants was perceived as a useful memory aid. The usefulness of the guidance document was evidenced by the fact that midwives and obstetricians wanted to share it with their colleagues, and suggested that they would distribute it in form of an educational resource and would put it up in a place where it would be visible to colleagues such as on a notice board.

Previous disclosure interventions have focused on raising awareness of the moral and legal elements of disclosure (Gunderson et al., 2009; Halbach & Sullivan, 2005; Kiersma et al., 2009; Madigosky et al., 2006; Moskowitz et al., 2007; Paxton et al., 2010; Wayman et al., 2007; Sukalich et al., 2014; Langer et al., 2017; White et al., 2017; Bonnema et al., 2009; Posner et al., 2011; Kim et al., 2017). However as noted by previous research, it is just as important for healthcare professionals to be able to manage their own emotions in response to adverse events (Birks, 2014) and this is an element that was missing from previous disclosure interventions. The emotional element related to disclosure was incorporated into the intervention within the current study. As identified by participants, one of the strengths of this training intervention was the incorporation of the emotional element of being involved in adverse events and disclosure. Being involved in an adverse event can trigger an emotional stress response (Sirriyeh et al, 2010). Distress, panic, self-doubt, fear, guilt, and shame are all commonly experienced in the aftermath of an adverse event (Harrison et al., 2015). Whilst in the grip of such strong reactions, composing and preparing oneself for a disclosure conversation with the patient and their family involved can be incredibly difficult. Managing one's own emotions before conducting disclosure can help to be in the correct frame of mind and be mentally prepared, resulting in a more effective disclosure. Healthcare professional's emotional distress after being involved in an adverse event was an aspect that was not acknowledged by Trusts, and healthcare

professionals often felt that they had to deal with their emotions by themselves. This aspect of the training provided a forum to share thoughts and feelings that participants had experienced after being involved in an adverse event. Discussions about the sources of support available for healthcare professionals after being involved in an adverse event was also described as important and participants believed that more healthcare professionals needed to be made aware of these.

The two main areas for improvement identified by participants in the follow-up interviews were the use of standardised patients within the role play element and targeting the training at those earlier in their career. Although role plays were viewed to be important for learning, role-playing with colleagues lacked realism and were not taken seriously. To increase the effectiveness and engagement with the role plays, the use of standardised patients or actors was suggested by a number of participants. Previous research also supports the effectiveness of standardised patients for teaching adverse event disclosure skills (Kaldjian et al., 2007; Stroud, Mcllory & Levinson, 2009; Gunderson et al., 2009; Sukalich et al., 2014) and simulated encounters with standardised patients have been used to improve disclosure skills and confidence (Gunderson et al., 2009). Such methods were not included in this intervention due to the high cost of involving standardised patients in training. Role-plays were integrated into the training intervention as one of the benefits of this included the opportunity to practice disclosure in a safe environment and due to alternating roles between each other, it allowed healthcare professionals to put themselves in the patient's shoes.

As senior obstetricians had already learnt how to conduct disclosure through experience. It was suggested that targeting junior obstetricians would also allow them to learn the skills and coping strategy before they would be exposed to an adverse event. Feedback from other participants suggested that it would be more appropriate to have separate training sessions for junior and senior obstetricians as each group faced different issues, and separating the training in this way would allow the training sessions to be tailored to each group.

5.11.2 Feasibility of delivering the training intervention

In total, 39 participants were recruited for the training intervention, and 31 attended the training. However, there was an imbalance between the number of midwives (6) and obstetricians (25) who took part in the intervention. Although many efforts were made to recruit midwives and arrange the training sessions, this proved to be very difficult. A lack of allocated training time available for midwives and short staffing were obstacles. In addition to the 39 participants, 10 participants were initially recruited for the sessions

which were later cancelled due to lack of availability of a sufficient number of participants for a session to be run. These findings indicate that if this training intervention is run as part of a trial, it is important to over-recruit participants as the dropout rate for this study was 36%. It was found that it was feasible to deliver the training intervention within the allocated three hours.

In total, it took eight months to arrange and deliver the training intervention sessions. This was due to the four of the initial booked intervention sessions being cancelled as healthcare professionals had to cover clinical duties. This resulted in an insufficient number of participants available for the training sessions. These findings highlight the challenges of delivering this intervention to a group of 6-8 maternity healthcare professionals using a trust-by-trust approach. This is due to the busy environment that healthcare professionals work in and the limited time they have available to take part in training. Compared to the recruitment of obstetricians, recruiting a group of midwives to take part in the training with obstetricians, proved to be much more difficult. This was due to the lack of allocated training time. It was therefore not feasible to deliver this training intervention to midwives using a trust-by-trust approach. An alternative mode of recruiting and delivering the training to midwives is needed. The intervention sessions could be delivered at a regional level, where maternity healthcare professionals from a number of trusts are invited to attend. Another alternative (proposed by the consultant obstetrician working with the researcher and supervisory team) is that the training could be delivered as part of the annual yearly training programmes.

These findings have broader implications for maternity. Maternity services are mainly delivered by teams rather than individuals. Reports such as the Safe Births Inquiry (The King's Fund, 2008) which have examined the safety of maternity services in England highlight the link between poor team work and communication across professional groups (such as midwives and obstetricians) and patient safety. Similarly, reports from the Confidential Enquiry into Maternal and Child Health (CEMACH) have highlighted a lack of communication and teamwork between different professional groups (Lewis et al 2007). The Safe Births Inquiry (The Kings Fund, 2008) emphasised the need for different professional groups to work together and appreciate each other's roles. This report also recommends that teams who work together should train together (The Kings Fund, 2008). However, as discussed above, findings from the feasibility study suggested that it was very challenging to recruit midwives to attend training with obstetricians. Therefore, if it is not possible to bring together both professional groups in training to learn from each other,

and understand the others role and perspective, changes to culture are likely to be difficult to achieve.

5.11.3 Feasibility and appropriateness of data collection procedures

The findings also suggested that it was feasible to complete the included questionnaires as all participants completed the pre and post-training and feedback questionnaires. Surprisingly, there was no missing data and all questionnaires were completed in the allocated time (10 minutes for the pre-training and 10 minutes for the post-training questionnaires). These findings are similar to previous adverse event disclosure interventions where there has been a high response rate to completing questionnaires including pre and/or post-intervention self-efficacy questionnaires (Kim et al., 2017; Gunderson et al., 2009; Bonnema et al., 2009) as well as feedback questionnaires (Langer et al., 2016; White et al., 2017).

In terms of the follow-up response rates, only 12 out of the 31 participants took part in the follow-up interviews, even though retention strategies such as incentivising participants for taking part and sending reminder emails to participants to take part were used. Although sampling is an important consideration in conducting qualitative research in the context of process evaluations, in this study it was found that data saturation was achieved with the 12 participants, and recruiting more participants might not necessarily have provided any new knowledge, especially taking into account that there was little bias in those who took part in the interviews compared to those who did not. Therefore, if this study is trialled at a larger scale, it can be suggested that obtaining qualitative feedback from more than 40% may not be necessary for process evaluation, particularly if there is little bias in those who took part in the follow-up interviews compared to those who did not.

5.11.4 Knowledge of adverse event disclosure

The findings suggest that although participant's level of knowledge was good before taking part in the training intervention, the training still achieved an improvement in their knowledge of adverse event disclosure. However, these results must be interpreted with caution as this was not a formal assessment of knowledge related to adverse event disclosure, but an MCQ for the purpose of this study. Questions related to only the broad elements of disclosure were included in this MCQ. One of the reasons for using a brief questionnaire was to avoid a non-response rate which is more likely to occur when a questionnaire is longer, whereas shorter questionnaires are found to be more effective in increasing response rate (Sahlqvist et al., 2011). It was also important to be mindful to not

burden participants as they were completing including a number of questionnaires, before and after taking part in the intervention. It is also important to note that the MCQ questions were based on disclosure practices within the UK and were developed based on the current Duty of Candour regulation and discussions with consultant obstetricians within the UK, therefore limiting the generalisability of this tool to other countries. Very few previous studies have assessed whether there has been any impact on participant's knowledge of disclosure after taking part in training programmes. One previous intervention study which examined participant's knowledge of adverse event disclosure using a five-item MCQ developed for the purpose of the study found that knowledge of disclosure had increased after taking part in the intervention (Madigosky et al., 2006).

5.11.5 Self-efficacy (confidence) in disclosure skills

The scores from the pre and post-self-efficacy questionnaire suggested that the training intervention improved participant's self-efficacy (confidence) in various aspects of adverse event disclosure. Overall, healthcare professionals were more confident in disclosing adverse events to patients after taking part in the training intervention. Self-efficacy assessments are predictive of future behaviours (Reuter et al., 2010) and have been useful for identifying individuals who need remediation (Artino, Hemmer & Durning et al., 2011). Previous studies have also assessed changes in self-efficacy after taking part in disclosure training and have found similar results. One study which investigated the effects of medical disclosure training in a simulated setting for paediatric oncology nurses (N=16) found that there was a significant increase in nurse's communication self-efficacy to carry out medical disclosure (Wayman et al., 2007). A similar study using a standardised patient encounter tutorial (N=55) also found that first-year resident's self-efficacy for disclosing medical errors improved after attending disclosure training (Sukalich et al., 2014). Like the current study, both of these studies have used a pre-post study design. These findings suggest that interventions focusing on adverse event disclosure can successfully improve self-efficacy for disclosure. A study by Kim et al (2017) reported that after taking part in a disclosure education programme (N=85), 65% of participants felt more confident in coping with medical errors through the simulated experience provided during the programme. However, this study did not assess self-efficacy before taking part in the training, and confidence assessment was based on a statement of how participants felt, rather than a questionnaire. The study by Sukalich et al (2014) asked participants to rate their confidence in performing a number of different aspects of disclosure, which is similar to the approach taken by the current study. However, the study by Kim et al (2017) only measured self-efficacy by asking a single question rather than focusing on different aspects of disclosure. These previous studies

have adopted the use of standardised patients as a major component of their disclosure training programmes, whereas the current study used an educational approach to disclosure, combining a number of didactic elements with group discussions and role-play exercises. Although research suggests that standardised patients offer a number of benefits as they are an effective way to teach disclosure skills (Gunderson et al, 2009; Stroud et al., 2009; Raper, Resnick & Morris, 2014;) and can help to improve confidence to disclose (Gunderson et al., 2009; Sukalich et al., 2014) the current study found an increase in self-efficacy to disclose without the use of such methods. Therefore, to increase self-efficacy it is not necessary to include standardised patients.

5.11.6 Strengths and limitations

Previous literature has focused on developing and delivering adverse event disclosure interventions outside of the UK. This study extends this literature by providing the first preliminary evidence indicating that maternity healthcare professionals perceive benefits of a training intervention developed specifically for UK maternity services and that this could be useful for increasing their knowledge of adverse event disclosure and increasing their confidence in conducting disclosure with patients and/or their families. It is important to consider that delivering this adverse event disclosure training requires 3 hours of healthcare professional's time away from clinical duties. The training was delivered by two psychologists with the assistance of a consultant obstetrician. It may be important that aspects of the training that have a psychological element such as the Cognitive Behavioural Model in relation to adverse events and the psychological strategies on managing emotions are delivered by a trained psychologist. It is important to be mindful that further delivery of this training intervention involving psychologists could be costly, particularly when delivering it a number of times. An alternative cost-effective method to this could be that course leaders are allocated within each Trust, who are trained by psychologists to deliver this training.

A pre and post, single-arm study design was used and although this allowed the comparison of knowledge of disclosure and self-efficacy in conducting disclosure before and after taking part in the training intervention, the findings are limited and the study design is weak. As this study design did not include a control group, it was not possible to test the feasibility of randomising participants to an intervention or waitlist control group. The uncontrolled design of the study also means that the findings cannot be interpreted as evidence of effectiveness and it is not possible to know whether the improvements in knowledge and self-efficacy were as a result of the intervention. A multiple arm pre and post design, where there is a comparison arm, where the no intervention arm would act as

a control would have been a stronger study design. However, the choice of design for this study was chosen due to the limited availability of study participants and time constraints (Thiese, 2014). Although this study has the strength to temporarily suggest that knowledge of adverse event disclosure and self-efficacy in conducting disclosure may be impacted by the training intervention, it does not have control over other elements that also changing at the same time as the intervention is implemented.

Changes in self-efficacy were measured in this study but this does not assess actual skill or behaviour. It is possible that obstetricians and midwives may have overestimated their increase in ability to conduct disclosure due to the training intervention, and this subjectively rated confidence may not match their actual skills in practice. Previous research has suggested that there can be a mismatch between clinical confidence and observed competence (Wynne et al. 1987; Barnsley et al. 2004; Katowa-Mukwato & Banda, 2016). Therefore, perceived self-efficacy may not be a true reflection of healthcare professional's actual ability to conduct disclosure. Self-reports of confidence are subjective and therefore, future iterations of this training workshop can be improved by using an objective-structured clinical examination, a mini clinical examination or other observation tools to directly assess skills or behaviour. It is possible that healthcare professionals may have subjectively rated their confidence to be higher than it was, due to the fear of being perceived as less competent by others in the training workshop. It is also possible that there may have been a response bias and participants may have provided higher self-efficacy scores after taking part in the training workshop, as they were aware that the purpose of the intervention was to enhance skills for disclosure. A limitation of measuring changes in knowledge is that an increase in knowledge does not necessarily result in an increase in disclosure behaviour. Therefore, it is important to assess whether increases in knowledge are reflected in disclosure practices.

Another limitation is the design of this study. The data from this study must also be interpreted with caution as only thirty-one participants completed the intervention. Attempts were made to minimise bias such as the use of anonymised questionnaires and encouraging participants to provide honest feedback to help improve the training workshop. However, participants had the knowledge that one of the course leaders had developed the intervention, and the knowledge that the intervention was part of the course leaders PhD may have influenced their feedback, as they could have been concerned about causing offence. As participants had volunteered to take part in this study and had the knowledge that it was a training intervention to enhance skills for disclosing adverse events, they are likely to have been interested in disclosure and

approached the programme with a positive attitude. It is also important to note that knowledge of adverse event disclosure and self-efficacy to disclose are proximal outcomes and were included to assess whether the training had the potential to improve knowledge and confidence to disclose. However, in a larger scale trial, the long-term impact of the training needs to be assessed, and outcomes such as the number of adverse events disclosed, patient satisfaction, or staff-wellbeing after conducting disclosure would need to be measured. It is also important to note that it is not known whether the benefits of intervention last beyond the day of the training, therefore a longer-term follow up is essential.

5.11.7 Future directions

Further research needs to adopt a stronger study design with a larger sample size, such as a waitlist control design where the control group consists of a group of participants who are put on a waiting list to receive the intervention after the experimental study group does. The purpose of this design is that it provides an untreated comparison for the experimental group to determine if the intervention has had an effect. By serving as a comparison group, it is possible to examine the impact of the training intervention. It also allows the wait-listed participants an opportunity to take part in the training intervention at a later date. Future delivery of the training intervention should target junior midwives and obstetricians, and deliver separate workshops to senior maternity healthcare professionals. Modifying intervention components such as the case studies could allow the training intervention to be replicated in other settings of healthcare. The incorporation of standardised patients in the training intervention could enhance the acceptability and potential effectiveness of the training. Further iterations of the intervention need to assess the longer-term impact of the training such as whether it has the potential to increase disclosure rates and patient satisfaction with the disclosure process.

5.12 Conclusions

Healthcare professionals advocate the disclosure of adverse events and believe that honesty, transparency, and openness are important principles of disclosure. However, appropriate disclosure practices are hindered by a number of barriers which include a lack of skills and training on adverse event disclosure. A novel training intervention was developed to enhance maternity healthcare professional's skills with disclosure. The findings from this study suggest that this training intervention is acceptable to healthcare professionals. This study provides preliminary evidence that the training intervention has the potential to improve knowledge of disclosure and increase self-efficacy to disclose

adverse events. In order to improve the feasibility of recruitment and delivery, the intervention could be delivered at a regional level, and include healthcare professionals from a number of different healthcare organisations.

Chapter 6: General discussion

6.1 Chapter summary: *This final chapter begins by providing a recap of the thesis aims and objectives, and the research studies that have been conducted to address them. As each study has been discussed extensively in the previous chapters, the aim of this chapter is to 1). Provide a very brief summary of the main findings of each of the studies, 2). Integrate the findings of the thesis as a whole and discuss in relation to the broader literature on patient safety, 3). Provide implications of findings for national policies and strategies, 4). Provide implications for practice and 5). Directions for future research.*

6.2 Thesis aims:

The overall aim of this thesis was to investigate how healthcare professionals within maternity services can be supported to communicate the news to patients that an adverse event has occurred. It aimed to understand the current disclosure practices within UK maternity services, how adverse event disclosure affects the wellbeing of healthcare professionals and whether providing training in this area had the potential to enhance skills in disclosing adverse events to patients. The thesis objectives were to:

1. Systematically review the literature to understand the views and experiences of patients and healthcare professionals on adverse event disclosure within healthcare.
2. Understand the current views and experiences on disclosure practices within UK maternity services, how this process affects healthcare professional's wellbeing, and the current training available on disclosure.
3. Identify the most important components of a training intervention within the area of disclosure and develop a communication training intervention to support maternity healthcare professionals with the disclosure process.
4. Pilot and evaluate the new training intervention to assess the feasibility and acceptability by healthcare professionals within maternity services.

These aims were addressed using a step-by-step approach as recommended by the MRC guidelines for developing and evaluating complex interventions to improve health (MRC, 2000; MRC, 2008). An iterative development process was involved in this research, where a series of studies were conducted, including a systematic review (chapter 2), an interview

study (chapter 3), intervention development (chapter 4), and a feasibility study (chapter 5).

6.3 Summary of the main findings

1). Systematically reviewing the literature to understand the views and experiences of patients and healthcare professionals on adverse event disclosure within healthcare.

The findings from the systematic review and meta-ethnographic synthesis revealed that there was a difference in perspectives and attitudes of patients and healthcare professionals on how disclosure should be conducted and what the disclosure conversation should entail. Patients expressed a need for information relevant to the adverse event, an apology, and wanted to be assured that the same mistake would not happen in the future. Patients were also more likely to seek legal help when this information was not proactively made available to them or if they struggled to obtain the relevant information from the clinicians involved. Although healthcare professionals advocated disclosure of adverse events, they faced several barriers that hindered appropriate disclosure practices. These included the fear of honest disclosure in a blame culture, a wish to avoid litigation, a lack of skills and training in conducting disclosure conversations, and inconsistent practical guidance. A novel finding of this review was that by synthesising the views of both patients/families and healthcare professionals, the key elements of an ideal disclosure conversation desired by patients and the facilitators for healthcare professionals which can increase the likelihood of this taking place were identified. Key elements of disclosure included relevant information about the adverse event, accountability and an apology, and commitment to preventing future recurrences Facilitators included clarity regarding legal aspects of disclosure, modelling appropriate disclosure practices, development of an open transparent culture, and training on adverse event disclosure. This systematic review also revealed that most evidence to date originates from the USA, Australia, and Canada with a particular absence of UK data regarding experiences of adverse event disclosure. Only one study was conducted within the UK (Harrison et al., 2017).

2). Understanding the current views on and experiences of disclosure practices within UK maternity services, how this process is perceived to affect healthcare professional's wellbeing, and the current training available on disclosure

This was the first study to explore the experiences and perspectives of midwives and obstetricians on the disclosure of adverse events within the NHS in the UK. The findings revealed that the disclosure conversation allowed healthcare professionals to unburden their emotions and move on from the adverse event. Complications were described as common occurrences within maternity and healthcare professionals described that there was a blurred line between complications and adverse events. This resulted in a struggle on how to approach disclosure. This is a novel finding, and perhaps one that is specific within the context of maternity. The link between the two types of incidents is an interesting line of inquiry that requires much further research.

Healthcare professionals described facing emotional distress when anticipating disclosure of an adverse event and although there was an emphasis on the importance of being honest and transparent, at times there was hesitancy to disclose. This stemmed from worries about the investigation process and fears of malpractice liability. The inadequacies and poor routines of the investigation process added to the emotional distress of healthcare professionals. A number of different areas for clarity and support during the disclosure process were needed. One area of support identified by participants was a need for training specific to adverse event disclosure in the UK. Although healthcare professionals were aware of the existence of the Duty of Candour regulation, most were not familiar with the specific legal requirements contained within it. Frameworks were viewed as useful in aiding and providing structure to the disclosure process, however, there was currently no formalised framework to assist with disclosure. Healthcare professionals expressed a preference for peer group training sessions, as individuals would bring different experiences to the group and it would allow for collaborative discussions. In addition to providing healthcare professionals with factual guidance on disclosure, findings illuminated the need to be transparent about the emotional consequences of being involved in an adverse event and disclosure.

3). Identifying the most important components of a training intervention within the area of disclosure and developing a training intervention to support maternity healthcare professionals with the disclosure process

In order to address the distinct need to provide adverse event disclosure training, a training intervention to enhance maternity healthcare professionals' skills with the

disclosure of adverse events was developed using the MRC guidelines (MRC, 2000; MRC, 2008). The relevant existing evidence on adverse event disclosure interventions was identified. Thirteen intervention studies were identified from an existing systematic review (Birks et al., 2014) which were designed to improve or promote adverse event disclosure (Gunderson et al., 2009; Halbach & Sullivan, 2005; Kiersma et al., 2009; Madigosky et al., 2006; Moskowitz et al., 2007; Paxton & Rubinfeld, 2010; Wayman et al., 2007; Sukalich et al., 2014; Langer et al., 2017; White et al., 2017; Bonnema et al., 2009), one in Canada (Posner & Nakajima, 2011) and one in South Korea (Kim et al., 2017). No training interventions to improve or promote adverse event disclosure were identified within the UK. These interventions included the following components: didactic lecture sessions, pre-reading materials, DVD materials, observation, small group work and discussions, and role-play or simulated training to practise disclosure, often including feedback sessions. Following the MRC guidelines (MRC, 2008) which propose that an intervention needs to have a coherent theoretical basis, a number of psychological, learning, and educational theories were identified which contributed towards intervention development. The theory-informed content was combined with existing research evidence from previous interventions and primary qualitative research to design the training intervention. The purpose of the training intervention was to enhance maternity healthcare professional's skills for disclosing adverse events to patients. This was a 3-hour training workshop, which included a mixture of interactive lecture-based components with facilitated group discussions and exercises. This training intervention was novel in the sense that it was the first intervention which was focused on disclosure within the UK and integrated the current UK policies and requirements of disclosure.

4). Piloting and evaluating the new training intervention to assess the feasibility and acceptability by healthcare professionals within maternity services.

After developing the intervention, it was necessary to pilot and evaluate the intervention to assess whether it was feasible to deliver and acceptable by maternity healthcare professionals. A mixed-methods approach was used to assess the feasibility and acceptability of the training intervention. 31 maternity healthcare professionals took part in the training intervention (6 midwives and 25 obstetricians). The findings of this study suggested that the training intervention was acceptable to healthcare professionals. Overall, the training was rated as effective in its delivery and an effective use of time. In terms of content, the training was rated as having provided adequate time to learn skills and concepts, described skills applicable to the healthcare professional's hospital, the role play and case study elements were useful, the guidance document for adverse event disclosure was useful and awareness of the psychological strategies was also useful.

Healthcare professionals described that there was a perceived sense of improvement in disclosure after taking part in the intervention. The findings from this study also suggest that it might not be feasible to recruit and deliver the training intervention to a single Trust as part of a larger evaluation due to the difficulty of recruiting a group of midwives and/or obstetricians to be available together at the same time. To improve the feasibility of recruitment and delivery, the intervention could be delivered at a regional level, and include healthcare professionals from a number of different healthcare organisations. This study also provides preliminary evidence that the training intervention has the potential to improve knowledge of disclosure and increase self-efficacy to disclose adverse events. The two main areas for improvement identified by participants in the follow-up interviews was the use of standardised patients within the role play element and targeting the training at those earlier in their career.

6.4 Strengths and limitations

The strengths and limitations of the individual studies are discussed in the preceding chapters. The overall strengths and limitations of this research are summarised here. A key strength of this research is the consultations and collaborations with midwives and obstetricians during each stage of the research process including the development, piloting, and delivery of the training intervention. Due to their first-hand experience of adverse event disclosure, these healthcare professionals had much to offer towards the development of the training intervention. These collaborations further aided understanding of the types of training workshops which would be the most useful and practical, and decisions about who should deliver the intervention, intervention format, and setting, session frequency, and duration. A second key strength of this PhD research is that the intervention development included theory-informed content, combined with existing evidence from previous adverse event disclosure interventions and primary qualitative research from maternity healthcare professionals, whilst taking into account practical issues. The majority of previous adverse event disclosure interventions lacked theoretical underpinnings or failed to describe these, despite recommendations that the use of appropriate theory enhances intervention development (MRC, 2008). Another strength of this research was the use of a mixed-methods approach. The use of both qualitative and quantitative methods was able to provide rich comprehensive data than a single method alone. The qualitative methods were used to explore and obtain an in-depth understanding of healthcare professionals perceptions of the training intervention that was delivered, and the quantitative methods allowed the exploration of whether the

training intervention resulted in any preliminary changes in knowledge of disclosure and self-efficacy to disclose.

Limitations of the research predominantly relate to issues with the study design. A pre and post-intervention study design was used. A pre and post-single-arm study design was used and although this allowed the comparison of knowledge of disclosure and self-efficacy in conducting disclosure before and after taking part in the training intervention, the findings are limited and the study design is weak. A multiple arm pre and post design, where there is a control arm, where no intervention is delivered would have been a stronger study design. Alternatively, a wait-list control group design would have been appropriate. However, the choice of design for this study was chosen due to the limited availability of study participants and time constraints (Thiese, 2014). It was also appropriate given that the primary aim was to understand whether the intervention was acceptable to participants and feasible to deliver, rather than whether it was effective. Although this study suggests that knowledge of disclosure and self-efficacy in conducting disclosure is impacted by the training intervention, it does not have control over other elements that are also changing at the same time as the intervention is implemented. A second limitation is related to the small sample size used within the feasibility study. The thirty-one participants who took part provided valuable data for analysis and insights into the feasibility of the training intervention. Only six midwives were recruited compared to twenty-five obstetricians, indicating that the intervention is less feasible to deliver to this group. It is possible that the Trust by Trust approach used for this study affected the feasibility of recruiting and delivering such an intervention.

6.5 How do the findings from the thesis contribute to existing knowledge in patient safety?

Below, the findings of the PhD thesis are discussed in relation to the broader literature within patient safety.

Patient involvement in patient safety

In recent decades, the patient's role in healthcare has evolved from a passive recipient of healthcare to an active, empowered, co-producer of health (WHO, 2013). Initiatives to involve patients can be found in a number of aspects of healthcare delivery, including patient safety (Kok, Leistikow, & Bal, 2018). The shift towards understanding that patients and/or their families could play a role in promoting safety has now become an international policy priority (Lawton et al., 2017). For example, the World Health

Organisation's 'patients for patient safety program' aims to incorporate patients, families, and the community voice into all levels of healthcare through engagement and empowerment. This is being reflected in the involvement of patients at multiple levels (Baker, Fancott, Judd, & O'Connor, 2016; Carman et al., 2013). At an individual or direct care level, patient's involvement can range from decision-making or managing their own health. At an organisational and governance level, patients are involved in working alongside healthcare professionals to deliver and evaluate care, e.g. by participating in quality improvement projects (Sahlström, Partanen, , Azimirad, Selander, & Turunen, 2019). Considering patient involvement at a higher level, patients can help to set agendas with healthcare professionals and leaders (Sahlstrom et al., 2019). At a policy level, in collaboration with policymakers, patient involvement includes the development, implementation, and evaluation of local and national health care policies (Carman et al., 2013). Patient involvement has the potential to improve communication, patient experiences, and reduce the financial costs (Weingart et al., 2011).

Findings from this thesis (chapter 2) revealed that after an adverse event, patients/family members often felt that they did not receive the information that they needed from the disclosure conversation. This left them feeling unsatisfied with the disclosure that they had received. Although healthcare professionals discussed the importance of disclosure, there was a difference in expectations of disclosure between patients and healthcare professionals. In order to meet the patient's needs and requirements for disclosure, there is a need to reduce this gap. Involving patients and family members in adverse event investigations is one of the potential ways to do this. There is increasing recognition that when things go wrong within a patient's care, patients or families' voices should be heard and patients should be involved in the incident investigation process (Etchegary et al., 2016; Grissinger, 2011; Zimmerman & Amori, 2007; Iedema and Allen, 2012). Interestingly, however, within chapter 2 patient's views and experiences of disclosure did not reflect or describe involvement during the investigation process. This may suggest that although the involvement of patients and families is advocated, this is currently not being implemented. By being involved in the incident investigation, patients can receive answers in relation to the adverse event that they could not obtain from the disclosure conversation itself. Patients can also provide valuable insights into how future adverse events should be disclosed to meet their needs. One of the findings from chapter 2 was that patients wanted to know that the healthcare organisation was committed to preventing recurrences to ensure the same adverse event did not occur with others. Involving patients and/or families in the investigations may bring valuable knowledge to inform learning from what has gone wrong to prevent the same incident from reoccurring

and therefore has the potential to improve patient safety (Etchegaray et al., 2016). The patient's or family's perspective can differ from a healthcare professional's perspective (Iedema, Allen, Britton, K & Gallagher, 2012; Rowley & Waring, 2011; Vincent & Amalberti, 2016) and this can offer key insights that may otherwise be overlooked (Amori & Popp, 2007).

Second Victims and Just Culture

Throughout the thesis, there was a running theme in relation to the emotional impact of adverse events on healthcare professionals. The findings of this thesis can contribute towards existing knowledge of second victims and the organisational culture of organisations in a number of ways which are discussed further on. Healthcare professionals faced a range of negative emotional consequences as a result of being responsible for the adverse event. These included feelings of shame, anxiety, grief and frustration, and guilt, which were viewed as a burden that would have a long-lasting effect. These are consistent with findings from the existing second victim literature (Aasland & Forde, 2005; Schelbred & Nord, 2007; Sirriyeh et al., 2010; Seys et al., 2013; Han et al., 2017). The term second victim is used to refer to healthcare professionals who have been involved in an adverse event and are victimised in the sense that they are impacted and traumatised by that event (Scott et al., 2009). Anticipating the disclosure process, including uncertainty about the patient's reaction caused healthcare professionals further distress. Further worries resulted from the anticipation of a potential investigation after the initial disclosure. An interesting finding emerged where healthcare professionals adopted either a 'professional' or 'personalised' approach to disclosure. The former did not elicit strong feelings or emotions and disclosure was viewed as an aspect of routine care, whereas the latter resulted in intense negative emotions and rumination about the incident. It may be useful to raise awareness surrounding these two different approaches to disclosure, discussing the differences between each way of thinking about disclosure in order to reduce some of the distress faced by healthcare professionals after an adverse event.

Although healthcare professionals suffered emotional distress after being involved in an adverse event, sufficient support was not provided by healthcare organisations to help them cope with this distress. Being involved in an adverse event was described as lonesome (chapter 5). Within the training intervention that was delivered to healthcare professionals (chapter 5), the element surrounding the emotional impact of adverse events on healthcare professionals was perceived as important. The group discussions within the training provided healthcare professionals with an opportunity to share their

experiences of adverse events and disclosure with colleagues. This was described as a rare but valued opportunity; as such discussions were neglected within maternity. Healthcare professionals described a sense of feeling less alone and reassured after hearing what other colleagues had experienced, particularly after realising that most colleagues had been involved in an adverse event. It was perceived that there was a lot to learn from hearing about colleague's good and bad experiences, as well as ways that they managed and coped with adverse event situations. There is evidently a need to support for second victims, however, this is currently lacking. Recently, the website secondvictim.co.uk has been developed which offers support for second victims, their colleagues, and employing organisations.

The findings from this thesis suggest that providing healthcare professionals with a forum to discuss experiences surrounding adverse events is one of the ways to support them. This is consistent with previous research which suggests that opportunities to talk and share difficult experiences about adverse events are coping mechanisms (Engel et al., 2006). Such a support mechanism also provides learning opportunities, and this may also help healthcare professionals cope. The emotional turmoil faced by healthcare professionals can have a significant impact on their personal and professional lives, including loss of confidence, damaged relationships, and decreased job satisfaction (Harrison et al., 2014). In terms of adverse event disclosure, as well as organisational support, healthcare professionals need to be able to manage their own emotions in response to adverse events as this can help to be in the correct frame of mind and be mentally prepared, resulting in a more effective disclosure. Findings from the feasibility study suggest that awareness of the psychological strategies for healthcare professionals to manage their own emotions was viewed as valuable knowledge and identified the need to disseminate these more widely so others could make use of them. These were thought to be useful coping strategies to help one feel in control of their thoughts and feelings after being involved in an adverse event. Research also suggests that a healthy recovery after an adverse event is grounded in highly individualised coping skills such as validation of emotions and self-forgiveness (Delacroix, 2017).

Contributing to the second victim phenomenon is the unreasonable notion of infallibility which exists in the professional culture (Kirkup, 2019; White & Delacroix, 2020). This culture of absolute perfectionism results in negative emotional reactions such as shame and embarrassment and significantly increases healthcare professional's stress (Han et al., 2017). This emotional turmoil makes it challenging to be open and transparent about the

adverse event. In addition to facing these emotional consequences, healthcare professionals also face the likelihood of blame not only from patients and families but also from their healthcare organisations. This organisational blame approach to adverse events focuses on seeking adverse events and identifying the individual responsible, and punishment follows (Boysen, 2013). However, a punitive approach does not resolve the issue and is damaging to both the healthcare professional and the safety of the healthcare organisation. Although an individual healthcare professional may be at fault, contributing problems within the system also exist (Boysen et al, 2013). In an attempt to move away from this blame culture, a more balanced and reflective approach to learning from incidents and supporting healthcare professionals has been proposed (Petschonek et al, 2013). This is known as a Just Culture. This organisational approach consists of a balance of fairness, justice, and learning, whilst taking into account responsibility and accountability for actions (Kerrigan, 2020). A recently published report from the NHS Resolution, 'Being fair' sets out the argument for a just and learning culture within the NHS and emphasises the importance of adopting a Just Culture. Taking such an approach can help to improve levels of patient care (Kerrigan, 2020), promote learning, facilitate the disclosure of adverse events, and improve patient safety.

Findings from this thesis (chapter 2) also revealed that one of the barriers to disclosure reported by healthcare professionals was the difficulty of disclosure in a blame culture (Gallagher et al., 2003; McLennan et al., 2016; Harrison et al., 2017; Coffey et al., 2010; Fein et al., 2005). Healthcare professionals suggested the move towards a more open and transparent culture to facilitate effective disclosure practices. Fear of a damaged reputation and workplace sanctions were also described as reasons to conceal adverse events. These findings suggest that there is a need to develop a just culture and frameworks specifically identifying the need to support healthcare professionals with the disclosure and investigation process after an adverse event. All but one of the studies that discussed blame culture as a barrier to disclosure were conducted outside of the UK. Interestingly, blame culture was not discussed by UK maternity healthcare professionals in the subsequent studies (chapters 3 and 5). Even when participants were asked about their experiences of adverse event disclosure within the UK, the culture of their organisations was not discussed as a barrier to being open. This could be due to the recent emphasis on the importance of the move towards a Just Culture within the NHS and the adoption of this approach by the organisations of those healthcare professionals who participated in the research. Although these findings may be viewed as positive, as a

culture of openness is a necessary step to improvements in patient safety, these findings are not conclusive because culture was also not discussed as a facilitator.

6.6 Contributions to methodological development

Findings from this thesis have contributed towards developing further guidance for conducting a meta-ethnographic synthesis of the literature. The range of different methods for synthesising qualitative research has grown in recent years (Barnett-Page & Thomas, 2009). There are now several different qualitative synthesis methods including qualitative meta-synthesis, narrative synthesis, thematic synthesis, interpretative synthesis, grounded theory, and meta-ethnography. Meta-ethnography is an inductive, interpretative approach upon which most interpretative qualitative synthesis methods are based (Paterson, 2011) and is the most commonly utilised qualitative synthesis approach in healthcare research (Hannes & Macaitis, 2012). A meta-ethnography differs from other qualitative synthesis approaches as the reviewer re-interprets the conceptual data (themes, concepts, or metaphors) created by the authors of the primary study whilst taking into account the primary data (participant quotes) using a unique translation synthesis method to transcend the findings of individual study accounts and create higher-order themes (Noblit & Hare, 1988).

Although meta-ethnography is a widely used qualitative literature synthesis method within healthcare research, it is poorly demarcated and there is a lack of clarity surrounding the description of the data synthesis process. A number of previous reviews have used a meta-ethnographic approach (Scott & Grant, 2018; Elmir & Schmied, 2016; Cullinan, O'Mahony, Fleming & Byrne, 2014; Purc-Stephenson & Thrasher, 2010; Toye, Seers & Barker, 2017; Rubio-Valera, Pons-Vigués, Martínez-Andrés, Moreno-Peral, Berenguera & Fernández A, 2014). However, they do not provide a fully rigorous description of the stages involved in the analysis process. The ultimate aim of qualitative research synthesis in healthcare is to contribute towards improvements in patient care and experience, as well as improving the processes for healthcare professionals involved (Atkinson & Cipriani, 2018). For a meta-ethnography synthesis to be considered to be of high quality and useful, the meta-ethnographic approach needs to be rigorous and consistent. Therefore, a clear understanding of the steps included in a meta-ethnography is vital to produce a synthesis that is rigorous and comprehensive. It was important to provide detailed guidance on each of the steps involved in conducting a meta-ethnography. There was a need for transparency on how each of the stages should be conducted and there is a lack of clarity surrounding the exact stages reviewers utilise to reach their final synthesis.

In order to fill this gap, a practical guide that outlined a step-by-step method for conducting a meta-ethnography was developed as part of this thesis. Within this guide, the PhD researcher described their own interpretations of each of the seven steps *(1. Getting started, 2. Deciding what is relevant to the initial interest, 3. Reading the studies, 4. Determining how the studies are related, 5. Translating the studies into one another, 6. Synthesising the translations and 7. Expressing the synthesis)* outlined by Noblit and Hare (1988), who first proposed this approach. Adaptations and developments were incorporated from recent research. The systematic review in chapter 2 was used as a worked example, and where applicable, annotations, and examples were provided to assist in describing the stages involved. The detailed guide is available in Appendix 4.

6.7 The implications of findings for national policy and strategy

The findings from this thesis have a number of implications for national policies and strategies which are discussed in detail below.

The Patient Safety Strategy

The NHS patient safety strategy was introduced within the UK in 2019 and describes how the NHS will continuously improve patient safety within the next five to ten years, with the main focus on building on the foundations of a safer culture and safer systems (NHS England & NHS Improvement, 2019). This strategy is underpinned by a systems approach that suggests moving away from individual blame. One of the findings from this PhD was related to the difficulty of disclosure in a blame culture (chapter 2) and the need to shift away from such a culture to one which encourages openness. A culture of fairness, openness, and learning where healthcare professionals can speak up without fearing blame is a necessary step to make improvements in patient safety, and this patient safety strategy aims to promote the move towards a Just Culture. A strand of the patient safety strategy focuses on aiming to ensure that healthcare professionals have the skills and opportunities to improve patient safety. The National Institute for Health and Care Excellence (NICE), which provides national guidance and advice to improve health and social care within the UK highlights the importance of healthcare professionals being proficient in communication skills (NICE, 2012). Findings from this PhD suggest that a lack of communication skills on how to conduct effective disclosure with patients can result in not providing patients with the disclosure they required, and when patients did not receive the information they needed, they sought legal help (chapter 2). Disclosure is a

complex communication task and the training intervention developed to enhance healthcare professional's skills in disclosing adverse events to patients (chapter 5) can be one of the ways to improve communication skills.

Patient Safety Incident Response Framework

The Patient Safety Incident Response Framework (NHS England & NHS improvement, 2020) has been introduced very recently within the UK. It is an introductory framework, which guides the NHS on how to respond to patient safety incidents in a way that ensures learning and improvement, and to avoid unless necessary, holding an individual accountable. This framework has not yet been implemented within the NHS, as a phased approach to implementation is being taken. It describes that the purpose of a patient safety incident investigation is to look back at what happened and why and take actions to help prevent or significantly reduce the chances of a similar incident in the future. The findings from this thesis support and provide concrete approaches for implementing the recommendations proposed by the Patient Safety Incident Response Framework (PSIRF) in a number of ways. The findings from the current research suggest that some of the key elements of disclosure desired by patients is an apology and knowing that an organisation is committed to preventing recurrences. Within this framework, the need to apologise and be open with patients to help them overcome the adverse event is reiterated. It is also recommended that even when an investigation does not take place, patients and families should be provided with information about how the organisation has responded to the adverse event including ways to prevent a similar occurrence in the future. By adhering to these recommendations, healthcare professionals can meet patient's requirements for disclosure.

The PSIRF also discusses the importance of supporting the involved healthcare professionals during the investigation process. This framework is based on a number of principles which includes the need for a Just Culture environment for learning and improvement, transparency, support and engagement for those (including healthcare professionals) who have been involved in adverse events, clarifying the purpose of the investigations and planning investigations within a specific timeframe of no longer than six months. The findings of this PhD revealed that anticipating the investigation process caused worries for healthcare professionals and often made them hesitant to disclose as an investigation process may follow the disclosure. These worries were due to the poor routines involved in this process, inappropriate management of the case, a lengthy wait for a decision, and a lack of support from organisations. In light of these findings, the

introduction of the PSIRF and the included principles is greatly valued, is very much needed, and has the potential to improve the investigation process for healthcare professionals and support them through this process. The implementation of the PSIRF could therefore support healthcare professionals with the investigation process to an extent. However, although this framework suggests that healthcare professionals should have the opportunity to contribute to other responses that allow learning from the incident; it does not advocate the inclusion of healthcare professionals in investigation meetings. Based on the findings from chapter 3, it is recommended that involving healthcare professionals in the investigation meetings can help to reduce some of the emotional distress that they experience during this process and help them feel further supported. Therefore, this element should be implemented into the PSIRF. The PSIRF also suggests that after identification of an adverse event, obligations of the Duty of Candour (CQC, 2015) must be upheld. However, this can be difficult for healthcare professionals when they lack familiarity with this regulation (chapter 3). Therefore, there is a need for individual organisations to raise awareness of the requirements of the Duty of Candour to ensure disclosure is conducted in accordance with this. The training intervention developed within this PhD, directly addresses this need by integrating the Duty of Candour requirements. The PSIRF also sets expectations for engaging patients and families with investigations. Although the training intervention developed within this research focuses on disclosing the adverse event rather than the investigation which follows, the training takes a first step in addressing the mandate to take into account the needs of patients and ways in which healthcare professionals can be supported to meet these needs.

An important element that this framework does not cover is the legal implications of involvement in adverse events which may follow an adverse event. One of the findings which emerged from this PhD research was fear of malpractice liability when disclosing adverse events to patients (chapters 2 and 3). There is a need for transparency surrounding the processes of liability and malpractice laws within the UK, and currently, there is no policy or guidance in relation to this. Such guidance needs to be developed and disseminated to healthcare professionals, as awareness of the legal aspect of disclosure is necessary to reduce the fear of liability and the associated emotional distress that healthcare professionals face.

The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC)

Within the UK, openness and honesty towards patients and/or their families when things go wrong within their care is supported by several professional bodies including the GMC

for doctors and the NMC for nurses and midwives. However, although these professional bodies advocate and emphasise that all healthcare professionals have a responsibility to follow a duty of candour after an adverse event, the findings from this PhD research suggest that healthcare professionals varied in their knowledge of the Duty of Candour regulation. Some were familiar with the disclosure principles whereas others were only aware of its existence. Although there was an emphasis on the Duty of Candour, the principles were not always implemented in practice. Therefore, these findings highlight the need for organisations to raise awareness of this policy and requirements, to ensure that disclosure is conducted transparently and respectfully. One of the challenges faced by maternity healthcare professionals was the struggle to draw the line between which incidents would be classed as an adverse event and a complication. When it was difficult to tease apart the two types of events (in effect those that were avoidable and those that were not), healthcare professionals struggled with how to approach disclosure. It is important that professional bodies such as those mentioned above, develop national guidance to assist healthcare professionals in determining which incidents can be classed as adverse events or a complication, and how to approach disclosure when it is still unclear what type of incident has occurred.

The findings from this PhD have also highlighted the emotional burden that healthcare professionals experience after being involved in an adverse event and disclosure, particularly when they were personally responsible for the adverse event. However, there is currently a lack of support that is available for them (chapter 3). Recent efforts are being made by professional bodies to provide emotional support for healthcare professionals. The NMC has recently launched a new emotional and practical support service in 2019 for healthcare professionals who are involved in fitness to practice. However, emotional support for those who have been involved in an adverse event is currently still lacking. Professional bodies must develop support systems and services specific to involvement in an adverse event and make these resources available for healthcare professionals.

6.8 Implications of findings for practice

The training intervention designed to enhance skills in conducting adverse event disclosure was acceptable by maternity healthcare professionals, viewed as useful and relevant, had the potential to improve knowledge of disclosure and improve confidence in conducting disclosure with patients. Previous disclosure interventions have focused on raising awareness of the moral and legal elements of disclosure and an important element

that was previously missing from interventions and incorporated into the current intervention was the emotional element of adverse events and disclosure. This was identified as one of the strengths of this intervention by participants. At an organisational level, this training intervention can be integrated into the allocated training times available for obstetricians in the UK. However, currently, midwives do not have allocated training time set aside. It is vital that organisations also provide training opportunities for midwives, to ensure that they can also benefit from training initiatives such as this. Future delivery of this training workshop to midwives needs to adopt an alternative approach. Instead of delivering the training at an organisational level, a larger group training workshop aimed at midwives can be delivered at a national level, to ensure that midwives from across the different regions have the opportunity to attend. A multi-disciplinary training including both midwives and obstetricians may also be an effective approach.

It is important to take into account the practical considerations for delivering the training intervention. Delivering this adverse event disclosure training requires three hours of healthcare professional's time away from clinical duties. The training intervention was delivered by two psychologists with the assistance of a consultant obstetrician. It is important that certain aspects of the training which had a psychological element are delivered by a trained psychologist. The psychologists were also key in managing the group discussions which took place and ensuring that emotional difficulties described by participants were managed and responded to appropriately. It is important to be mindful that further delivery of this training intervention involving psychologists could be costly, particularly when delivering it a number of times. An alternative cost-effective method to this could be that course leaders are allocated within each Trust, who are trained by psychologists to deliver this training.

Although the Duty of Candour is implemented at a policy level within the UK, the findings from this PhD suggest that further awareness of this regulation and the requirements needs to be raised by individual organisations. One of the ways to do this is by distributing the Duty of Candour guidance document (see figure 4.1) to healthcare professionals, which have been developed as part of the workshop in the form of an educational resource. Also, given the significant emotional burden of being involved in an adverse event and the disclosure process, there is a need to develop and implement support systems for midwives and obstetricians. Although no formal support previously existed for obstetricians, midwifery supervision was the first line of support utilised by midwives, which is no longer available. One of the ways in which organisations can develop a support system is by introducing informal peer group sessions, where healthcare professionals

have the opportunity to discuss and share experiences related to adverse events. The findings from this PhD revealed that as well as being a useful learning opportunity, group discussions with colleagues about experiences of adverse events helped to reduce feelings of isolation and increased reassurance that they were not alone in experiencing adverse events and the associated emotions.

6.9 Directions for future research

Further development and evaluation of the current intervention

The feasibility study has identified that there is a need to incorporate standardised patients within the role play element when delivering the training intervention in the future. This will assist in making this aspect more realistic and increase engagement. Separate training sessions need to be delivered for junior and senior obstetricians. This would involve adapting and tailoring content such as the case studies to ensure they are appropriate for each group. Future research could tailor the training intervention and deliver, and evaluate it with healthcare professionals across different areas of healthcare. It is recommended that the current intervention is considered for further evaluation using a wait-list control design. Such a design provides an untreated comparison for the experimental group to determine if the intervention has had an effect. By serving as a comparison group, it will be possible to examine the impact of the training intervention.

The feasibility study only assessed self-efficacy to disclose and not actual skills or behaviour. It is important to understand whether this training intervention has a long-term impact on behaviour or performance and assess participant's ability to use their newly learned knowledge and skills of adverse event disclosure within their organisations. One of the ways to achieve this is by having six months follow up with participants which can be in the form of telephone interviews. A longer-term evaluation may assess intervention effectiveness by examining whether litigation rates have changed after healthcare professionals have taken part in the training workshop or whether the patient and/or family ratings of disclosure have improved. Interview findings from a recent report (Birks, Aspinal & Bloor, 2018) suggest that individuals may pursue litigation for a number of reasons. Whilst some individuals seek litigation for financial purposes, others would do so when they did not receive answers about their care from healthcare professionals and organisations. Although there is limited evidence to suggest that communication alone prevents progression to claims, this is one of the potential ways to measure the long-term impact of the training intervention. Research in patient safety has predominantly focused

on hospital-based, secondary care (Cooper and Chuter, 2015). Estimates suggest that substantial patient harm from adverse events occurs in 1 in 20 encounters in primary care (Panesar et al., 2016). It would be interesting for future research to adapt and deliver the training intervention within primary care, to assess whether there is the potential for it to be applicable across different areas of healthcare.

6.10 Providing training on disclosure and the complexities of disclosure in the UK health service

Disclosure within the NHS in the UK is a complex process, and although disclosure is advocated in policies such as the Duty of Candour regulation (CQC, 2015) and the Being Open framework (NPSA, 2009), in order to improve the process of disclosure and for an effective change to occur, organisational changes need to be made. The organisational culture refers to a shared set of beliefs from those working together about how work is accomplished (Etchegaray et al., 2012); Schein, 2010; Sexton et al., 2006). Changing the culture within NHS organisations is one of the fundamental changes that have been highlighted in the systematic review in chapter 2 as well as in frameworks such as the Patient Safety Incident Response Framework (NHS England & NHS Improvement, 2020) for learning, improvement and transparency of adverse events. Although healthcare professionals have a responsibility to be honest with patients when things go wrong, the culture of blame which currently exists within NHS organisations and inappropriate blame is damaging to both healthcare professionals and the safety of organisations. Such a culture can hinder disclosure practices as healthcare professionals may fear blame when acknowledging and disclosing adverse events. Organisational culture has been identified as an important factor which determines whether training is successfully transferred from a training workshop to the workplace setting (Blume et al., 2010; Grossman & Salas, 2011). Although a training intervention to support healthcare professionals with the disclosure of adverse events has been developed, until there is system-wide move towards a Just Culture, providing healthcare professionals with training on disclosure will be limited in its effectiveness.

Healthcare professionals may attend the training intervention and learn the knowledge and skills required for conducting an effective disclosure, but if they are working in an organisation where the culture does not allow for openness and transparency without fear, then they are unlikely to implement these skills into practice and the intervention will remain largely ineffective. Therefore, it is important to note that training on

communication skills such as disclosure is a small element in attempting to improve the disclosure process, and training alone cannot improve this process. In order for healthcare professionals to deliver an effective disclosure, alongside attending training workshops such as these, these wider system issues also must be addressed. An example of an NHS healthcare organisation which aimed to address its culture is the Mersey Care NHS Foundation Trust (Mersey Care NHS Foundation Trust, 2019). Research suggested that healthcare professionals feared being blamed for adverse events, and due to the lack of openness and compassion within the Trust, they felt inhibited to speak out about adverse events. A Restorative Just learning Culture was implemented to change responses to incidents, patient harm and complaints. A restorative just culture is based on the principles of repairing and building trust and relationships when things have not gone as planned (Dekker, 2018). This requires the development of working practices that move away from fear and blame, and address the wellbeing needs of healthcare staff to ensure they work safely (Kerrigan, 2020). It was found that the introduction of this approach resulted in improvements including an increase in reporting of adverse events and healthcare professionals feeling more engaged and able to be open about adverse events (Kaur et al., 2019).

6.11 Development of other approaches to support disclosure

The training intervention was aimed at midwives and obstetricians who work on the frontline within the NHS, as these healthcare professionals are involved in the direct care of patients within maternity services. Therefore, when things go wrong within their care, they are primarily responsible for disclosing adverse events to patients and/or their families. Addressing the needs for these healthcare professionals in terms of providing training on adverse event disclosure (Gallagher et al., 2006) was important to ensure that they are well equipped to deliver an effective disclosure. Although training these frontline healthcare professionals is needed, this approach relies on individuals to implement disclosure practices in situ within the organisation (Sorenson et al., 2008). An alternative approach is to move implementation away from relying on individuals to establishing organisations which promote and ground disclosure into local practice (Sorenson et al., 2008). This can be achieved by targeting those higher up in the system such as those at senior positions within organisations. One of the ways in which this can be done is by providing disclosure training to those in senior management or risk management, who would then be able to train healthcare professionals on the frontline (White et al., 2017). Those who have been trained in senior management have the potential to guide planning for disclosure conversations and to advocate disclosure within departments and across

organisations. This can help to embrace a value of transparency and openness amongst leaders, which can help to improve the rate of disclosure within organisations. Therefore, coaching those higher up in the system has the potential to result in sustained and efficient organisational changes (White et al., 2017). An example of such an approach has been highlighted by White et al (2017), where a multicentre study has focused on the development and implementation of an error disclosure coaching model.

It is also important to support a different type of approach to safety, where disclosure is viewed as essential to learning from all perspectives about adverse events and how they can be prevented (Kaur et al., 2019). One of the ways in which this can be achieved is by the implementation of restorative Just Culture practices. These recognise the importance of dealing with adverse events by asking questions such as who is hurt; what do they need and whose obligation is it to meet those needs?' and considers accountability in a forward-looking manner, where it asked what needs to be done going forwards (Kaur et al., 2019). Such an approach views disclosure as something that is told and shared, and by doing so, disclosure may result in organisational learning and improvements to prevent the same adverse event from occurring again (Dekker and Breaky, 2016).

6.12 Thesis summary

The overall aim of this thesis was to investigate how healthcare professionals within maternity services can be supported to communicate the news to patients that an adverse event has occurred. The novelty of this research is within the maternity settings in which this research has been conducted. The findings from this PhD research suggest that after an adverse event, patients desire a disclosure which includes the relevant information, an apology, and a commitment to preventing future recurrences. However, healthcare professionals who are often experiencing emotional distress after involvement in an adverse event, lack skills on how to conduct this disclosure. An intervention was developed which meets patients' needs for disclosure, whilst also addressing those of healthcare professionals. The intervention has proven to be acceptable and feasible, particularly with some modifications to delivery. Future research should evaluate the long term effectiveness and cost-effectiveness of the intervention.

List of References

1. Aasland, O. G., & Førde, R. (2005). Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues. *BMJ Quality & Safety*, *14*(1), 13-17. doi: http://dx.doi.org/10.1136/qshc.2002.003657

2. Abadie, R. (2010). *The professional guinea pig: Big pharma and the risky world of human subjects*. USA: Duke University Press.

3. Adams, N. E. (2015). Bloom's taxonomy of cognitive learning objectives. *Journal of the Medical Library Association: JMLA*, *103*(3), 152. doi: https://dx.doi.org/10.3163%2F1536-5050.103.3.010

4. Allan, A., & McKillop, D. (2010). The health implications of apologizing after an adverse event. *International Journal for Quality in Health Care*, *22*(2), 126-131.

5. Allman, J. (1998). Bearing the burden or baring the soul: Physicians' self-disclosure and boundary management regarding medical mistakes. *Health communication*, *10*(2), 175-197.

6. American Medical Association. (2019). *Code of Medical Ethics*. Retrieved 2nd August 2019 from https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview

7. Amori, G., & Popp, P. L. (2007). The timing of early resolution: working at the patient's pace. *Journal of Healthcare Risk Management*, *27*(3), 19-23. doi: https://doi.org/10.1002/jhrm.5600270305

8. Arigo, D., Pagoto, S., Carter-Harris, L., Lillie, S. E., & Nebeker, C. (2018). Using social media for health research: Methodological and ethical considerations for recruitment and intervention delivery. *Digital health*, *4*, 2055207618771757. doi: https://doi.org/10.1177/2055207618771757

9. Arimitsu, K., & Hofmann, S. G. (2017). Effects of compassionate thinking on negative emotions. *Cognition and Emotion*, *31*(1), 160-167. doi: https://doi.org/10.1080/02699931.2015.1078292

10. Artino Jr, A. R., Hemmer, P. A., & Durning, S. J. (2011). Using self-regulated learning theory to understand the beliefs, emotions, and behaviors of struggling medical students. *Academic Medicine*, *86*(10), S35-S38. doi: 10.1097/ACM.0b013e31822a603d

11. Aspden, P., Corrigan, J. M., Wolcott, J., & Erickson, S. M. (2004). Institute of Medicine (Committee on Data Standards for Patient Safety). Patient safety achieving a new standard for care.

12. Atkins, S., Lewin, S., Smith, H., Engel, M., Fretheim, A., & Volmink, J. (2008). Conducting a meta-ethnography of qualitative literature: lessons learnt. *BMC medical research methodology*, *8*(1), 21. doi: https://doi.org/10.1186/1471-2288-8-21

13. Atkinson, L. Z., & Cipriani, A. (2018). How to carry out a literature search for a systematic review: a practical guide. *BJPsych Advances*, *24*(2), 74-82. doi: https://doi.org/10.1192/bja.2017.3

14. Australian Commission on Safety and Quality in Health Care. (2013). *Australian Open Disclosure Framework*. Retrieved 2nd August 2019 from https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf

15. Baile, W. F., Buckman, R., Lenzi, R., Glober, G., Beale, E. A., & Kudelka, A. P. (2000). SPIKES—a six-step protocol for delivering bad news: application to the patient with cancer. *The oncologist*, *5*(4), 302-311. doi: 10.1634/theoncologist.5-4-302

16. Baker, G. R., Fancott, C., Judd, M., & O'Connor, P. (2016). Expanding patient engagement in quality improvement and health system redesign: three Canadian case studies. *Healthcare Management Forum, 29* (5), 176-182. doi: https://doi.org/10.1177%2F0840470416645601

17. Bandura A. (1997). The exercise of control. Freeman.

18. Bandura, A. (1986). *Social foundations of thought and action.* Prentice-Hall.

19. Barach, P., & Small, S. D. (2000). Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *Bmj*, *320*(7237), 759-763. doi: https://doi.org/10.1136/bmj.320.7237.759

20. Barnett-Page, E., & Thomas, J. (2009). Methods for the synthesis of qualitative research: a critical review. *BMC medical research methodology*, *9*(1), 1-11. doi: 10.1186/1471-2288-9-59

21. Barnsley, L., Lyon, P. M., Ralston, S. J., Hibbert, E. J., Cunningham, I., Gordon, F. C., & Field, M. J. (2004). Clinical skills in junior medical officers: a comparison of self-reported confidence and observed competence. *Medical education*, *38*(4), 358-367. doi: https://doi.org/10.1046/j.1365-2923.2004.01773.x

22. Becher, E. C., & Chassin, M. R. (2001). Improving quality, minimizing error: making it happen. *Health Affairs*, *20*(3), 68-81. doi: https://doi.org/10.1377/hlthaff.20.3.68

23. Beck, J. S. (1964). *Cognitive Therapy: Basics and Beyond*. Guildford Press.

24. Bell, S. K., Moorman, D. W., & Delbanco, T. (2010). Improving the patient, family, and clinician experience after harmful events: the "when things go wrong" curriculum. *Academic Medicine*, *85*(6), 1010-1017.

25. Benoot, C., Hannes, K., & Bilsen, J. (2016). The use of purposeful sampling in a qualitative evidence synthesis: A worked example on sexual adjustment to a cancer trajectory. *BMC medical research methodology*, *16*(1), 21. doi: https://doi.org/10.1186/s12874-016-0114-6

26. Berlin, L., Murphy, D. R., & Singh, H. (2014). Breakdowns in communication of radiological findings: an ethical and medico-legal conundrum. *Diagnosis*, *1*(4), 263-268. doi: https://doi.org/10.1515/dx-2014-0034

27. Berwick, D. M. (2013). *A promise to learn – a commitment to act: Improving the safety of patients in England.* London, UK: Stationery Office.

28. Birks, Y. (2014). Duty of candour and the disclosure of adverse events to patients and families. *Clinical Risk*, *20*(1-2), 19-23. https://doi.org/10.1177%2F1356262213516937

29. Birks, Y., Aspinal, F., & Bloor, K. (2018). *Understanding the Drivers of Litigation in Health Services*. Retrieved 16th August, 2020 from https://www.york.ac.uk/media/healthsciences/images/research/prepare/UnderstandingDriversOfLitigationInHealthServices.pdf

30. Birks, Y., Entwistle, V., Harrison, R., Bosanquet, K., Watt, I., & Iedema, R. (2015). Being open about unanticipated problems in health care: the challenges of uncertainties. *Journal of health services research & policy*, *20*(1_suppl), 54-60. doi: https://doi.org/10.1177%2F1355819614558100

31. Birks, Y., Harrison, R., Bosanquet, K., Hall, J., Harden, M., Entwistle, V., ... & Adamson, J. (2014). An exploration of the implementation of open disclosure of adverse events in the UK: a scoping review and qualitative exploration. *Health Services and Delivery Research*, *2(20)*.

32. Blume, B. D., Ford, J. K., Baldwin, T. T., & Huang, J. L. (2010). Transfer of training: A meta-analytic review. *Journal of management*, *36*(4), 1065-1105. doi: https://doi.org/10.1177%2F0149206309352880

33. Bondas, T., & Hall, E. O. (2007). Challenges in approaching metasynthesis research. *Qualitative health research*, *17*(1), 113-121. doi: https://doi.org/10.1177%2F1049732306295879

34. Bonnema, R. A., Gosman, G. G., & Arnold, R. M. (2009). Teaching error disclosure to residents: a curricular innovation and pilot study. *Journal of graduate medical education*, *1*(1), 114-118. doi: 10.4300/01.01.0019

35. Booth, A., Carroll, C., Ilott, I., Low, L. L., & Cooper, K. (2013). Desperately seeking dissonance: identifying the disconfirming case in qualitative evidence synthesis. *Qualitative health research*, *23*(1), 126-141. doi: https://doi.org/10.1177%2F1049732312466295

36. Boyatzis, R.E. (1998*). Transforming qualitative information: thematic analysis and code development*. Sage Publications.

37. Boysen, P. G. (2013). Just culture: a foundation for balanced accountability and patient safety. *Ochsner Journal*, *13*(3), 400-406.

38. Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, *3*(2), 77-101.

39. Britten, N. (1995). Qualitative research: qualitative interviews in medical research. *Bmj*, *311*(6999), 251-253.
doi: https://doi.org/10.1136/bmj.311.6999.251

40. Britten, N., Campbell, R., Pope, C., Donovan, J., Morgan, M., & Pill, R. (2002). Using meta ethnography to synthesise qualitative research: a worked example. *Journal of health services research & policy*, *7*(4), 209-215.
doi: https://doi.org/10.1258/135581902320432732

41. Buckman, R. A. (2005). Breaking bad news: the SPIKES strategy. *Community oncology*, *2*(2), 138-142.

42. Burney, V. H. (2008). Applications of social cognitive theory to gifted education. *Roeper Review*, *30*(2), 130-139.
doi: https://doi.org/10.1080/02783190801955335

43. Cachia, M., & Millward, L. (2011). The telephone medium and semi-structured interviews: a complementary fit. *Qualitative Research in Organizations and Management: An International Journal*.
doi: https://doi.org/10.1108/17465641111188420

44. Cahill, M., Robinson, K., Pettigrew, J., Galvin, R., & Stanley, M. (2018). Qualitative synthesis: a guide to conducting a meta-ethnography. *British journal of occupational therapy*, *81*(3), 129-137.
doi: https://doi.org/10.1177/0308022617745016

45. Campbell, R., Pound, P., Morgan, M., Daker-White, G., Britten, N., Pill, R., ... & Donovan, J. (2012). Evaluating meta ethnography: systematic analysis and synthesis of qualitative research. *Health Technology Assessment*, *15*, 1-164.
doi: https://doi.org/10.3310/hta15430

46. Campbell, R., Pound, P., Pope, C., Britten, N., Pill, R., Morgan, M., & Donovan, J. (2003). Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of

diabetes and diabetes care. *Social science & medicine*, *56*(4), 671-684. doi: https://doi.org/10.1016/S0277-9536(02)00064-3Get

47. Canadian Patient Safety Institute. (2011). *Canadian Disclosure Guidelines*. Retrieved 2nd August 2019 from https://www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Documents/CPSI%20Canadian%20Disclosure%20Guidelines.pdf

48. Carayon, P., & Gürses, A. P. (2005). A human factors engineering conceptual framework of nursing workload and patient safety in intensive care units. *Intensive and Critical Care Nursing*, *21*(5), 284-301. doi: https://doi.org/10.1016/j.iccn.2004.12.003

49. Care Quality Commission (CQC). (2015). *Regulation 20: Duty of Candour*. Retrieved December 2016 from https://www.cqc.org.uk/sites/default/files/20150327_duty_of_candour_guidance_final.pdf

50. Carman, K. L., Dardess, P., Maurer, M., Sofaer, S., Adams, K., Bechtel, C., & Sweeney, J. (2013). Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health Affairs*, *32*(2), 223-231. doi: https://doi.org/10.1377/hlthaff.2012.1133

51. Carr, E. C., & Worth, A. (2001). The use of the telephone interview for research. *NT research*, *6*(1), 511-524. doi: https://doi.org/10.1177%2F136140960100600107

52. Cavallo, D. N., Tate, D. F., Ries, A. V., Brown, J. D., DeVellis, R. F., & Ammerman, A. S. (2012). A social media–based physical activity intervention: a randomized controlled trial. *American journal of preventive medicine*, *43*(5), 527-532. doi: https://doi.org/10.1016/j.amepre.2012.07.019

53. Chen, Y. F., Huang, X. Y., Chien, C. H., & Cheng, J. F. (2017). The effectiveness of diaphragmatic breathing relaxation training for reducing anxiety. *Perspectives in psychiatric care*, *53*(4), 329-336. doi: https://doi.org/10.1111/ppc.12184

54. Clara, I. P., Cox, B. J., & Enns, M. W. (2007). Assessing self-critical perfectionism in clinical depression. *Journal of Personality Assessment*, *88*(3), 309-316. doi: https://doi.org/10.1080/00223890701317046

55. Clarke, V., & Braun, V. (2013). Teaching thematic analysis: Overcoming challenges and developing strategies for effective learning. *The psychologist*, *26*(2).

56. Classen, D. C., & Kilbridge, P. M. (2002). The roles and responsibility of physicians to improve patient safety within health care delivery systems. *Academic Medicine*, *77*(10), 963-972.

57. Coffey, M., Thomson, K., Tallett, S., & Matlow, A. (2010). Pediatric residents' decision-making around disclosing and reporting adverse events: the importance of social context. *Academic Medicine*, *85*(10), 1619-1625. doi: 10.1097/ACM.0b013e3181f046a6

58. Cooper, A., & Chuter, A. (2015). Patient safety research in primary care: where are we now?. *BJGP, 65* (641), 622-623.

59. Cope, D. G. (2015). Conducting pilot and feasibility studies. *Oncology Nursing Forum, 42*(2), 196-197.

60. Coventry, P. A., Small, N., Panagioti, M., Adeyemi, I., & Bee, P. (2015). Living with complexity; marshalling resources: a systematic review and qualitative meta-synthesis of lived experience of mental and physical multimorbidity. *BMC family practice*, *16*(1), 1-12. doi: http://dx.doi.org/10.1186/s12875-015-0345-3

61. Craiovan, P. M. (2014). Correlations between perfectionism, stress, psychopathological symptoms and burnout in the medical field. *Procedia-Social and Behavioral Sciences*, *127*, 529-533. doi: https://doi.org/10.1016/j.sbspro.2014.03.304

62. Cresswell, J. W., & Plano Clark, V. L. (2011). *Designing and conducting mixed method research*. (2nd ed.). Sage Publications.

63. Creswell, J. W. (2009). *Research Design: Qualitative, quantitative, and mixed methods approaches* (3rd ed.). Sage Publications.

64. Creswell, J. W., & Clark, V. L. P. (2017). *Designing and conducting mixed methods research*. USA: Sage publications.

65. Critical Appraisal Skills Programme (CASP). (2018). *CASP qualitative checklist*. Retrieved 22nd November 2018 from https://casp-uk.net/wp-content/uploads/2018/01/CASP-Qualitative-Checklist-2018.pdf.

66. Cullinan, S., O'Mahony, D., Fleming, A., & Byrne, S. (2014). A meta-synthesis of potentially inappropriate prescribing in older patients. *Drugs & aging*, *31*(8), 631-638.

67. Daker-White, G., Hays, R., McSharry, J., Giles, S., Cheraghi-Sohi, S., Rhodes, P., & Sanders, C. (2015). Blame the patient, blame the doctor or blame the system? A meta-synthesis of qualitative studies of patient safety in primary care. *PloS one*, *10*(8), e0128329. doi: https://doi.org/10.1371/journal.pone.0128329

68. Dekker S. (2018). *Restorative Just Culture Checklist*. Retrieved 9th March 2021 from https://www.safetydifferently.com/wp-content/uploads/2018/12/RestorativeJustCultureChecklist-1.pdf.

69. Dekker, S. W., & Breakey, H. (2016). 'Just culture:'Improving safety by achieving substantive, procedural and restorative justice. *Safety science*, *85*, 187-193. doi: https://doi.org/10.1016/j.ssci.2016.01.018

70. Delacroix, R. (2017). Exploring the experience of nurse practitioners who have committed medical errors: A phenomenological approach. *Journal of the American Association of Nurse Practitioners*, *29*(7), 403-409. doi: https://doi.org/10.1002/2327-6924.12468

71. Delbanco, T., & Bell, S. K. (2007). Guilty, afraid, and alone—struggling with medical error. *New England Journal of Medicine*, *357*(17), 1682-1683. doi: 10.1056/NEJMp078104

72. Denham, C. R. (2007). TRUST: the 5 rights of the second victim. *Journal of Patient Safety*, *3*(2), 107-119. doi: 10.1097/01.jps.0000236917.02321.fd

73. Diep, C. S., Chen, T. A., Davies, V. F., Baranowski, J. C., & Baranowski, T. (2014). Influence of behavioral theory on fruit and vegetable intervention effectiveness among

children: a meta-analysis. *Journal of nutrition education and behavior*, *46*(6), 506-546. doi: https://doi.org/10.1016/j.jneb.2014.05.012

74. Dinning, C., Branowicki, P., O'Neill, J. B., Marino, B. L., & Billett, A. (2005). Chemotherapy error reduction: a multidisciplinary approach to create templated order sets. *Journal of Pediatric Oncology Nursing*, *22*(1), 20-30. doi: https://doi.org/10.1177%2F1043454204272530

75. Dixon-Woods, M., Bonas, S., Booth, A., Jones, D. R., Miller, T., Sutton, A. J., ... & Young, B. (2006). How can systematic reviews incorporate qualitative research? A critical perspective. *Qualitative research*, *6*(1), 27-44. doi: https://doi.org/10.1177%2F1468794106058867

76. Dixon-Woods, M., Booth, A., & Sutton, A. J. (2007). Synthesizing qualitative research: a review of published reports. *Qualitative Research*, *7*(3), 375-422. doi: https://doi.org/10.1177%2F1468794107078517

77. Dixon-Woods, M., Shaw, R. L., Agarwal, S., & Smith, J. A. (2004). The problem of appraising qualitative research. *BMJ Quality & Safety*, *13*(3), 223-225. doi: http://dx.doi.org/10.1136/qshc.2003.008714

78. Donaldson, L. J. (2000). *An organisation with a memory: report of an expert group on learning from adverse events in the NHS*. Stationery Office.

79. Donaldson, M. S., Corrigan, J. M., & Kohn, L. T. (2000). *To err is human: building a safer health system* (Vol. 6). National Academies Press.

80. Doyle, L. H. (2003). Synthesis through meta-ethnography: paradoxes, enhancements, and possibilities. *Qualitative Research*, *3*(3), 321-344. doi: https://doi.org/10.1177%2F1468794103033003

81. Dubovsky, S. L., & Schrier, R. W. (1983). The mystique of medical training: is teaching perfection in medical house-staff training a reasonable goal or a precursor of low self-esteem?. *JAMA*, *250*(22), 3057-3058. doi:10.1001/jama.1983.03340220025026

82. Duclos, C. W., Eichler, M., Taylor, L., Quintela, J., Main, D. S., Pace, W., & Staton, E. W. (2005). Patient perspectives of patient–provider communication after adverse

events. *International Journal for Quality in Health Care*, *17*(6), 479-486.
doi: https://doi.org/10.1093/intqhc/mzi065

83. Dures, E., Rumsey, N., Morris, M., & Gleeson, K. (2011). Mixed methods in health psychology: Theoretical and practical considerations of the third paradigm. *Journal of health psychology*, *16*(2), 332-341.
doi: https://doi.org/10.1177%2F1359105310377537

84. Eggly, S., Penner, L., Albrecht, T. L., Cline, R. J., Foster, T., Naughton, M., ... & Ruckdeschel, J. C. (2006). Discussing bad news in the outpatient oncology clinic: rethinking current communication guidelines. *Journal of Clinical Oncology*, *24*(4), 716-719.
doi: 10.1200/JCO.2005.03.0577

85. Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PloS one*, *11*(3), e0150205.
doi: https://doi.org/10.1371/journal.pone.0150205

86. Elmir, R., & Schmied, V. (2016). A meta-ethnographic synthesis of fathers′ experiences of complicated births that are potentially traumatic. *Midwifery*, *32*, 66-74.
doi: https://doi.org/10.1016/j.midw.2015.09.008

87. Engel, K. G., Rosenthal, M., & Sutcliffe, K. M. (2006). Residents' responses to medical error: coping, learning, and change. *Academic Medicine*, *81*(1), 86-93.

88. Erasmus, E. (2014). The use of street-level bureaucracy theory in health policy analysis in low-and middle-income countries: a meta-ethnographic synthesis. *Health policy and planning*, *29*(3), 70-78.
doi: https://doi.org/10.1093/heapol/czu112

89. Espin, S., Levinson, W., Regehr, G., Baker, G. R., & Lingard, L. (2006). Error or “act of God”? A study of patients' and operating room team members' perceptions of error definition, reporting, and disclosure. *Surgery*, *139*(1), 6-14.
doi: https://doi.org/10.1016/j.surg.2005.07.023

90. Etchegaray, J. M., & Thomas, E. J. (2012). Comparing two safety culture surveys: safety attitudes questionnaire and hospital survey on patient safety. *BMJ quality & safety*, *21*(6), 490-498.
doi: http://dx.doi.org/10.1136/bmjqs-2011-000449

91. Etchegaray, J. M., Ottosen, M. J., Aigbe, A., Sedlock, E., Sage, W. M., Bell, S. K., ... & Thomas, E. J. (2016). Patients as partners in learning from unexpected events. *Health services research*, *51*, 2600-2614.
doi: https://doi.org/10.1111/1475-6773.12593

92. Fahrenkopf, A. M., Sectish, T. C., Barger, L. K., Sharek, P. J., Lewin, D., Chiang, V. W., ... & Landrigan, C. P. (2008). Rates of medication errors among depressed and burnt out residents: prospective cohort study. *Bmj*, *336*(7642), 488-491.
doi: https://doi.org/10.1136/bmj.39469.763218.BE

93. Fallowfield, L., & Jenkins, V. (2004). Communicating sad, bad, and difficult news in medicine. *The Lancet*, *363*(9405), 312-319.
doi: https://doi.org/10.1016/S0140-6736(03)15392-5

94. Faulkner, A., Maguire, P., & Regnard, C. (1994). Breaking bad news-a flow diagram. *Palliative Medicine*, *8*(2), 145-151.
doi: https://doi.org/10.1177/026921639400800208

95. Feast, A., Orrell, M., Charlesworth, G., Poland, F., Featherstone, K., Melunsky, N., & Moniz-Cook, E. (2018). *Using meta-ethnography to synthesize relevant studies: capturing the bigger picture in dementia with challenging behavior within families.* SAGE Publications Ltd.

96. Fein, S. P., Hilborne, L. H., Spiritus, E. M., Seymann, G. B., Keenan, C. R., Shojania, K. G., ... & Wenger, N. S. (2007). The many faces of error disclosure: a common set of elements and a definition. *Journal of general internal medicine*, *22*(6), 755-761.

97. Fein, S., Hilborne, L., Kagawa-Singer, M., Spiritus, E., Keenan, C., Seymann, G., ... & Wenger, N. (2005). A conceptual model for disclosure of medical errors*. Agency for Healthcare Research and Quality, 2,* 483-494.

98. Fenn, K., & Byrne, M. (2013). The key principles of cognitive behavioural therapy. *InnovAiT*, *6*(9), 579-585.
doi: https://doi.org/10.1177%2F1755738012471029

99. Finfgeld-Connett, D. (2014). Metasynthesis findings: potential versus reality. *Qualitative health research*, *24*(11), 1581-1591. doi: https://doi.org/10.1177%2F1049732314548878

100. Finkelstein, D., Wu, A. W., Holtzman, N. A., & Smith, M. K. (1997). When a physician harms a patient by a medical error: ethical, legal, and risk-management considerations. *The Journal of clinical ethics*, *8*(4), 330.

101. Flemming, K., Graham, H., Heirs, M., Fox, D., & Sowden, A. (2013). Smoking in pregnancy: a systematic review of qualitative research of women who commence pregnancy as smokers. *Journal of advanced nursing*, *69*(5), 1023-1036. doi: https://doi.org/10.1111/jan.12066

102. Forster, A. J., Rose, N. G., Van Walraven, C., & Stiell, I. (2007). Adverse events following an emergency department visit. *BMJ Quality & Safety*, *16*(1), 17-22.

103. Fortescue, E. B., Kaushal, R., Landrigan, C. P., McKenna, K. J., Clapp, M. D., Federico, F., ... & Bates, D. W. (2003). Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. *Pediatrics*, *111*(4), 722-729. doi: https://doi.org/10.1542/peds.111.4.722

104. Fossey, E., Harvey, C., McDermott, F., &, L. (2002). Understanding and evaluating qualitative research. *Australian & New Zealand Journal of Psychiatry*, *36*(6), 717-732. doi: https://doi.org/10.1046/j.1440-1614.2002.01100.x

105. France, E. F., Cunningham, M., Ring, N., Uny, I., Duncan, E. A., Jepson, R. G., ... & Britten, N. (2019). Improving reporting of meta-ethnography: the eMERGe reporting guidance. *BMC medical research methodology*, *19*(1), 25.

106. France, E. F., Ring, N., Thomas, R., Noyes, J., Maxwell, M., & Jepson, R. (2014). A methodological systematic review of what's wrong with meta-ethnography reporting. *BMC medical research methodology*, *14*(1), 1-16. doi: https://dx.doi.org/10.1186%2F1471-2288-14-119

107. France, E. F., Uny, I., Ring, N., Turley, R. L., Maxwell, M., Duncan, E. A., ... & Noyes, J. (2019b). A methodological systematic review of meta-ethnography conduct to articulate the complex analytical phases. *BMC medical research methodology*, *19*(1), 1-18.

108. Francis, R. (2013). *Report of the Mid Staffordshire NHS Foundation Trust public inquiry*. London, UK: Stationery Office.

109. Frandsen, M., Walters, J., & Ferguson, S. G. (2014). Exploring the viability of using online social media advertising as a recruitment method for smoking cessation clinical trials. *Nicotine & tobacco research*, *16*(2), 247-251. doi: https://doi.org/10.1093/ntr/ntt157

110. Gallagher, T. H., Brundage, G., Summy, E. A., Bommarito, K. M., Ebers, A. G., Waterman, A. D., ... & Dunagan, C. (2006). National survey: Risk managers' attitudes and experiences regarding patient safety and error disclosure. *Journal of Healthcare Risk Management*, *26*(3), 11-16. https://doi.org/10.1002/jhrm.5600260305

111. Gallagher, T. H., Studdert, D., & Levinson, W. (2007). Disclosing harmful medical errors to patients. *New England Journal of Medicine*, *356*(26), 2713-2719.

112. Gallagher, T. H., Waterman, A. D., Ebers, A. G., Fraser, V. J., & Levinson, W. (2003). Patients' and physicians' attitudes regarding the disclosure of medical errors. *Jama*, *289*(8), 1001-1007.

113. Garbutt, J., Brownstein, D. R., Klein, E. J., Waterman, A., Krauss, M. J., Marcuse, E. K., ... & Gallagher, T. H. (2007). Reporting and disclosing medical errors: pediatricians' attitudes and behaviors. *Archives of pediatrics & adolescent medicine*, *161*(2), 179-185. doi:10.1001/archpedi.161.2.179

114. Garrouste-Orgeas, M., Philippart, F., Bruel, C., Max, A., Lau, N., & Misset, B. (2012). Overview of medical errors and adverse events. *Annals of intensive care*, *2*(1), 2.

115. Garside, R. (2008). *A comparison of methods for the systematic review of qualitative research: two examples using meta-ethnography and meta-study*. (Doctoral Thesis, University of Exeter & University of Plymouth, United Kingdom). Retrieved from https://ore.exeter.ac.uk/repository/handle/10036/116289

116. Gazoni, F. M., Amato, P. E., Malik, Z. M., & Durieux, M. E. (2012). The impact of perioperative catastrophes on anesthesiologists: results of a national survey. *Anesthesia & Analgesia*, *114*(3), 596-603.

117. Goldberg, R. M., Kuhn, G., Andrew, L. B., & Thomas Jr, H. A. (2002). Coping with medical mistakes and errors in judgment. *Annals of emergency medicine*, *39*(3), 287-292.
doi: https://doi.org/10.1067/mem.2002.121995

118. Grissinger, M. (2011). Including patients on root cause analysis teams: pros and cons. *Pharmacy and Therapeutics*, *36*(12), 778.

119. Grossman, R., & Salas, E. (2011). The transfer of training: what really matters. *International Journal of Training and Development*, *15*(2), 103-120.
doi: https://doi.org/10.1111/j.1468-2419.2011.00373.x

120. Gunderson, A. J., Smith, K. M., Mayer, D. B., McDonald, T., & Centomani, N. (2009). Teaching medical students the art of medical error full disclosure: evaluation of a new curriculum. *Teaching and learning in medicine*, *21*(3), 229-232.
doi: https://doi.org/10.1080/10401330903018526

121. Halbach, J. L., & Sullivan, L. L. (2005). Teaching medical students about medical errors and patient safety: evaluation of a required curriculum. *Academic medicine*, *80*(6), 600-606.

122. Hall, L. W., & Scott, S. D. (2012). The second victim of adverse health care events. *Nursing Clinics*, *47*(3), 383-393.
doi: https://doi.org/10.1016/j.cnur.2012.05.008

123. Han, K., Bohnen, J. D., Peponis, T., Martinez, M., Nandan, A., Yeh, D. D., ... & Kaafarani, H. M. (2017). The surgeon as the second victim? Results of the Boston intraoperative adverse events surgeons' attitude (BISA) study. *Journal of the American College of Surgeons*, *224*(6), 1048-1056.
doi: https://doi.org/10.1016/j.jamcollsurg.2016.12.039

124. Hannawa, A. F. (2009). Negotiating medical virtues: toward the development of a physician mistake disclosure model. *Health Communication*, *24*(5), 391-399.

125. Hannawa, A. F., Shigemoto, Y., & Little, T. D. (2016). Medical errors: Disclosure styles, interpersonal forgiveness, and outcomes. *Social science & medicine*, *156*, 29-38.

126. Hannes, K., & Macaitis, K. (2012). A move to more systematic and transparent approaches in qualitative evidence synthesis: update on a review of published papers. *Qualitative Research*, *12*(4), 402-442. doi: https://doi.org/10.1177%2F1468794111432992

127. Harrison, R., Birks, Y., Bosanquet, K., & Iedema, R. (2017). Enacting open disclosure in the UK National Health Service: A qualitative exploration. *Journal of Evaluation in Clinical Practice*, *23*(4), 713-718. doi: https://doi.org/10.1111/jep.12702

128. Harrison, R., Lawton, R., & Stewart, K. (2014). Doctors' experiences of adverse events in secondary care: the professional and personal impact. *Clinical Medicine*, *14*(6), 585. doi: https://dx.doi.org/10.7861%2Fclinmedicine.14-6-585

129. Harrison, R., Lawton, R., Perlo, J., Gardner, P., Armitage, G., & Shapiro, J. (2015). Emotion and coping in the aftermath of medical error: a cross-country exploration. *Journal of patient safety*, *11*(1), 28-35. doi: 10.1097/PTS.0b013e3182979b6f

130. Hausner, E., Waffenschmidt, S., Kaiser, T., & Simon, M. (2012). Routine development of objectively derived search strategies. *Systematic reviews*, *1*(1), 19. doi: http://dx.doi.org/10.1186/PREACCEPT-1545996677607630

131. Haynes, A. B., Weiser, T. G., Berry, W. R., Lipsitz, S. R., Breizat, A. H. S., Dellinger, E. P., ... & Merry, A. F. (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. *New England Journal of Medicine*, *360*(5), 491-499.

132. Hebert, P. C. (2001). Disclosure of Adverse Events and Errors in Healthcare. *Drug safety*, *24*(15), 1095-1104.

133. Heyhoe, J., Birks, Y., Harrison, R., O'Hara, J. K., Cracknell, A., & Lawton, R. (2016). The role of emotion in patient safety: are we brave enough to scratch beneath the surface?. *Journal of the Royal Society of Medicine*, *109*(2), 52-58.

134. Hobgood, C., Hevia, A., Tamayo-Sarver, J. H., Weiner, B., & Riviello, R. (2005). The influence of the causes and contexts of medical errors on emergency medicine residents' responses to their errors: an exploration. *Academic Medicine*, *80*(8), 758-764.

135. Hobgood, C., Peck, C. R., Gilbert, B., Chappell, K., & Zou, B. (2002). Medical errors—what and when: what do patients want to know?. *Academic Emergency Medicine*, *9*(11), 1156-1161.
doi: https://doi.org/10.1197/aemj.9.11.1156

136. Hobgood, C., Xie, J., Weiner, B., & Hooker, J. (2004). Error identification, disclosure, and reporting: practice patterns of three emergency medicine provider types. *Academic Emergency Medicine*, *11*(2), 196-199.

137. Hoffman, J. R., & Kanzaria, H. K. (2014). Intolerance of error and culture of blame drive medical excess. *Bmj*, *349*, g5702.
doi: https://doi.org/10.1136/bmj.g5702

138. Hogan, H., Healey, F., Neale, G., Thomson, R., Vincent, C., & Black, N. (2012). Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Quality & Safety, 21*, 737-745.
doi: 0.1136/bmjqs-2012-001159

139. Holloway, I., & Wheeler, S. (2010). The nature and utility of qualitative research. *Qualitative Research in Nursing and Health Care. Chichester: Wiley-Blackwell*.

140. Holt, A. (2010). Using the telephone for narrative interviewing: a research note. *Qualitative research*, *10*(1), 113-121.
doi: https://doi.org/10.1177/1468794109348686

141. Hughes, R. G., & Ortiz, E. (2005). Medication Errors: Why they happen, and how they can be prevented. *Journal of infusion nursing*, *28*, 14-24.

142. Iedema, R. A., Mallock, N. A., Sorensen, R. J., Manias, E., Tuckett, A. G., Williams, A. F., ... & Hegney, D. G. (2008b). The National Open Disclosure Pilot: evaluation of a policy implementation initiative. *Medical Journal of Australia*, *188*(7), 397-400.

143. Iedema, R., & Allen, S. (2012). Anatomy of an incident disclosure: the importance of dialogue. *The Joint Commission Journal on Quality and Patient Safety*, *38*(10), 435-442.
doi: https://doi.org/10.1016/S1553-7250(12)38057-4

144. Iedema, R., Allen, S., Britton, K., & Gallagher, T. H. (2012). What do patients and relatives know about problems and failures in care?. *BMJ quality & safety*, *21*(3), 198-205.
doi: http://dx.doi.org/10.1136/bmjqs-2011-000100

145. Iedema, R., Allen, S., Britton, K., Piper, D., Baker, A., Grbich, C., ... & Manias, E. (2011). Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study. *Bmj*, *343*.
doi: https://doi.org/10.1136/bmj.d4423

146. Iedema, R., Sorensen, R., Manias, E., Tuckett, A., Piper, D., Mallock, N., ... & Jorm, C. (2008a). Patients' and family members' experiences of open disclosure following adverse events. *International Journal for Quality in Health Care*, *20*(6), 421-432.
doi: https://doi.org/10.1093/intqhc/mzn043

147. Institute of Medicine. (2001). Crossing the quality chasm. USA, Washington: National Academy Press.

148. Johnson, J., Panagioti, M., Bass, J., Ramsey, L., & Harrison, R. (2017). Resilience to emotional distress in response to failure, error or mistakes: A systematic review. *Clinical psychology review*, *52*, 19-42.
doi: https://doi.org/10.1016/j.cpr.2016.11.007

149. Johnson, R. B., Onwuegbuzie, A. J., & Turner, L. A. (2007). Toward a definition of mixed methods research. *Journal of mixed methods research*, *1*(2), 112-133.
doi: https://doi.org/10.1177%2F1558689806298224

150. Johnson, S. P., Adkinson, J. M., & Chung, K. C. (2014). Addressing medical errors in hand surgery. *The Journal of hand surgery*, *39*(9), 1877-1882.
doi: https://doi.org/10.1016/j.jhsa.2014.01.027

151. Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics: The Journal of Applied Statistics in the Pharmaceutical Industry*, *4*(4), 287-291.
doi: https://doi.org/10.1002/pst.185

152. Kaldjian, L. C., Jones, E. W., & Rosenthal, G. E. (2006). Facilitating and impeding factors for physicians' error disclosure: a structured literature review. *The Joint*

Commission Journal on Quality and Patient Safety, *32*(4), 188-198. https://doi.org/10.1016/S1553-7250(06)32024-7

153. Kaldjian, L. C., Jones, E. W., Wu, B. J., Forman-Hoffman, V. L., Levi, B. H., & Rosenthal, G. E. (2007). Disclosing medical errors to patients: attitudes and practices of physicians and trainees. *Journal of general internal medicine*, *22*(7), 988-996.

154. Kalra, J., Kalra, N., & Baniak, N. (2013). Medical error, disclosure and patient safety: A global view of quality care. *Clinical biochemistry*, *46*(13-14), 1161-1169.

155. Kaplan, R. N. (2010). SPIKES: a framework for breaking bad news to patients with cancer. *Clinical journal of oncology nursing*, *14*(4), 514.

156. Katowa-Mukwato, P., & Banda, S. (2016). Self-perceived versus objectively measured competence in performing clinical practical procedures by final year medical students. *International journal of medical education*, *7*, 122. doi: https://dx.doi.org/10.5116%2Fijme.5709.2a7e

157. Kaur, M., De Boer, R. J., Oates, A., Rafferty, J., & Dekker, S. (2019). Restorative just culture: a study of the practical and economic effects of implementing restorative justice in an NHS trust. In *MATEC Web of Conferences* (Vol. 273, p. 01007).

158. Keogh, B. (2013). *Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report*. Retrieved 24th August, 2020, from https://www.nhs.uk/nhsengland/bruce-keogh-review/documents/outcomes/keogh-review-final-report.pdf.

159. Kerrigan, L. (2020). Creating a just and learning culture through staff support. *The Veterinary Nurse*, *11*(2), 52-55. doi: https://doi.org/10.12968/vetn.2020.11.2.52

160. Kerrigan, L. (2020). Creating a just and learning culture through staff support. *The Veterinary Nurse*, *11*(2), 52-55. doi: https://doi.org/10.12968/vetn.2020.11.2.52

161. Khatri, N., Brown, G. D., & Hicks, L. L. (2009). From a blame culture to a just culture in health care. *Health care management review*, *34*(4), 312-322. doi: 10.1097/HMR.0b013e3181a3b709

162. Kiecolt-Glaser, J. K., McGuire, L., Robles, T. F., & Glaser, R. (2002). Emotions, morbidity, and mortality: new perspectives from psychoneuroimmunology. *Annual review of psychology*, *53*(1), 83-107.

163. Kiersma, M. E., Darbishire, P. L., Plake, K. S., Oswald, C., & Walters, B. M. (2009). Laboratory session to improve first-year pharmacy students' knowledge and confidence concerning the prevention of medication errors. *American journal of pharmaceutical education*, *73*(6).
doi: https://dx.doi.org/10.5688%2Faj730699

164. Kim, C. W., Myung, S. J., Eo, E. K., & Chang, Y. (2017). Improving disclosure of medical error through educational program as a first step toward patient safety. *BMC medical education*, *17*(1), 1-6.
doi: https://doi.org/10.1186/s12909-017-0880-9

165. Kim, S., Brock, D., Prouty, C. D., Odegard, P. S., Shannon, S. E., Robins, L., ... & Gallagher, T. (2011). A web-based team-oriented medical error communication assessment tool: development, preliminary reliability, validity, and user ratings. *Teaching and learning in medicine*, *23*(1), 68-77.
doi: https://doi.org/10.1080/10401334.2011.536896

166. King's Fund. (2008). *Safe births: Everybody's business. An independent enquiry into the safety of maternity services in England*. Retrieved 12th March 2021 from https://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/safe-births-everybodys-business-onora-oneill-february-2008.pdf.

167. Kirkup, B. (2015). *The report of the Morecambe Bay Investigation*. Retrieved 16th August, 2020 from
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

168. Kirkup, B. (2019). NHS Improvement's Just Culture Guide: good intentions failed by flawed design. *Journal of the Royal Society of Medicine*, *112*(12), 495-497.
doi: https://doi.org/10.1177/0141076819877556

169. Kitto, S. C., Chesters, J., & Grbich, C. (2008). Quality in qualitative research. *Medical journal of Australia*, *188*(4), 243-246.

170. Kok, J., Leistikow, I., & Bal, R. (2018). Patient and family engagement in incident investigations: exploring hospital manager and incident investigators' experiences and challenges. *Journal of Health Services Research & Policy*, *23*(4), 252-261. doi: https://doi.org/10.1177%2F1355819618788586

171. Kraman, S. S., & Hamm, G. (1999). Risk management: extreme honesty may be the best policy. *Annals of internal medicine*, *131*(12), 963-967. doi: https://doi.org/10.7326/0003-4819-131-12-199912210-00010

172. Kroll, L., Singleton, A., Collier, J., & Rees Jones, I. (2008). Learning not to take it seriously: junior doctors' accounts of error. *Medical education*, *42*(10), 982-990.

173. Kuper, A., Lingard, L., & Levinson, W. (2008). Critically appraising qualitative research. *Bmj*, *337*. doi: https://doi.org/10.1136/bmj.a1035

174. Landrigan, C. P., Parry, G. J., Bones, C. B., Hackbarth, A. D., Goldmann, D. A., & Sharek, P. J. (2010). Temporal trends in rates of patient harm resulting from medical care. *New England Journal of Medicine*, *363*(22), 2124-2134.

175. Langer, T., Martinez, W., Browning, D. M., Varrin, P., Lee, B. S., & Bell, S. K. (2016). Patients and families as teachers: a mixed methods assessment of a collaborative learning model for medical error disclosure and prevention. *BMJ Quality & Safety*, *25*(8), 615-625. doi: http://dx.doi.org/10.1136/bmjqs-2015-004292

176. Lawton, R., O'Hara, J. K., Sheard, L., Armitage, G., Cocks, K., Buckley, H., ... & Watt, I. (2017). Can patient involvement improve patient safety? A cluster randomised control trial of the Patient Reporting and Action for a Safe Environment (PRASE) intervention. *BMJ quality & safety*, *26*(8), 622-631. doi: http://dx.doi.org/10.1136/bmjqs-2016-005570

177. Lazare, A. (1995). *The medical interview*. New York, USA: Springer.

178. Lechuga, V. M. (2012). Exploring culture from a distance: The utility of telephone interviews in qualitative research. *International Journal of Qualitative Studies in Education*, *25*(3), 251-268. doi: https://doi.org/10.1080/09518398.2010.529853

179. Lee, R. P., Hart, R. I., Watson, R. M., & Rapley, T. (2015). Qualitative synthesis in practice: some pragmatics of meta-ethnography. *Qualitative Research*, *15*(3), 334-350. doi: https://doi.org/10.1177%2F1468794114524221

180. Levinson, W., Roter, D. L., Mullooly, J. P., Dull, V. T., & Frankel, R. M. (1997). Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. *Jama*, *277*(7), 553-559. doi: 10.1001/jama.1997.03540310051034

181. Lewin, S., Booth, A., Glenton, C., Munthe-Kaas, H., Rashidian, A., Wainwright, M., ... & Carlsen, B. (2018). Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series. *Implementation Science, 13*(2).

182. Lewis, G. (2007). *Confidential Enquiry Into Maternal and Child Health: Saving Mother's Lives: Reviewing Maternal Deaths to Make Motherhood Safer-2003-2005: Executive Summary and Key Recommendations: December 2007*. Retrieved 9th March 2021 from https://www.oaa-anaes.ac.uk/assets/_managed/editor/File/Reports/2003-2005_saving_mothers_full_report.pdf.

183. Liang, B. A. (2002). A system of medical error disclosure. *BMJ Quality & Safety*, *11*(1), 64-68. doi: http://dx.doi.org/10.1136/qhc.11.1.64

184. Linthorst, G. E., Kallimanis-King, B. L., Douwes Dekker, I., Hoekstra, J. B. L., & De Haes, J. C. J. M. (2012). What contributes to internists' willingness to disclose medical errors. *Neth J Med*, *70*(5), 242-8.

185. Madigosky, W. S., Headrick, L. A., Nelson, K., Cox, K. R., & Anderson, T. (2006). Changing and sustaining medical students' knowledge, skills, and attitudes about patient safety and medical fallibility. *Academic Medicine*, *81*(1), 94-101. doi: http://dx.doi.org/10.1097/00001888-200601000-00022

186. Majid, U., & Vanstone, M. (2018). Appraising qualitative research for evidence syntheses: a compendium of quality appraisal tools. *Qualitative health research*, *28*(13), 2115-2131. doi: https://doi.org/10.1177%2F1049732318785358

187. Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *Bmj*, *353*.
doi: https://doi.org/10.1136/bmj.i2139

188. Malpass, A., Shaw, A., Sharp, D., Walter, F., Feder, G., Ridd, M., & Kessler, D. (2009). "Medication career" or "moral career"? The two sides of managing antidepressants: a meta-ethnography of patients' experience of antidepressants. *Social science & medicine*, *68*(1), 154-168.
doi: https://doi.org/10.1016/j.socscimed.2008.09.068

189. Marjanovic, S., Ball, S., Harshfield, A., Dimova, S., Prideaux, R., Carpenter, A., ... & Simmons, R. (2019). *Involving NHS staff in research*. The Healthcare Improvement Studies Institute. Retrieved 23rd September 2019 from https://www.thisinstitute.cam.ac.uk/wp-content/uploads/2019/02/Involving-NHS-Staff-In-Research-1.pdf.

190. Martins Pereira, S., Fonseca, A. M., & Sofia Carvalho, A. (2011). Burnout in palliative care: A systematic review. *Nursing Ethics*, *18*(3), 317-326.

191. Mays, N., & Pope, C. (2000). Assessing quality in qualitative research. *BMJ, 320* (7226), 50-52.

192. Mazor, K. M., Goff, S. L., Dodd, K. S., Velten, S. J., & Walsh, K. E. (2010). Parents' perceptions of medical errors. *Journal of Patient Safety*, *6*(2), 102-107.
doi: 10.1097/PTS.0b013e3181ddfcd0

193. Mazor, K. M., Greene, S. M., Roblin, D., Lemay, C. A., Firneno, C. L., Calvi, J., ... & Gallagher, T. H. (2013). More than words: patients' views on apology and disclosure when things go wrong in cancer care. *Patient education and counseling*, *90*(3), 341-346.
doi: https://doi.org/10.1016/j.pec.2011.07.010

194. McFarlane, J., Riggins, J., & Smith, T. J. (2008). SPIKE $: a six-step protocol for delivering bad news about the cost of medical care. *Journal of Clinical Oncology*, *26*(25), 4200-4204.
doi: 10.1200/JCO.2007.15.6208

195. McKibbon, K. A., Wilczynski, N. L., & Haynes, R. B. (2006). Developing optimal search strategies for retrieving qualitative studies in PsycINFO. *Evaluation & the*

Health Professions, *29*(4), 440-454.
doi: https://doi.org/10.1177%2F0163278706293400

196. McLennan, S. R., Diebold, M., Rich, L. E., & Elger, B. S. (2016). Nurses' perspectives regarding the disclosure of errors to patients: a qualitative study. *International journal of nursing studies*, *54*, 16-22.
doi: https://doi.org/10.1016/j.ijnurstu.2014.10.001

197. Medical Research Council. (2008). *Developing and Evaluating Complex Interventions: New Guidance*. Retrieved 14th February 2018, from https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/

198. Mersey Care NHS Foundation Trust. (2019). *Implementation of a just and learning culture – Mersey Care NHS Foundation Trust*. Retrieved 9th March 2021 from

199. Michie, S., & Prestwich, A. (2010). Are interventions theory-based? Development of a theory coding scheme. *Health psychology*, *29*(1), 1.
doi: https://psycnet.apa.org/doi/10.1037/a0016939

200. Mira, J. J., Ferrús, L., Silvestre, C., & Olivera, G. (2017). What, who, when, where and how to inform patients after an adverse event: A qualitative study. *Enfermería Clínica (English Edition)*, *27*(2), 87-93.

201. Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., & Prisma Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS med*, *6*(7), e1000097.
doi: https://doi.org/10.1371/journal.pmed.1000097

202. Morse, J. M., & Field, P. A. (1995). *Qualitative research methods for health professionals*. London, UK: Chapman & Hall.

203. Moskowitz, E., Veloski, J. J., Fields, S. K., & Nash, D. B. (2007). Development and evaluation of a 1-day interclerkship program for medical students on medical errors and patient safety. *American Journal of Medical Quality*, *22*(1), 13-17.
doi: https://doi.org/10.1177%2F1062860606296669

204. Musal, B., Taskiran, C., Gursel, Y., Ozan, S., Timbil, S., & Velipasaoglu, S. (2008). An example of program evaluation project in undergraduate medical education. *Education for Health*, *21*(1), 113.

205. Musselwhite, K., Cuff, L., McGregor, L., & King, K. M. (2007). The telephone interview is an effective method of data collection in clinical nursing research: A discussion paper. *International journal of nursing studies*, *44*(6), 1064-1070. doi: https://doi.org/10.1016/j.ijnurstu.2006.05.014

206. Nabavi, R. T. (2012). Bandura's social learning theory & social cognitive learning theory. *Theory of Developmental Psychology*, 1-24.

207. Napolitano, M. A., Whiteley, J. A., Mavredes, M. N., Faro, J., DiPietro, L., Hayman, L. L., ... & Simmens, S. (2017). Using social media to deliver weight loss programming to young adults: design and rationale for the Healthy Body Healthy U (HBHU) trial. *Contemporary clinical trials*, *60*, 1-13. doi: https://doi.org/10.1016/j.cct.2017.06.007

208. National Institute for Health Research (NIHR). (2019). *Guidance on applying for feasibility studies*. National Institute for Health Research. Retrieved 4th May 2020 from https://www.nihr.ac.uk/documents/nihr-research-for-patient-benefit-rfpb-programme-guidance-on-applying-for-feasibility-studies/20474

209. National Patient Safety Agency. (2009). *Being Open*. Retrieved 2nd August 2019 from https://www.hsj.co.uk/download?ac=1293677

210. NHS England & NHS Improvement. (2018). *A just Culture Guide*. Retrieved 15th July 2020 from https://improvement.nhs.uk/resources/just-culture-guide/.

211. NHS England & NHS Improvement. (2019). *The NHS Patient Safety Strategy.* Retrieved 15th July 2020 from https://www.england.nhs.uk/wp-content/uploads/2020/08/190708_Patient_Safety_Strategy_for_website_v4.pdf.

212. NHS England & NHS improvement. (2020). *Patient Safety Incident Response Framework.* Retrieved 12th August 2020 from https://www.england.nhs.uk/wp-content/uploads/2020/08/200312_Introductory_version_of_Patient_Safety_Incident_Response_Framework_FINAL.pdf.

213. NHS improvement. (2017). *Guidance notes on National Reporting and Learning System official statistics publications*. Retrieved 12th August 2020 from https://improvement.nhs.uk/documents/1728/Guidance_notes_on_NRLS_officia_statistics_Sept_2017.pdf.

214. NHS Improvement. (2020). *Patient Safety*. Retrieved 20th August 2020 from https://improvement.nhs.uk/improvement-hub/patient-safety/.

215. NHS Resolution. (2019). *Being Fair*. Retrieved 12th August 2020 from https://resolution.nhs.uk/wp-content/uploads/2019/07/NHS-Resolution-Being-Fair-Report.pdf.

216. NHS Resolution. (2020a). *About NHS Resolution*. Retrieved 16th September 2020 from https://resolution.nhs.uk/about/.

217. NHS Resolution. (2020b*). Annual Report and Accounts, 2019/2020*. Retrieved 16th September 2020 from https://resolution.nhs.uk/wp-content/uploads/2020/07/NHS-Resolution-2019_20-Annual-report-and-accounts-WEB.pdf.

218. NICE. (2012). *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services*. Retrieved November 2019 from doi: https://www.nice.org.uk/guidance/cg138/chapter/1-Guidance.

219. Noblit, G. W., & Hare, R. D. (1988). *Meta-ethnography: Synthesizing qualitative studies* (Vol. 11). California, USA: SAGE publications.

220. Noyes, J., Popay, J., Pearson, A., & Hannes, K. (2008). 20 Qualitative research and Cochrane reviews. *Cochrane handbook for systematic reviews of interventions*, 571.

221. Nye, E., Melendez-Torres, G., & Bonell, C. (2016). Origins, methods, and advances in qualitative meta-synthesis*. Review of Education, 4 (*1), 57-79.

222. Ock, M., Kim, H. J., Jo, M. W., & Lee, S. I. (2016). Perceptions of the general public and physicians regarding open disclosure in Korea: a qualitative study. *BMC medical ethics*, *17*(1), 50.

223. O'Connor, E., Coates, H. M., Yardley, I. E., & Wu, A. W. (2010). Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care*, *22*(5), 371-379.
doi: https://doi.org/10.1093/intqhc/mzq042

224. Orsmond, G. I., & Cohn, E. S. (2015). The distinctive features of a feasibility study: Objectives and guiding questions. *OTJR: occupation, participation and health*, *35*(3),

169-177.
doi: https://doi.org/10.1177%2F1539449215578649

225. Oxtoby, C. (2018). Shifting from a blame culture to a learning culture. *Companion Animal*, *23*(11), 623-627.
doi: https://doi.org/10.12968/coan.2018.23.11.623

226. Pagoto, S. L., Waring, M. E., Schneider, K. L., Oleski, J. L., Olendzki, E., Hayes, R. B., ... & Lemon, S. C. (2015). Twitter-delivered behavioral weight-loss interventions: a pilot series. *JMIR research protocols*, *4*(4), e123.

227. Panesar, S. S., Desilva, D., Carson-Stevens, A., Cresswell, K. M., Salvilla, S. A., Slight, S. P., ... & Bates, D. W. (2016). How safe is primary care? A systematic review. *BMJ quality & safety*, *25*(7), 544-553.
doi: http://dx.doi.org/10.1136/bmjqs-2015-004178

228. Park, E., Oh, H., & Kim, T. (2013). The effects of relaxation breathing on procedural pain and anxiety during burn care. *Burns*, *39*(6), 1101-1106.
doi: https://doi.org/10.1016/j.burns.2013.01.006

229. Paterson, B. L. (2012). It looks great but how do I know if it fits?": an introduction to Meta-synthesis research. *Synthesizing qualitative research: Choosing the right approach*, 1-20.

230. Patton, M.Q. (1990). *Qualitative evaluation and research methods.* (2nd ed.). Sage Publications.

231. Paxton, J. H., & Rubinfeld, I. S. (2010). Medical errors education: a prospective study of a new educational tool. *American Journal of Medical Quality*, *25*(2), 135-142.
doi: https://doi.org/10.1177%2F1062860609353345

232. Penson, R. T., Svendsen, S. S., Chabner, B. A., Lynch Jr, T. J., & Levinson, W. (2001). Medical mistakes: a workshop on personal perspectives. *The oncologist*, *6*(1), 92-99.

233. Perry, C. L., Baranowski, T., & Parcel, G. S. (1990). *How individuals, environments, and health behavior interact: Social learning theory.* In K. Glanz, F. M. Lewis, & B. K. Rimer (Eds.), *The Jossey-Bass health series. Health behavior and health education: Theory, research, and practice* (p. 161–186). Jossey-Bass/Wiley.

234. Peters, M., & King, J. (2012). Perfectionism in doctors. *BMJ. 344,* 1674. doi:10.1136/bmj.e1674 pmid:22427311

235. Petronio, S., Torke, A., Bosslet, G., Isenberg, S., Wocial, L., & Helft, P. R. (2013). Disclosing medical mistakes: a communication management plan for physicians. *The Permanente Journal*, *17*(2), 73.

236. Petschonek, S., Burlison, J., Cross, C., Martin, K., Laver, J., Landis, R. S., & Hoffman, J. M. (2013). Development of the Just Culture Assessment Tool (JCAT): Measuring the perceptions of healthcare professionals in hospitals. *Journal of patient safety*, *9*(4), 190. doi: 10.1097/PTS.0b013e31828fff34

237. Pham, J. C., Story, J. L., Hicks, R. W., Shore, A. D., Morlock, L. L., Cheung, D. S., ... & Pronovost, P. J. (2011). National study on the frequency, types, causes, and consequences of voluntarily reported emergency department medication errors. *The Journal of emergency medicine*, *40*(5), 485-492.

238. Philpot, V. D., & Bamburg, J. W. (1996). Rehearsal of positive self-statements and restructured negative self-statements to increase self-esteem and decrease depression. *Psychological Reports*, *79*(1), 83-91. doi: https://doi.org/10.2466%2Fpr0.1996.79.1.83

239. Posner, G., & Nakajima, A. (2011). Assessing residents' communication skills: disclosure of an adverse event to a standardized patient. *Journal of Obstetrics and Gynaecology Canada*, *33*(3), 262-268. doi: https://doi.org/10.1016/S1701-2163(16)34828-9

240. Pramanik, T., Pudasaini, B., & Prajapati, R. (2010). Immediate effect of a slow pace breathing exercise Bhramari pranayama on blood pressure and heart rate. *Nepal Med Coll J*, *12*(3), 154-157.

241. Prestwich, A., Sniehotta, F. F., Whittington, C., Dombrowski, S. U., Rogers, L., & Michie, S. (2014). Does theory influence the effectiveness of health behavior interventions? Meta-analysis. *Health psychology*, *33*(5), 465. doi: https://psycnet.apa.org/doi/10.1037/a0032853

242. Prestwich, A., Webb, T. L., & Conner, M. (2015). Using theory to develop and test interventions to promote changes in health behaviour: evidence, issues, and recommendations. *Current Opinion in Psychology*, *5*, 1-5. doi: https://doi.org/10.1016/j.copsyc.2015.02.011

243. Pronovost, P. J., & Goeschel, C. A. (2010). Viewing health care delivery as science: challenges, benefits, and policy implications. *Health services research*, *45*(5p2), 1508-1522.
doi: https://doi.org/10.1111/j.1475-6773.2010.01144.x

244. Pronovost, P. J., Goeschel, C. A., Colantuoni, E., Watson, S., Lubomski, L. H., Berenholtz, S. M., ... & Marsteller, J. A. (2010). Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study. *Bmj*, *340*.

245. Pronovost, P. J., Jenckes, M. W., Dorman, T., Garrett, E., Breslow, M. J., Rosenfeld, B. A., ... & Bass, E. (1999). Organizational characteristics of intensive care units related to outcomes of abdominal aortic surgery. *Jama*, *281*(14), 1310-1317.
doi:10.1001/jama.281.14.1310

246. Pronovost, P., Needham, D., Berenholtz, S., Sinopoli, D., Chu, H., Cosgrove, S., ... & Bander, J. (2006). An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine*, *355*(26), 2725-2732.

247. Ptacek, J. T., Ptacek, J. J., & Ellison, N. M. (2001). "I'm Sorry To Tell You..." Physicians' Reports of Breaking Bad News. *Journal of behavioral medicine*, *24*(2), 205-217.

248. Purc-Stephenson, R. J., & Thrasher, C. (2010). Nurses' experiences with telephone triage and advice: A meta-ethnography. *Journal of advanced nursing*, *66*(3), 482-494.
doi: https://doi.org/10.1111/j.1365-2648.2010.05275.x

249. Radhakrishna, S. (2015). Culture of blame in the National Health Service; consequences and solutions. *BJA*, 115(5), 653-655.
doi: https://doi.org/10.1093/bja/aev152

250. Raper, S. E., Resnick, A. S., & Morris, J. B. (2014). Simulated disclosure of a medical error by residents: development of a course in specific communication skills. *Journal of surgical education*, *71*(6), 116-126.
doi: https://doi.org/10.1016/j.jsurg.2014.06.020

251. Rassin, M., Kanti, T., & Silner, D. (2005). Chronology of medication errors by nurses: accumulation of stresses and PTSD symptoms. *Issues in mental health nursing*, *26*(8), 873-886.

252. Reason, J. (1990). *Human error*: Cambridge University Press.

253. Reuter, T., Ziegelmann, J. P., Wiedemann, A. U., Geiser, C., Lippke, S., Schüz, B., & Schwarzer, R. (2010). Changes in intentions, planning, and self-efficacy predict changes in behaviors: An application of latent true change modeling. *Journal of health psychology*, *15*(6), 935-947.
doi: https://doi.org/10.1177%2F1359105309360071

254. Richards, L., & Morse, J. M. (2012). *Readme first for a user's guide to qualitative methods*. USA: Sage.

255. Robertson, J. J., & Long, B. (2018). Suffering in silence: medical error and its impact on health care providers. *The Journal of emergency medicine*, *54*(4), 402-409.

256. Robinson, A. R., Hohmann, K. B., Rifkin, J. I., Topp, D., Gilroy, C. M., Pickard, J. A., & Anderson, R. J. (2002). Physician and public opinions on quality of health care and the problem of medical errors. *Archives of Internal Medicine*, *162*(19), 2186-2190.

257. Roland, M., Rao, S. R., Sibbald, B., Hann, M., Harrison, S., Walter, A., ... & Campbell, E. G. (2011). Professional values and reported behaviours of doctors in the USA and UK: quantitative survey. *BMJ quality & safety*, *20*(6), 515-521.
doi: http://dx.doi.org/10.1136/bmjqs.2010.048173

258. Rosenzweig, M. Q. (2012). Breaking bad news: a guide for effective and empathetic communication. *The Nurse Practitioner*, *37*(2), 1.

259. Rowe, M. (2004). Doctors' responses to medical errors. *Critical reviews in oncology/hematology*, *52*(3), 147-163.

260. Rowley, E., & Waring, J. (2011). *A socio-cultural perspective on patient safety*. Ashgate Publishing Ltd.

261. Rubin, H., & Rubin, I. (2012). Research philosophy and qualitative interviews. *HJ Rubin & IS Rubin, Qualitative Interviewing: The Art of Hearing Data*, 13-24.

262. Rubio-Valera, M., Pons-Vigués, M., Martínez-Andrés, M., Moreno-Peral, P., Berenguera, A., & Fernández, A. (2014). Barriers and facilitators for the implementation of primary prevention and health promotion activities in primary

care: a synthesis through meta-ethnography. *PLOS one*, *9*(2), e89554. doi: https://doi.org/10.1371/journal.pone.0089554

263. Ryan, R. M., & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American psychologist*, *55*(1), 68.

264. Sahlqvist, S., Song, Y., Bull, F., Adams, E., Preston, J., Ogilvie, D., & iConnect Consortium. (2011). Effect of questionnaire length, personalisation and reminder type on response rate to a complex postal survey: randomised controlled trial. *BMC medical research methodology*, *11*(1), 62.

265. Sahlström, M., Partanen, P., Azimirad, M., Selander, T., & Turunen, H. (2019). Patient participation in patient safety—An exploration of promoting factors. *Journal of Nursing Management*, *27*(1), 84-92. doi: https://doi.org/10.1111/jonm.12651

266. Salkind, N. J. (2010). *Encyclopedia of research design* (Vol. 1). USA: Sage.

267. Saura, D. M., & Balsas, P. R. (2014). Interviewing and surveying over the phone: A reflexive account of a research on parenting. *Quality & Quantity*, *48*(5), 2615-2630.

268. Schein, E. H. (2010). *Organizational culture and leadership* (Vol. 2). USA: John Wiley & Sons.

269. Schelbred, A. B., & Nord, R. (2007). Nurses' experiences of drug administration errors. *Journal of advanced nursing*, *60*(3), 317-324. doi: https://doi.org/10.1111/j.1365-2648.2007.04437.x

270. Schelbred, A. B., & Nord, R. (2007). Nurses' experiences of drug administration errors. *Journal of advanced nursing*, *60*(3), 317-324. doi: https://doi.org/10.1111/j.1365-2648.2007.04437.x

271. Schwappach, D.L.B., & Boluarte, T. A. (2008). The emotional impact of medical error involvement on physicians: a call for leadership and organizational accountability. *Swiss medical weekly*, *139*(0102).

272. Scott, D. A., & Grant, S. M. (2018). A meta-ethnography of the facilitators and barriers to successful implementation of patient complaints processes in health-care

settings. *Health Expectations*, *21*(2), 508-517.
doi: https://doi.org/10.1111/hex.12645

273. Scott, S. D., Hirschinger, L. E., Cox, K. R., McCoig, M., Brandt, J., & Hall, L. W. (2009). The natural history of recovery for the healthcare provider "second victim" after adverse patient events. *BMJ Quality & Safety*, *18*(5), 325-330.

274. Scott, S. D., Hirschinger, L. E., Cox, K. R., McCoig, M., Hahn-Cover, K., Epperly, K. M., ... & Hall, L. W. (2010). Caring for our own: deploying a systemwide second victim rapid response team. *Joint Commission journal on quality and patient safety*, *36*(5), 233-240.
doi: https://doi.org/10.1016/S1553-7250(10)36038-7

275. Seale, C. (1999). Quality in qualitative research. *Qualitative inquiry*, *5*(4), 465-478.
doi: https://doi.org/10.1177%2F107780049900500402

276. Sexton, J. B., Helmreich, R. L., Neilands, T. B., Rowan, K., Vella, K., Boyden, J., ... & Thomas, E. J. (2006). The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. *BMC health services research*, *6*(1), 1-10.
doi: https://doi.org/10.1186/1472-6963-6-44

277. Seys, D., , S., Wu, A., Van Gerven, E., Vleugels, A., Euwema, M., ... & Vanhaecht, K. (2013). Supporting involved health care professionals (second victims) following an adverse health event: a literature review. *International Journal of Nursing Studies*, *50*(5), 678-687.
doi: https://doi.org/10.1016/j.ijnurstu.2012.07.006

278. Shannon, S. E., Foglia, M. B., Hardy, M., & Gallagher, T. H. (2009). Disclosing errors to patients: perspectives of registered nurses. *The Joint Commission Journal on Quality and Patient Safety*, *35*(1), 5-12.
doi: https://doi.org/10.1016/S1553-7250(09)35002-3

279. Shojania, K. G., & Thomas, E. J. (2013). Trends in adverse events over time: why are we not improving?. *BMJ quality & safety, 22,* 273-277

280. Shuy, R. W., Holstein, J. A., & Gubrium, J. F. (2003). Inside Interviewing. New Lenses, New Concerns. *Thousand Oaks: SAGE Publications*.

281. Silverman, J., Kurtz, S., & Draper, J. (2016). *Skills for communicating with patients*. Florida, USA: CRC press.

282. Sim, J., & Lewis, M. (2012). The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *Journal of clinical epidemiology*, *65*(3), 301-308.
doi: https://doi.org/10.1016/j.jclinepi.2011.07.011

283. Singh J. (2013). Critical appraisal skills programme. Journal of pharmacology and *Pharmacotherapeutics, 4*(76).

284. Sirriyeh, R., Lawton, R., Gardner, P., & Armitage, G. (2010). Coping with medical error: a systematic review of papers to assess the effects of involvement in medical errors on healthcare professionals' psychological well-being. *Quality and safety in health care*, *19*(6), e43-e43.
doi: http://dx.doi.org/10.1136/qshc.2009.035253

285. Slade, S. C., Kent, P., Patel, S., Bucknall, T., & Buchbinder, R. (2016). Barriers to primary care clinician adherence to clinical guidelines for the management of low back pain. *The Clinical journal of pain*, *32*(9), 800-816.
doi: https://doi.org/10.1097/AJP.0000000000000324

286. Slade, S., Patel, S., Underwood, M., & Keating, J. (2015). What are patient beliefs and perceptions about exercise for non-specific chronic low back pain: a systematic review of qualitative research. *Physiotherapy*, *101*, e1407.

287. Sleijpen, M., Boeije, H. R., Kleber, R. J., & Mooren, T. (2016). Between power and powerlessness: a meta-ethnography of sources of resilience in young refugees. *Ethnicity & health*, *21*(2), 158-180.
doi: https://doi.org/10.1080/13557858.2015.1044946

288. Smidt, A., Balandin, S., Sigafoos, J., & Reed, V. A. (2009). The Kirkpatrick model: A useful tool for evaluating training outcomes. *Journal of Intellectual and Developmental Disability*, *34*(3), 266-274.

289. Smith, M. L., & Forster, H. P. (2000). Morally managing medical mistakes. *Cambridge Q. Healthcare Ethics*, *9*, 38.

290. Sorensen, R., Iedema, R., Piper, D., Manias, E., Williams, A., & Tuckett, A. (2008). Health care professionals' views of implementing a policy of open disclosure of errors. *Journal of health services research & policy*, *13*(4), 227-232. doi: https://doi.org/10.1258%2Fjhsrp.2008.008062

291. Sorrell, J. M. (2017). Ethics: ethical issues with medical errors: shaping a culture of safety in healthcare. *OJIN: The Online Journal of Issues in Nursing*, *22*(2). doi: 10.3912/OJIN.Vol22No02EthCol01

292. Spinhoven, P., Klein, N., Kennis, M., Cramer, A. O., Siegle, G., Cuijpers, P., ... & Bockting, C. L. (2018). The effects of cognitive-behavior therapy for depression on repetitive negative thinking: A meta-analysis. *Behaviour Research and Therapy*, *106*, 71-85. doi: https://doi.org/10.1016/j.brat.2018.04.002

293. Stephens, N. (2007). Collecting data from elites and ultra elites: telephone and face-to-face interviews with macroeconomists. *Qualitative research*, *7*(2), 203-216. doi: https://doi.org/10.1177%2F1468794107076020

294. Stewart, K., Lawton, R., & Harrison, R. (2015). Supporting "second victims" is a system-wide responsibility. *Bmj*, *350*. doi: https://doi.org/10.1136/bmj.h2341

295. Strang, H., & Sherman, L. W. (2003). Repairing the harm: Victims and restorative justice. *Utah L. Rev.*, 15.

296. Stroud, L., McIlroy, J., & Levinson, W. (2009). Skills of internal medicine residents in disclosing medical errors: a study using standardized patients. *Academic Medicine*, *84*(12), 1803-1808. doi: 10.1097/ACM.0b013e31828f898f

297. Sturges, J. E., & Hanrahan, K. J. (2004). Comparing telephone and face-to-face qualitative interviewing: a research note. *Qualitative research*, *4*(1), 107-118. doi: https://doi.org/10.1177/1468794104041110

298. Sukalich, S., Elliott, J. O., & Ruffner, G. (2014). Teaching medical error disclosure to residents using patient-centered simulation training. *Academic Medicine*, *89*(1), 136-

143.
doi: 10.1097/ACM.0000000000000046

299. Suri, H. (2011). Purposeful sampling in qualitative research synthesis. *Qualitative research journal*, *11*(2), 63.

300. Sweet, L. (2002). Telephone interviewing: is it compatible with interpretive phenomenological research?. *Contemporary Nurse*, *12*(1), 58-63.
doi: https://doi.org/10.5172/conu.12.1.58

301. Tangney, J. P., Wagner, P., Fletcher, C., & Gramzow, R. (1992). Shamed into anger? The relation of shame and guilt to anger and self-reported aggression. *Journal of personality and social psychology*, *62*(4), 669.

302. Tarrier, N., & Johnson, J. (Eds.). (2015). *Case formulation in cognitive behaviour therapy: The treatment of challenging and complex cases*. Routledge.

303. Tashakkori, A., Teddlie, C., & Teddlie, C. B. (1998). *Mixed methodology: Combining qualitative and quantitative approaches* (Vol. 46). USA: Sage.

304. Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., ... & Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how. *BMC medical research methodology*, *10*(1), 1.

305. The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews. Checklist for Qualitative Research. (2017). *The Joanna Briggs Institute.* Retrieved 26th September 2020 from https://joannabriggs.org/critical-appraisal-tools

306. Thiese, M. S. (2014). Observational and interventional study design types; an overview. *Biochemia medica: Biochemia medica*, *24*(2), 199-210.
doi: https://doi.org/10.11613/BM.2014.022

307. Thorne, S., Jensen, L., Kearney, M. H., Noblit, G., & Sandelowski, M. (2004). Qualitative metasynthesis: reflections on methodological orientation and ideological agenda. *Qualitative health research*, *14*(10), 1342-1365. doi: https://doi.org/10.1177%2F1049732304269888

308. Toye, F., Seers, K., & Barker, K. L. (2017). Meta-ethnography to understand healthcare professionals' experience of treating adults with chronic non-malignant pain. *BMJ open*, *7*(12), e018411. doi: http://dx.doi.org/10.1136/bmjopen-2017-018411

309. Toye, F., Seers, K., Allcock, N., Briggs, M., Carr, E., & Barker, K. (2014). Meta-ethnography 25 years on: challenges and insights for synthesising a large number of qualitative studies. *BMC medical research methodology*, *14*(1), 1-14. doi: https://doi.org/10.1186/1471-2288-14-80

310. Toye, F., Seers, K., Allcock, N., Briggs, M., Carr, E., Andrews, J., & Barker, K. (2013). 'Trying to pin down jelly'-exploring intuitive processes in quality assessment for meta-ethnography. *BMC Medical Research Methodology*, *13*(1), 46. doi: https://doi.org/10.1186/1471-2288-13-46

311. Trier-Bieniek, A. (2012). Framing the telephone interview as a participant-centred tool for qualitative research: a methodological discussion. *Qualitative research*, *12*(6), 630-644. doi: https://doi.org/10.1177%2F1468794112439005

312. Ullström, S., Sachs, M. A., Hansson, J., Øvretveit, J., & Brommels, M. (2014). Suffering in silence: a qualitative study of second victims of adverse events. *BMJ quality & safety*, *23*(4), 325-331.

313. Ushie, B. A., Salami, K. K., Jegede, A. S., & Oyetunde, M. (2013). Patients' knowledge and perceived reactions to medical errors in a tertiary health facility in Nigeria. *African health sciences*, *13*(3), 820-828. doi: https://doi.org/10.4314/ahs.v13i3.43

314. Valenza, M. C., Valenza-Peña, G., Torres-Sánchez, I., González-Jiménez, E., Conde-Valero, A., & Valenza-Demet, G. (2014). Effectiveness of controlled breathing techniques on anxiety and depression in hospitalized patients with COPD: a randomized clinical trial. *Respiratory care*, *59*(2), 209-215. doi: https://doi.org/10.4187/respcare.02565

315. Vicent, C. & Amalberti, R. (2016). *Safer Healthcare: Strategies for the real world*. Springer Open.

316. Vincent, C. (2007). Incident reporting and patient safety. *BMJ Quality & Safety. 334(51)*. doi: https://doi.org/10.1136/bmj.39071.441609.80

317. Vincent, C. (2010). Integrating safety and quality. *Patient safety. 2nd ed. Chichester, West Sussex: Wiley-Blackwell*.

318. Vincent, C., & Amalberti, R. (2016). *Safer healthcare: strategies for the real world.* New York, USA: Springer Nature.

319. Vincent, C., Neale, G., & Woloshynowych, M. (2001). Adverse events in British hospitals: preliminary retrospective record review. *Bmj*, *322*(7285), 517-519.

320. Vincent, C., Phillips, A., & Young, M. (1994). Why do people sue doctors? A study of patients and relatives taking legal action. *The Lancet*, *343*(8913), 1609-1613. doi: https://doi.org/10.1016/S0140-6736(94)93062-7

321. Waterman, A. D., Garbutt, J., Hazel, E., Dunagan, W. C., Levinson, W., Fraser, V. J., & Gallagher, T. H. (2007). The emotional impact of medical errors on practicing physicians in the United States and Canada. *The Joint Commission Journal on Quality and Patient Safety*, *33*(8), 467-476.

322. Wayman, K. I., Yaeger, K. A., Sharek, P. J., Trotter, S., Wise, L., Flora, J. A., & Halamek, L. P. (2007). Simulation-based medical error disclosure training for pediatric healthcare professionals. *Journal for Healthcare Quality*, *29*(4), 12-19. doi: https://doi.org/10.1111/j.1945-1474.2007.tb00200.x

323. Weiner, B. (1995). *Judgments of responsibility: A foundation for a theory of social conduct*. New York: Guilford Press.

324. Weingart, S. N., Zhu, J., Chiappetta, L., Stuver, S. O., Schneider, E. C., Epstein, A. M., ... & Weissman, J. S. (2011). Hospitalized patients' participation and its impact on quality of care and patient safety. *International Journal for Quality in Health Care*, *23*(3), 269-277.
doi: https://doi.org/10.1093/intqhc/mzr002

325. Wemmers, J. A. M. (1996). *Victims in the criminal justice system*. Amsterdam, The Netherlands: Kugler publications.

326. West, C. P., Huschka, M. M., Novotny, P. J., Sloan, J. A., Kolars, J. C., Habermann, T. M., & Shanafelt, T. D. (2006). Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *Jama*, *296*(9), 1071-1078.

327. White, A. A., Bell, S. K., Krauss, M. J., Garbutt, J., Dunagan, W. C., Fraser, V. J., ... & Gallagher, T. H. (2011). How trainees would disclose medical errors: educational implications for training programmes. *Medical education*, *45*(4), 372-380.
doi: https://doi.org/10.1111/j.1365-2923.2010.03875.x

328. White, A. A., Brock, D. M., McCotter, P. I., Shannon, S. E., & Gallagher, T. H. (2017). Implementing an error disclosure coaching model: A multicenter case study. *Journal of Healthcare Risk Management*, *36*(3), 34-45.
doi: https://doi.org/10.1002/jhrm.21260

329. White, A. A., Brock, D. M., McCotter, P. I., Shannon, S. E., & Gallagher, T. H. (2017). Implementing an error disclosure coaching model: a multicenter case study. *Journal of Healthcare Risk Management*, *36*(3), 34-45.
doi: https://doi.org/10.1002/jhrm.21260

330. White, A. A., Gallagher, T. H., Krauss, M. J., Garbutt, J., Waterman, A. D., Dunagan, W. C., ... & Larson, E. B. (2008). The attitudes and experiences of trainees regarding disclosing medical errors to patients. *Academic Medicine*, *83*(3), 250-256.
doi: 10.1097/ACM.0b013e3181636e96

331. White, R. M., & Delacroix, R. (2020). Second victim phenomenon: Is 'just culture'a reality? An integrative review. *Applied Nursing Research*, 151319. doi: https://doi.org/10.1016/j.apnr.2020.151319

332. Wise, J. (2019). Maternity care failings in Shropshire stretch back four decades. *BMJ, 8224 (367)*, 16656. doi: https://doi.org/10.1136/bmj.l6656

333. Witman, A. B., Park, D. M., & Hardin, S. B. (1996). How do patients want physicians to handle mistakes?: A survey of internal medicine patients in an academic setting. *Archives of Internal Medicine*, *156*(22), 2565-2569. doi: 10.1001/archinte.1996.00440210083008

334. Wolf, Z. R., & Hughes, R. G. (2008). Error reporting and disclosure. In *Patient safety and quality: An evidence-based handbook for nurses*. Agency for Healthcare Research and Quality (US).

335. Wolf, Z. R., Serembus, J. F., Smetzer, J., Cohen, H., & Cohen, M. (2000). Responses and concerns of healthcare providers to medication errors. *Clinical Nurse Specialist*, *14*(6), 278-290.

336. Wong SS, Wilczynski NL, Haynes RB. (2004). Developing optimal search strategies for detecting clinically relevant qualitative. *MedInfo*, *107*, 311.

337. World Health Organisation. (2020). Patient Safety. Retrieved 22nd August 2020, from https://www.who.int/patientsafety/en/.

338. Worthington, E. L., & Scherer, M. (2004). Forgiveness is an emotion-focused coping strategy that can reduce health risks and promote health resilience: Theory, review, and hypotheses. *Psychology & Health*, *19*(3), 385-405.

339. Wu, A. W. (2000). Medical error: the second victim: the doctor who makes the mistake needs help ,too. *BMJ, 320(726)*. doi: https://doi.org/10.1136/bmj.320.7237.726

340. Wu, A. W., & Steckelberg, R. C. (2012). Medical error, incident investigation and the second victim: doing better but feeling worse?. doi: http://dx.doi.org/10.1136/bmjqs-2011-000605

341. Wu, A. W., Boyle, D. J., Wallace, G., & Mazor, K. M. (2013). Disclosure of adverse events in the United States and Canada: an update, and a proposed framework for improvement. *Journal of Public Health Research*, *2*(3).

342. Wu, A. W., Folkman, S., McPhee, S. J., & Lo, B. (1991). Do house officers learn from their mistakes?. *Jama*, *265*(16), 2089-2094.

343. Wu, A. W., Folkman, S., McPhee, S. J., & Lo, B. (1993). How house officers cope with their mistakes. *Western Journal of Medicine*, *159*(5), 565.

344. Wu, A. W., Huang, I. C., Stokes, S., & Pronovost, P. J. (2009). Disclosing medical errors to patients: it's not what you say, it's what they hear. *Journal of General Internal Medicine*, *24*(9), 1012.

345. Wynne, G., Marteau, T. M., Johnston, M., Whiteley, C. A., & Evans, T. R. (1987). Inability of trained nurses to perform basic life support. *British medical journal (Clinical research ed.)*, *294*(6581), 1198. doi: https://dx.doi.org/10.1136%2Fbmj.294.6581.1198

346. Youngson, G. G. (2014). Medical error and disclosure–A view from the UK. *The Surgeon*, *12*(2), 68-72. doi: https://doi.org/10.1016/j.surge.2013.10.011

347. Zimmerman, T. M., & Amori, G. (2007). Including patients in root cause and system failure analysis: legal and psychological implications. *Journal of Healthcare Risk Management*, *27*(2), 27-34. doi: https://doi.org/10.1002/jhrm.5600270206

List of appendices

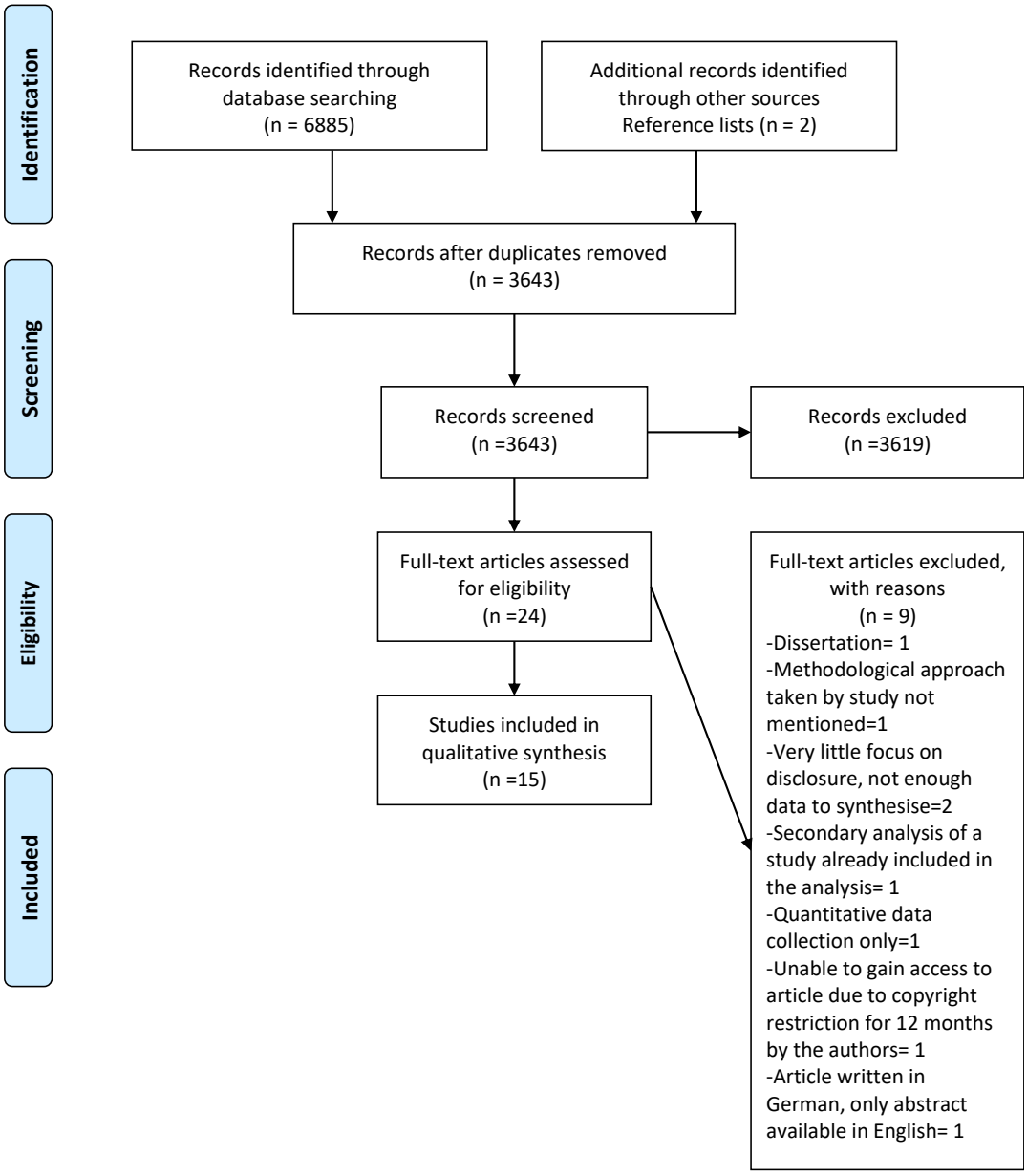
Appendices

Appendix 1: Search strategy

(Applied to PubMed) *(Inception- 03/02/18)*

1. Disclosure[MeSH Terms]	21396
2. Truth disclosure*	116
3. Open disclosure*	86
4. Doctor patient-relation*	91627
5. #1 OR #2 OR #3 OR #4	111636
6. Medical error [MeSH Terms]	18107
7. Medication error*	15336
8. Diagnostic error*	42556
9. Iatrogenic disease*	19139
10. Adverse event*	186139
11. Patient safety [MeSH Terms]	169,411
12. Patient safety incident*	341
13. Serious untoward event*	7
14. Risk management*	37966
15. Healthcare error*	24
16. Surgical error*	1438
17. Therapeutic error*	1429
18. #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17	491893
19. Attitude*	343537
20. Perception*	276475
21. Views*	60618
22. Experience*	940569
23. Perspective	132408
24. #19 OR #20 OR #21 OR #22 OR #23	1562664
25. #5 AND #18 AND #24	1966

Appendix 2: PRSIMA flow diagram



Appendix 3: Translations tables

Translation table of findings for patients/family members views of disclosure

Descriptor (Groups of similar concepts clustered together/ broad thematic headings)	First order data	Second order themes
Information provided during disclosure	'Well assuring recurrence prevention, this is a must, whatever the case….I'm sure when doctors say how sorry they are for what happened and reassure [the patients] that they'll make an effort to reduce possible complications, the patients will go back home feeling much better... No benefits whatsoever, but credibility will soar, I reckon' (Ock et al., 2016); 'I still see him even though my insurance has changed and he's no longer on my insurance. I have total confidence in him…well, he's honest. You know he laid it on the line and gave me the facts' (Duclos et al., 2005); 'I've been really impressed with the time he took to explain in a straightforward manner' (Mazor et al., 2013); 'The important thing is that it doesn't happen again'... 'The point that should be made is that she knew she made a mistake and will try harder not to do that again to anybody else'… 'Well I think she should have gone further in trying to figure out what did happen, because he does surgery all the time. He could endanger someone else's	Need to promise recurrence prevention in ambiguous medical errors (Ock et al., 2016); Communication (Duclos et al., 2005); Provide information on what happened (Mazor et al., 2013); Preventing recurrences (Mazor et al., 2013); Patient frustrations (Duclos et al., 2005); Patient worries (Duclos et al., 2005);

	life' (Mazor et al., 2013); '…That was extremely frustrating for me because nobody was willing to say that's they made a mistake' (Duclos et al., 2005); …'Not knowing what's really going to happen, not knowing if I'm ever going to come home again'…I was on antibiotics for weeks and they discontinued it because the antibiotics were affecting my kidneys. And it's like well, what else is going to happen to me now? It just seemed like one thing after another after another after another' (Duclos et al., 2005); 'I wanted as much…whether I understood it or not. I wanted to hear it. I wanted details because then I could sort through it in my head, and then come to my own conclusions'… 'It's refreshing to not be battling with insurance companies, hospitals, etc. we didn't have to get a lawyer' (Duclos et al., 2005); 'We want to know what happened that day. Why was she moved from the room?...That could have contributed to her disorientation…They said oh well, we can't really give you that information' (Iedema et al., 2011); 'After a week, ten days, the three of us decided that we wanted to see the notes, we…wanted to know what was going to happen to him…I rang up the GP…It took him ten days and then he called me' (Iedema et al., 2011); 'I've talked and talked and talked. I've tried to talk to counsellors and I've talked to midwives, I've talked to doctors and I've talked to a lot of people…and then finally yeah eighteen months, no fifteen months later we finally had the open disclosure' (Iedema et al., 2008a); 'At the end of the day, you know when an unfortunate incident happens like that, that [inappropriate disclosure communication] could be avoided in the future…it would be good to know that my dad's death, you know, sort of prompted some changes in that	Inadequate preparation for open disclosure (Iedema et al., 2011); Insufficient integration of open disclosure with improvement of patient safety (Iedema et al., 2011); Was the incident promptly disclosed to the patient and/ or family? (Iedema et al., 2008a); How formal was the disclosure meeting and did it match the patient's expectations? (Iedema et al., 2008a); Suggestions of ways to optimise the experience (Iedema et al., 2008b); Trust (Espin et al., 2006); What information to disclose about the error (Gallagher et al., 2003).

	area' (Iedema et al., 2011); 'I didn't receive the opportunity to follow up and try to understand the whole' (Iedema et al., 2008a); '…when we did go to the meeting [the patient liason officer] said he'd like to shut up and let me talk…he asked me… 'What do you want to get out of it?' And basically my answers were I wanted to make sure that it never happened again…and it was really good because [the liaison officer] allowed me to say that…I liked that I could talk and ask questions' (Iedema et al., 2008b); 'Well it's my body, it's not the surgeon's body, and so I would want to know all the details' (Espin et al., 2006); 'I'm sorry but due to an error of writing instructions and communication there was a misunderstanding and it caused an overdose of insulin. You have my deepest sympathy as far as the physical problems we caused for you. However, we're doing everything within our powers to correct this error and we can assure you this problem will not happen again because I'm not only going to address it as far as writing information down, but I'm also going to communicate it so the nurse will understand what is supposed to be given…I'm available to sit down and discuss with you in detail what happened and again, I'm sorry (patient describes how he would like the physician to describe an error) (Gallagher et al., 2003).	
Taking responsibility	'…As far as just the medical people involved. That was extremely frustrating for me because nobody was willing to say that they made a mistake' (Duclos et al., 2005); 'I just wanted him to take responsibility for it. 'Look I'm sorry I did this and I'll do whatever it takes to make things right'. Just own up to what happened' (Duclos et al., 2005); '…But it would have been nice if someone had have just acknowledged and said	Patient frustrations (Duclos et al., 2005); Was an apology offered and of what kind? (Iedema et al., 2008a); Responsibility (Iedema et al.,

	'this is our fault' (Iedema et al., 2008a); 'I definitely didn't like the defensive nature of the people involved' (Iedema et al., 2008a) ; 'They were blaming the cancer' (Iedema et al., 2008a); '…taking responsibility, that's kind of what it's all about' (Mazor et al., 2013); '…it made me feel that I could trust my PCP because I mean she took responsibility…had remorse about what happened. She wasn't defensive about it' (Mazor et al., 2013); '…it goes a long way for me if a person can acknowledge 'I made a mistake' (Mazor et al., 2013). 'When a patient is harmed or dies, we want a whole hearted apology. Medical disputes come later on. Money and whatnot comes second' (Ock et al., 2016); 'A good tongue is a good weapon, you know. With a heartfelt 'sorry'…' (Ock et al., 2016); 'But if doctors take responsibility and apologise for my loss, I would take it on my own shoulders even where I have to earn a living for myself. Because I accepted the apology' (Ock et al., 2016); 'When such a case arises, it's saying sorry for what's happened and any wrongdoing possibly caused by medical staff for example. And it doesn't necessarily mean you are admitting negligence' (Ock et al., 2016); '…the first meeting she apologised…then when I handed her the birth certificate that said staphylococcal chorioamionitis she backtracked and said 'no, no, no…' and that to me seemed like she just completely and utterly not sorry anymore' (Iedema et al., 2008a); 'The fact that that had happened to me' (Mazor et al., 2013); 'I think she did the right thing…she acknowledged that I'd been through a pretty terrible experience' (Mazor et al., 2013);	2008a); Taking responsibility (Mazor et al., 2013) Importance of delivering an apology in open disclosure (Ock et al., 2016); Apology not regarded as admitting negligence (Ock et al., 2016); What kind of apology was

	'…trying to explain it to me, I don't know if that would have helped any. I think what I really wanted to was someone to care, to say 'Oh I am so sorry…' (Mazor et al., 2013); 'There's got to be accountability. I don't want to hear 'I'm sorry'. 'I'm sorry' is nothing. I want to know what steps have you taken to correct the problem? Don't tell me you were sorry that the problem occurred. That just puts a band aid on something…I want to see results' (Mazor et al., 2013).	offered? (Iedema et al., 2008a) Apology & expressions of regret (Mazor et al., 2013); Importance of action (Mazor et al., 2013)

Translations table of findings for healthcare professional's views of disclosure

Descriptor (Groups of similar concepts clustered together/ broad thematic headings)	First order data	Second order themes
Information provided during disclosure	'Whatever the case, you should give an explanation to the caregivers. On why you did it and how things can go wrong... 'Well isn't it natural for them to want to know? All of a sudden, a patient dies after a surgery. Sure, the odds of death from a surgical complications, one in a million and whatnot, are well known. But they probably wouldn't have imagined anything like it happening in their own life not in a million years…'it's designated in medical ethics, and aren't we mandated to inform the	What should be delivered through open disclosure (Ock et al., 2016); Attitudes and experiences concerning disclosing errors to patients (McLennan et al., 2016);

	caregivers because it's just right?' (Ock et al., 2016); 'That is why we always go back and inform the patient. And we also always tell them exactly what we do next, so that the error does not happen again. The same applies also for the relatives. So far this has always gone well' (McLennan et al., 2016); 'If I think it could have been a serious error that might have caused this damage to the patient, it will be explained differently or in a way the patient cannot realise' (McLennan et al., 2016); 'I think the way it should happen in real life is that the doctor would go in and start with what happened 'You had a seizure, you fell out of bed, you broke your hip.' 'Why is that?' 'Well it seems like that your insulin dose lowered your blood sugar and you weren't getting any food' and answer any questions that occur. That I think, would be full disclosure without going in and wringing your hands' (Fein et al., 2007); 'I think you have to be a spin doctor all the time and put the right spin on it…I don't think you have to soft pedal the issue, but I think you have to try and put it in the best light. I think you have to be forthright with the patient to help them. And how you word it makes a big difference' (Gallagher et al., 2005); 'Everything you read and everything that you're told says that you are supposed to tell what errors you make as soon as you can. Let them know what you're thinking is, what you are going to do about it. And your chances of having an adverse litigation are less if you take that approach. Now the question is, how many of us believe that?' (Gallagher et al., 2005); 'The patient's gonna be told, but what you say about how that injury occurs depends' (Espin et al., 2006); 'The patient should always be informed'; 'It is the patients right';	Connect the dots (Fein et al., 2007); How to disclose (Gallagher et al., 2005); Trust (Espin et al., 2006); What information to give (Mira et al., 2017).

	'It is more likely for them to end up in a claim for damages or litigation against the health care professionals' (Mira et al., 2017).	
Acknowledging responsibility and apology	'If I'd made a mistake I've got to go and see that person and say look I am sorry, it was my fault. I am not saying it was right, you know it was me that did it and I did it and it was an error and I apologise. And if they then want to take that further, well that is their prerogative' (Harrison et al., 2017); 'I made an error. I discontinued a medication that I shouldn't have-by accident. You know, I picked up the error, presented it to the family. You know I tried to make it a system thing because the reason I did it was not because I'm a dummy. I'm sure it could have happened to the next guy in my shoes (Coffey et al., 2010); 'But I felt it was my responsibility to tell the family and I did' (Coffey et al., 2010); 'If I made a mistake, then it would be my responsibility to tell them [patient or family] (Gallagher et al., 2006); 'No matter what happens in the care of the patient…I am the one who is responsible for that patient' (Fein et al., 2005); 'It is your obligation to do so' (Fein et al., 2005); ' I really don't know what happened. I really can't explain what happened, but it shouldn't have happened, and I have to take the responsibility for it' (Iedema et al., 2008b); 'I don't literally bring up the word regrettable but I do it eventually…it's a Korean thing that you don't really need to put it into words to…the biggest problem is when you're about to discharge your patient after stitch removal, the last step of the surgery, the wound starts to open up. It'll drive you crazy and what can you say to the patient? Seems like you can't go home today…that's the Korean way of saying sorry…you don't really need to say it through	Open disclosure as a moral and professional duty (Harrison et al., 2017); Responsibility (Coffey et al., 2010); Social context in which the participant observed or experienced the error (Coffey et al., 2010); Who should tell the patient? (Gallagher et al., 2006); Influences on the decision to disclose a medical error (Fein et al., 2005); Support for open disclosure (Iedema et al., 2008b); How should open disclosure be carried out (Ock et al., 2016); Clarity (Harrison et al., 2017).

	words' (Ock et al., 2016); …And if somebody has made an error or I've made an error then I'm going to apologise (Harrison et al., 2017).	
When should an error be disclosed?	'I suppose medical errors causing minor harm will be even more problematic…Hmm I'd rather not say. This is a matter of preference I think. The patient might not feel the need either. Telling the truth is the right thing to do but since nothing really happened, I guess doctors would be inclined not to do so' (Ock et al., 2016); 'If I were a patient, I'd rather not know' (Ock et al., 2016); 'In general, the patient clearly has the right [to be informed], whether it is a small or big error. But when errors happen that have no effect on the patient, when nothing happens- small errors that have no effect or the patient would not see the error as an error- then we would not tell' (McLennan et al., 2016); 'You perceive this when dealing with patients; there are people who prefer not to know. And you need to somehow develop a sure instinct not to burden them' (McLennan et al., 2016); '...It's probably once a month or more often we'll have some old person come in with a massive intracranial fatal haemorrhage, and the INR is 4 or 6 or 10. We don't tell them' (Fein et al., 2007); 'there was once case that we had, a guy who got two doses of Lovenox back to back. Nursing error. And then he had a… haemorrhage and went to the unit. Now I filled out an incident report, but I didn't go running and talking to the patients family about giving him two Lovenox doses' (Fein et al., 2007); 'But especially- if the patient, if there's nothing that's happened, for instance it happens all the time. His sodium goes down to one-nineteen okay? And nothing really happens okay? You're not going to go in there and tell the patient that	When should open disclosure take place (Ock et al., 2016); Attitudes and experiences concerning disclosing errors to patients (McLennan et al., 2016); Non-disclosure (Fein et al., 2007); Connect the dots (Fein et al., 2007); It's like walking on eggshells (Gallagher et al., 2006); Error factors (Fein et al., 2005); Whether to disclose near misses (Gallagher et al., 2003); Trust (Espin et al., 2006).

	your sodium went down to one-nineteen because we didn't do our whatever. Now if the patient asks…then you tell the patient exactly what they want to know' (Fein et al., 2007); I don't know what they had told him down in the lab and it was kind of awkward and uncomfortable when he returned because I didn't know if i should be apologising that that had happened, or if I should just be pretending like 'well, the doctors decided not to do that procedure. I just wasn't going to lie to him, but I didn't know what he had been told and there was no communication between us [the healthcare team] of what he knew' (Gallagher et al., 2006); ' I don't know that we disclose all errors. We tend to focus on that have an impact on their care' (Fein et al., 2005); 'nothing happened, so there's no reason to bring up an issue that hasn't been brought up and the patient won't bring up' (Fein et al., 2005); 'There are near misses in the skies all the time. They do not get on the intercom and say you know what? We just came within 200 feet [of another plane]. But if a lot of people in the airplane see it, then they do come on and they explain it' (Fein et al., 2005); ' I think if we were held to disclose all of those [near misses], I think that happens so often we wouldn't have the opportunity to practise medicine' (Gallagher et al., 2003); 'My job is to relieve anxiety, not to create it. And to a certain extent when an error occurs that doesn't get to the patient, it's not their problem, it's my problem' (Gallagher et al., 2003); 'You form a therapeutic alliance by being in constant communication with the patient. So to me, a medical error with no adverse event is an opportunity to form a tighter bond with the patient….if no adverse event whatsoever occurs with a medical error, I'm just	

	delighted to tell the patient exactly what happened' (Gallagher et al., 2003); 'If a patient is 95 and bed-ridden, you might not want to tell them' (Espin et al., 2006); ' It could be upsetting, they will not understand this could happen to anyone with this case.' (Espin et al., 2006).	

Translation of findings for healthcare professionals views of the barriers and facilitators to disclosure

Descriptor (Groups of similar concepts clustered together/ broad thematic headings)	First order data	Second order themes
Organisational culture	'The common working culture can be beneficial or also hindering. For example, if you have to fear reprisal once you disclose an error, that this falls back on a person who is then ostracised or even loses their job' (McLennan et al., 2016); 'Sometimes there's a culture of well I admit I am wrong…my employer would sack me because I've been open and honest and if I don't say anything they can't sack me' (Harrison et al., 2017); 'I think there's an openness about- we've caught that near miss. Give everybody a pat on the back whereas if something then bad happens, I think there's less of an openness and then you get more into looking at well-rather than what the system did, you look at the people in the system' (Coffey et al., 2010); 'As an R1 you're starting and not	Barriers to disclosure (McLennan et al., 2016); Understanding the repercussions (Harrison et al., 2017); Degree of harm (Coffey et al., 2010); Experience level (Coffey et al., 2010); Reputation risk (Coffey et al., 2010); Provider

	many people know you and you feel as though you have to prove yourself. When you start you have a sense the nurses don't really trust you. The parents don't really trust you and you really feel that you have to prove that you're competent and things like that would just turn somebody I guess, from openly talking about little mistakes and things like that because you're afraid of, you know, perhaps the way the team will think of you, the nurses will think of you- whether they'll talk about you' (Coffey et al., 2010); '…and I guess you're also worried about how others perceive you or whether or not they would trust you' (Coffey et al., 2010); 'I think fear kind of captures a lot of different emotions that would prevent somebody [from disclosing]…fear of being mistrusted or fear of retribution, fear of damaging career opportunities' (Fein et al., 2005); '…one is fear of what your colleagues are going to think' (Fein et al., 2005); 'There needs to be a culture where individuals do not feel penalised for reporting errors. You should feel comfortable reporting to the chief of service of the head of nursing' (Fein et al., 2005).	factors (Fein et al., 2005); Institutional factor (Fein et al., 2005).
Litigation	'As a matter of character. How does one approach this incident and come to terms with it. I think this is the first decisive point: will one disclose it at all or not…The person concerned will always think of themselves first' (McLennan et al., 2016); 'Part of me was telling me you shouldn't do this, why ask for trouble, this is going to just lead to litigation or complaints…but you know every time I've done this has been a positive and rewarding experience and I've not regretted it' (Harrison et al, 2017); 'Through	Barriers to disclosure (McLennan et al., 2016); Positive past experiences (Harrison et al., 2017); Understanding the repercussions (Harrison et

	the course of my career, so many times I've seen very bad things have happened and patients have in the end not taken any legal action and not taken any grievance with doctors when they've immediately said: 'Look I'm very sorry, this went wrong and this is why it went wrong and this is what we're going to do to try and fix it' (Harrison et al., 2017); 'I've learned that it's also quite a self-preserving thing to do…the worst thing…is if they [patients] get it into their heads that there's some sort of cover up going on, then they get the bit between their teeth and solicitors get involved and it's all very difficult' (Harrison et al., 2017); 'If you are very honest and straightforward and treat the patients right then often they feel that, they take a very generous view towards the mistake as opposed to getting very litigatous about it, which I think they are more inclined to do if there's a big cover up and people aren't honest' (Harrison et al., 2017); 'I think there's still a fear of the action that might be taken against you, but I think people are much more aware of, and responsible really about the failure to disclose a mistake that they've made…[but] there's still a concern I guess for everyone that there will be a whole weight of something coming on them' (Harrison et al., 2017); 'If families for whatever reason feel that they have not received the best medical care, they're going to make a big stink and go to the paper and feel hard done by and I think in the situations where the families are pressing and the families raising doubts- it may be more difficult to disclose' (Coffey et al., 2010); '…two is fear of being sued and what is that going to do with your future' (Fein et al., 2005); 'You would love to be just straightforward. "Gosh, I wish I had checked that potassium yesterday. I was busy, I	al., 2017); Reputation risk (Coffey et al., 2010); Provider factors (Fein et al., 2005); Emotional impact of error (Gallagher et al., 2003).

	made a mistake, should have checked that. I can't believe I wouldn't do that. I will learn from my mistake and I will do better next time because this is how we learn as people''. But if you say that to a patient, which you would like to be able to say, honestly as just another human being, is that we have this whole thing, the wait to cash in through a lawsuit' (Gallagher et al., 2003).	
Training	'I have never learned (open disclosure). Can't make facial expressions. Can't come up with words to say… 'I have never seen anyone do it, so I have no clue on how to do it' (Ock et al., 2016); '…But in fact we are extremely sorry, but we just don't know how to express or convey it' (Ock et al., 2016); 'I haven't had any personal training. Certainly, the trust offers a sort of day if you like around breaking bad news, however I think that tends to be more related to breaking, you know, cancers and diagnoses type thing, rather than adverse events that happened (Harrison et al., 2017); 'My god this is really uncomfortable and I don't have the confidence about how to do it' (Fein et al., 2005); 'I learned how to discuss grief and loss…But error? No…it's all on-the-job' (Fein et al., 2005); 'As soon as it gets into the legal realm, suddenly as an attending physician, I feel like I need to be coached as to what can be said and how it can be said and so forth' (Fein et al., 2005); We might not train our physicians enough about how to go about [disclosing error]' (Fein et al., 2005); I can say right now that I do not know what the policy is' (Fein et al., 2005).	Absence of disclosure education (Ock et al., 2016); Role models and guidance (Harrison et al., 2017); Provider factors (Fein et al., 2005); Institutional culture (Fein et al., 2005).
Support	Communication is already a major focus in our training. But how do you do that when you have committed an error? This is not precise I believe. It has never been	Attitudes and experiences concerning disclosing errors

	substantiated. I think that's strange and uncomfortable for everybody' (McLennan et al., 2016); 'You are told not to discuss things between yourselves and not to discuss it with the family and not to approach the family but it seems to me that actually it is better if you can speak to your colleagues' (Harrison et al., 2017); 'If staff want to hide an error, the nuances of policy will allow them to justify it in their minds and they just won't tell anybody' (Shannon et al., 2009); 'I wouldn't have trouble going to my charge nurse and saying that [an error] has happened because any time I've seen that happen [to someone else] or it's happened to me…they've been very supportive' (Shannon et al., 2009); 'She actually got a big lecture saying 'you always run it by somebody before you disclose it to the families, because bedside nurses are not trained to discern litigiousness'…she felt like she did the right thing but was being told 'don't do that again'' (Shannon et al., 2009); 'The emphasis at least in my training, has been – don't talk about anything, keep quiet' (Fein et al., 2005); The remark- Goddamn, what were you thinking? – comes out pretty often. When you get that kind of response when you admit your error, you are very unlikely to continue admitting your errors' (Fein et al., 2005).	to patients (McLennan et al., 2016); Clarity (Harrison et al., 2017); Policies might help (Shannon et al., 2009); It all depends on your nurse manager (Shannon et al., 2009); Provider factors (Fein et al., 2005); Institutional culture (Fein et al., 2005).

Appendix 4: Detailed guidance for conducting a meta-ethnographic synthesis

Although meta-ethnography is a widely used qualitative literature synthesis method within healthcare research, it is poorly demarcated and there is a lack of clarity surrounding the description of the data analysis process. A number of reviews have used this approach (Scott & Grant, 2018; Elmir & Schmied, 2016; Cullinan, O'Mahony, Fleming & Byrne, 2014; Purc-Stephenson & Thrasher, 2010; Toye, Seers & Barker, 2017; Rubio-Valera et al., 2014) but do not provide a fully rigorous description of the stages involved in the analysis process. Given the value of qualitative meta-synthesis in integrating the findings from multiple studies into a higher conceptual level, it is important to provide detailed guidance on each of the steps involved in conducting a meta-ethnography. This paper aims to fill this gap by outlining a step-by-step method for conducting meta-ethnography. We describe our interpretation of each of the seven steps outlined by Noblit & Hare (1988) who first proposed this approach. We also incorporate adaptations and developments by recent researchers (Lee, Hart, Watson & Rapley, 2015) and provide annotations where applicable to assist in describing the stages involved.

The worked example being used is the systematic review and meta-ethnography conducted in chapter 2 of the thesis. Where applicable, illustrative examples from this review are provided alongside the each phase to demonstrate the process.

Within a meta-ethnographic synthesis, the process of translation is key and unique. It is defined as 'comparing the metaphors and concepts in one account with the metaphors and concepts in others' (Noblit & Hare, 1988). A meta-ethnography should involve a reciprocal and refutational translation, where possible combined with a line of argument synthesis (France et al., 2019a; France et al., 2019b). Reciprocal translation occurs when concepts in one study can incorporate those of another, whereas refutational translation explains and explores differences, exceptions, incongruities and inconsistencies (France et al. 2019a; Booth, Carroll, Ilott, Low & Cooper, 2013; Barnett-Page & Thomas, 2009). Reviewers often overlook refutational translation (Booth et al., 2013; Thorne, Jensen, Kearney, Noblit & Sandelowski, 2004); however studies may refute each other (Britten et al., 2002; Bondas & Hall, 2007) or concepts within studies may refute one another (Britten et al., 2002; Finfgeld-Connett, 2014). Therefore it may be possible to conduct both a reciprocal and refutational translation (France et al., 2019a). A line of argument synthesis is not an alternative to conducting a translation but is viewed as the next stage of analysis

(France et al., 2019b). A line of argument synthesis is the translation of accounts that interpret different aspects of the same phenomenon under study, which results in producing a whole that is greater than the sum of its individual parts (Noblit & Hare, 1988; Scott & Grant, 2018). Although Noblit & Hare (1988) describe meta-ethnography as a seven step process, it is important to acknowledge that this process is iterative and the phases are not discrete but may overlap and run in parallel (Noblit & Hare, 1988). A meta-ethnography reporting tool, eMERGE has very recently been developed, and provides a framework for reviewers to follow when reporting the important aspects of a meta-ethnography (France et al., 2019a).

Methods:

In order to identify relevant literature to inform the present guide, articles which described an evaluation or discussed methodological issues in conducting a meta-ethnography or provided guidance for reporting a meta-ethnography were searched for. We then scanned the reference lists of relevant articles to identify further relevant literature. We also drew on the results from two recent systematic reviews (France et al., 2019b; Cahill et al. 2018). As such, while the searches conducted for the present article were not systematic, the guide reflects recent methodological recommendations in the wider methodological literature. All relevant articles were read and recommendations were noted; where any disagreement between authors of papers was apparent, guidance which was based on systematic reviews of the evidence rather than individual reflections was prioritised.

Results

Conducting a meta-ethnographic synthesis: a step-by-step guide with illustrated examples

Phase 1: Getting started

The initial stage requires the authors to identify an area of interest (Noblit & Hare, 1988). The reviewers need to consider if a synthesis of the topic is required and whether a qualitative synthesis fits with the research question (Toye et al., 2013). It is also important to determine whether there is a large and growing body of qualitative research in this area, and whether synthesizing qualitative findings can contribute valuable knowledge to the existing literature (Toye et al., 2014). Campbell and colleagues (Campbell et al., 2011) have proposed that establishing a team of researchers who have different approaches,

opinions and the key skills to conduct this form of synthesis will add rigour to the meta-ethnography.

Example

I was interested in the disclosure of adverse events within healthcare; specifically in the perceptions and experiences of patients and healthcare professionals relating to these events. I was aware of the large and growing body of qualitative research in this area. Searches revealed that there was no qualitative synthesis specific to the experiences of adverse event disclosure. I believed that synthesizing the views, attitudes and experiences of both groups (patients and healthcare professionals) would enable the understanding of what patients require from the disclosure conversation and what healthcare professionals currently offer. The motivation for synthesizing the body of qualitative evidence was to inform future disclosure interventions which were acceptable to patients and practical for healthcare professionals to deliver. Synthesizing qualitative findings can make valuable knowledge accessible to healthcare professionals and policy makers (Toye et al., 2014).

Phase 2: Deciding what is relevant to the initial interest

Once you have chosen your topic of interest, phase 2 involves the following steps: a) defining the focus of the synthesis, b) selecting studies for inclusion in the synthesis and locating relevant studies, c) developing inclusion and exclusion criteria and d) quality assessment of the included studies (Atkins et al., 2008).

2a. Defining the focus of the synthesis

An important decision involves deciding whether to include all the studies within your chosen area of interest. It is necessary to find a balance between a review which has a broad scope, and a focus which will yield a manageable number of studies. The scope of a meta-ethnography is more restricted compared to other qualitative narrative reviews. This is due to the avoidance of making gross generalisations across disparate fields (Noblit & Hare, 1988; Britten et al., 2002). There is currently no agreement to how many studies should be included in the synthesis. Some researchers argue that synthesizing a large number of studies may interfere with the ability to produce a useful interpretative output and could result in an aggregative synthesis (France et al., 2019b). Synthesizing too few studies can result in underdeveloped theories/concepts (Booth et al., 2013; Finfgeld-Connett, 2014). A large number of studies have varied from 40 (Campbell et al., 2011) to over 100 (Thorne et al., 2004). The volume of data, rather than just the number of studies is important and team size and resources will affect the ability to manage this data (France et al., 2019a). It is recognised that focusing on a particular aspect of your chosen topic

interest and excluding certain aspects may result in some papers being overlooked. However it is important to make this choice to ensure that you have manageable number of studies (Atkins et al., 2008).

Example

The systematic review question focused on *'The views and experiences of patients and healthcare professionals on the disclosure of adverse events'.* I focused on studies which examined the views and experiences of patients (and/or family members, members of the general public) and healthcare professionals. I found that qualitative research in the area of adverse event disclosure was limited. As this was an under-researched area, we were able to include all the available qualitative studies in this research area (enabling the inclusion of both patients' and healthcare professionals' views on adverse event disclosure).

Phase 2b: Locating relevant studies

The second important step involves locating potentially relevant qualitative studies by conducting a systematic search of the literature. In order to conduct a systematic search, a well-constructed and comprehensive search strategy needs to be developed. Qualitative searches can yield a large number of search results, which can be daunting and time consuming to screen. One of the ways to make your search strategy more specific is through the use of qualitative search filters. Empirically tested search filters for qualitative studies have been developed (Wong, Wilczynski & Haynes, 2007; McKibbon, Wilczynski & Haynes, 2006). However it is possible that some of the potentially relevant studies may be missed when using such filters. Decisions regarding your search strategy and screening depend on your aims and resources available. It is advised for the use of a librarian for reaching decisions on the content of searches. Multiple databases are utilised to locate relevant articles and this can be further supplemented by hand searching. This is important as it can locate relevant articles which are not indexed or inaccurately indexed, and minimises the risk of missing relevant studies (Booth et al., 2013).

Some argue that a more purposive sampling approach may be more appropriate (Noyes, Popay, Pearson & Hannes, 2008; Dixon-Woods et al., 2006), which aims to provide a holistic interpretation of a phenomenon, where the extent of searching is driven by the need to reach theoretical saturation rather than to identify all eligible studies (Booth et al., 2013; Benoot, Hannes & Bilsen, 2016). Detailed information on purposive sampling technique is available (Booth et al., 2013; Finfgeld-Connett, 2014). Also, to avoid the

potential problem of having too few descriptively or conceptually-rich studies, knowledge-building and theory-generating systematic reviewers can conduct expansive searches of the literature (Finfgeld-Connett, 2014). We do not describe here how to conduct a systematic search of the literature; however there are a number of papers which describe this process (Atkinson & Cipriani, 2018; Hausner, Waffenschmidt, Kaiser & Simon, 2012).

Example

Five electronic databases were searched, and the search strategy included a combination of the three major concepts (disclosure, safety incident and experience). The database searches were supplemented by hand searching of relevant journals and reference lists. In order to capture all the possible relevant articles, it was decided that qualitative filters should not be applied.

Phase 2c: Decisions to include studies

A number of factors should be considered when deciding whether to include or exclude studies from the synthesis. An important consideration is the expertise of the review authors and the time available to complete the review (Noyes et al., 2008). Reviewers should consider the likelihood of excluding valuable insights on the basis of quality, and the contribution of these studies to the development and interpretation of findings. Would excluding such studies affect the coherence of qualitative synthesized findings? (Noyes et al., 2008). Also, an important consideration is the nature of the primary data which is available to synthesise (France et al., 2019a). Including predominantly thin descriptive data can be problematic as it is difficult to further interpret data which lacks depth (France et al., 2019a). Conceptually rich data which is explanatory, or rich descriptive data which provides sufficient detail to be further developed is suitable for meta-ethnography. Therefore selecting studies based on this suitability is one of the approaches reviewers should consider. Further discussion on decisions to include studies is available (Noyes et al., 2008).

Phase 2d: Quality appraisal

There is a lack of agreement surrounding the use of quality appraisal for qualitative studies (Toye et al., 2013). Some researchers argue there are difficulties with quality appraisal as some aspects of qualitative research are difficult to appraise and therefore depend on subjective judgement (Dixon-Woods, Booth & Sutton, 2007). Although this debate continues, we argue that at least some quality appraisal of studies needs to be considered to give an indication of the credibility of the included studies. Critically appraising the studies and assigning numerical scores to indicate level of quality is also

useful as it can be used as a way to order the studies for analysis. Previous published qualitative reviews have either used the highest scoring paper as the 'index study' (Scott & Grant, 2018) or have arranged all the papers in chronological order by date, and used the most recently published paper as the 'index study' (Flemming, Graham, Heirs, Fox & Sowden., 2013). One of the limitations is of assigning numerical scores using CASP and the use the highest scoring as an index study is that it focuses on the methodological rather than conceptual strength. Other reviewers have chosen a 'conceptually rich' index account (Garside, 2008; Nye, Melendez-Torres & Bonell, 2016); however it is unclear how this 'conceptually rich' index account should be selected. The different ways of ordering study accounts has yet to be formally empirically compared and there is no guidance for reviewers (France et al., 2019b). However the order could affect the synthesis output (Malpass et al., 2009; Atkins et al., 2008; Booth et al., 2013; France et al., 2014). There are different perspectives to the use of tools in the quality assessment of qualitative research (Majid & Vanstone, 2018). Some recommend the exclusion of studies based on a low-quality assessment and others refute this view and suggest that such tools may not truly assess the meaningfulness and potential impact of qualitative findings (Majid & Vanstone, 2018). However, we believe that these checklists can equip novice qualitative researchers with the resources to evaluate qualitative research efficiently.

Two common and widely used quality assessment tools are the Critical Appraisal Skills Programme (CASP) and the Qualitative Assessment and Review Instrument (JBI-QARI). The Critical Appraisal Skills Checklist (CASP) provides detailed instructions and decision rules on how to interpret the criteria (CASP, 2019). This checklist contains a number of questions which help the reviewer to assess the rigour, credibility and relevance of each study (Kitto, Chesters & Grbich, 2008; Kuper, Lingard & Levinson, 2008; Mays & Pope, 2000). All studies are critically appraised and each study is assigned a numerical score out of ten, where a higher score is correlated to a higher quality (Scot & Grant, 2018). The two studies ranked with the highest scores are used as index studies, and can be used as the first studies from which concepts are translated into other studies and therefore shaping the analysis (Atkins et al., 2008). Similarly, the Qualitative Assessment and Review Instrument (JBI-QARI) is a 10 item checklist which assesses the methodological quality of a study, and determines the extent to which a study has addressed the possibility of bias in its design, conduct and analysis (The Joanna Briggs Institute, 2017). Some researchers provide guidelines for determining and excluding studies which have major methodological flaws (Dixon-Woods et al., 2004). However, it can be argued that excluding studies based on quality criteria may result in the exclusion of insightful studies. GRADE-

CERQual is a recently developed approach which provides guidance for assessing how much confidence to place in findings from systematic reviews of qualitative research (Lewin et al., 2018). The application of GRADE-CERQual can be helpful for appraising the overall quality of the qualitative synthesis (Lewin et al., 2018) but a quality appraisal of primary studies is required before applying the CERQual tool.

Example

The CASP checklist was used to assess the quality of included studies. This was chosen as it propagates a systematic process through which the strengths and weaknesses of a research study can be identified (Singh, 2013). The CASP guidelines are easy to follow, especially for novice researchers (Singh, 2013). A decision was made in advance not to exclude studies with low quality scores, as although some authors may have failed to describe the methods in sufficient detail for us to determine that quality criteria had been met, lack of reporting did not necessarily mean it was poorly conducted research (Atkins et al., 2008). However the quality rating of the studies was used in the synthesis approach. The study ranked with the highest score was used as the 'index study' and was the first study from which concepts were translated into other studies and therefore shaping the analysis (Atkins et al., 2008).

Phase 3: Reading the studies

It is during this phase where the synthesis process begins. First, this involves repeatedly reading the included studies and familiarising yourself with the key concepts and metaphors. It is important at this stage to become as familiar as possible with the content and detail of the included studies. A concept is defined as 'having some analytical or conceptual power, unlike more descriptive themes (Britten et al., 2002). It is important to acknowledge that reading the studies is not a discrete phase; reading occurs throughout the synthesis process. The notion of first, second order and third order constructs (Britten et al., 2002) are useful in distinguishing the 'data' of the meta-ethnography which are defined in table 1 below.

Table 1: Key terms in a meta-ethnography

Primary authors	Refers to the authors of the original primary qualitative studies
Reviewers/team members	Refers to the individuals conducting the meta-ethnography
First order constructs	Represent the primary data reported in each paper (participant quotations).
Second order constructs	The primary authors' interpretations of the primary data (metaphorical themes or concepts).
Third order constructs	The reviewers higher order interpretations developed from a tertiary analysis of the first and second order constructs.

Once you have read through the chosen studies, the next step involves extracting the 'raw data' from the studies for the synthesis. The raw data for a meta-ethnographic synthesis are the first and second order constructs (Cahill et al., 2018; Toye et al., 2014). The data needs to be extracted from each of the studies, which can be done by using a standardised data extraction form (Malpass et al., 2009). Alternative ways to extract data include creating a list of metaphors and themes (Campbell et al., 2011) or coding concepts in Nvivo; a software programme for the analysis of qualitative data (Toye et al., 2014). The data should be extracted verbatim, so there is no risk of losing important data [10] and to preserve the original terminology used by the primary authors. However, some authors of a previous meta-ethnography chose to record summaries of primary author interpretations due to the large number of studies included in their synthesis (Atkins et al., 2008). However, one of the drawbacks of recording such summaries is that there is the risk of potentially losing important detail.

It is essential at this stage to extract information on study characteristics for each study, using a separate data extraction form as it provides context for interpretations and explanation of each study (Feast et al., 2018). This includes information on study sample, data collection methods, data analysis methods, study outcomes and study conclusions.

Example

Below an example is provided of a data extraction table that was used to extract the raw data (figure 1).

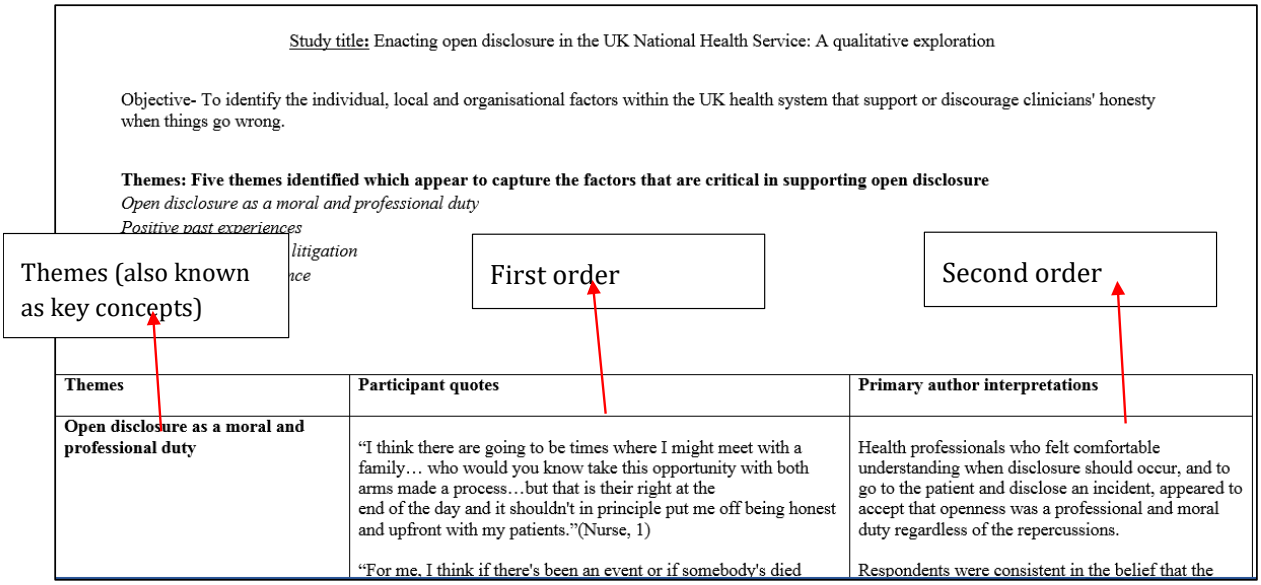


Figure 1: Example of a data extraction table

Phase 4: Determining how the studies are related

During this stage, the relationships between the key concepts from the different papers need to be considered. A concept is described as a '*meaningful idea that develops by comparing particular instances'* (France et al., 2014; Cahill et al., 2018). It is also important that concepts explain and do not only describe the data (France et al., 2014; Cahill et al., 2018) as one of the aims of qualitative analysis is to develop concepts which help to understand an experience and not just describe it (Seale, 1999). In order to consider the relationship between concepts from the different studies, you are required to look across the studies for common and recurring concepts. This can be done by creating a list of the themes (Noblit & Hare, 1988). These are then juxtaposed against each other to examine the relationships between the key concepts and metaphors these themes reflect and to identify common and recurring concepts. From this list, the themes from the different studies are then clustered into relevant categories, where we grouped common concepts from studies according to the common underlying metaphors, an approach which has previously been used (Atkins et al., 2008; Toye et al., 2014; Erasmus, 2014). During this phase it is essential to examine the contextual data about each study. This includes settings, aims and focuses. These newly formed categories are labelled using terminology which encompasses all the relevant concepts they contain. This phase is likely to be

iterative, and clusters may be revised through discussions within the review team of how they are related and by making reference to the original text.

Other authors have used diagrams (Campbell et al., 2011; Malpass et al., 2009) or coding using qualitative analysis software (Toye et al., 2014). The use of lists or tables in phase 4 is useful when synthesising a small number of studies, however such an approach would be unwieldy when there are hundreds of concepts, whereas coding in NVivo is efficient (France et al., 2019b). However, the recording of links between concepts within primary studies may be difficult when using NVivo (France et al., 2019b).

Example

During this phase, for the example review, a list of the themes from each paper was created (Figure 2) listed under each study name. As both healthcare professional and patient studies were included, it was also labelled whether the study had included patients, healthcare professionals or both groups.

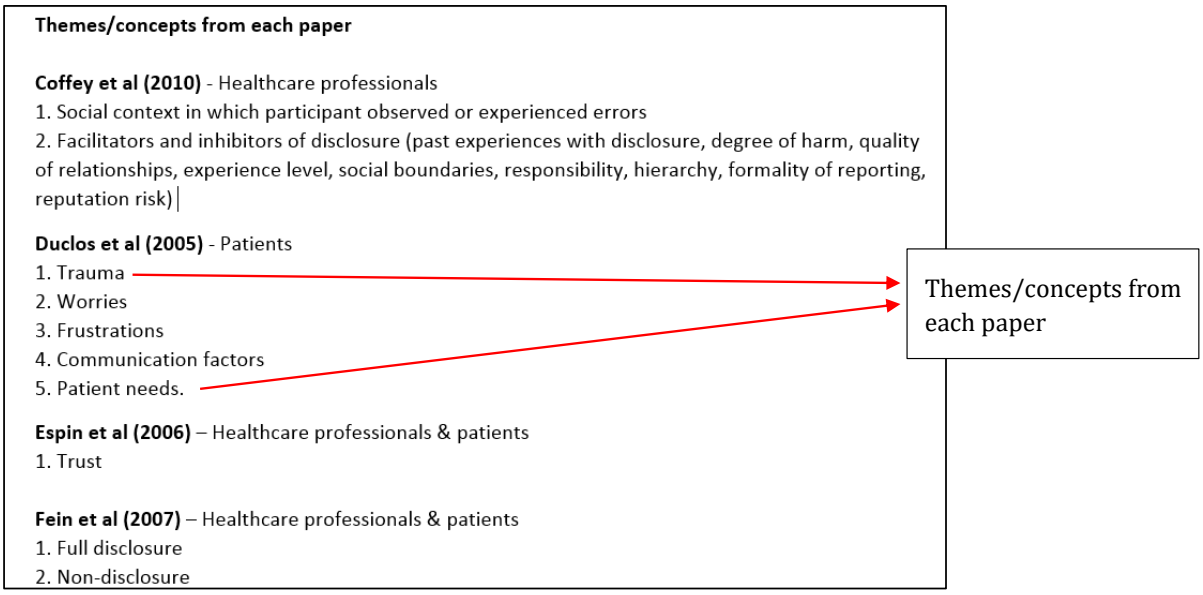


Figure 2: List of key metaphors/concepts from each study

The next step involved reducing the themes from the different studies into relevant categories (figure 3).

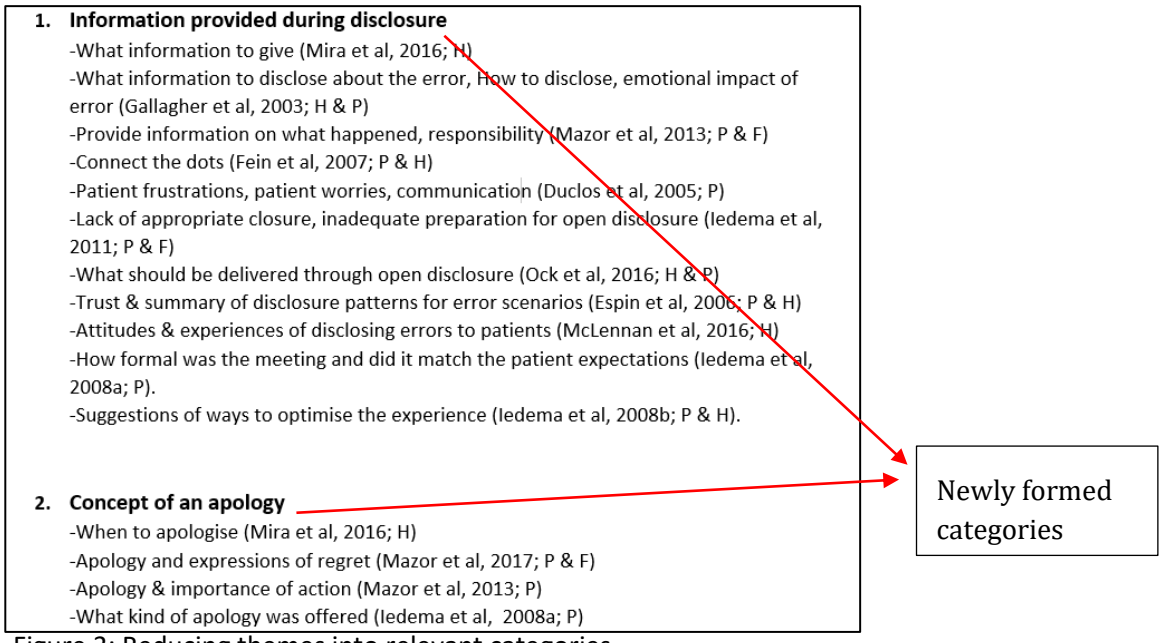


Figure 3: Reducing themes into relevant categories

It is important to note that the category labels you create during this phase are not the higher third order constructs, but are descriptive labels. The third order constructs are developed within the next two phases. However, the data within each category forms the basis of reciprocal translation or refutational synthesis in the next stages. This approach can work well when you have a manageable number of studies, however this can prove to be challenging when you have a larger number of studies. In previous meta-ethnographies where a large number of studies have been included, a thematic analysis of themes was carried out instead (Atkins et al., 2008).

Phase 5: Translating the studies into one another

The original method of meta-ethnography suggests that this phase involves 'comparing the metaphors and concepts in one account with the metaphors and concepts in others' (Noblit & Hare, 1988). However, despite a number of meta-ethnographies being conducted, it is unclear how this should be done and how this phase of the analysis should be recorded. To address this lack of clarity, we will now outline below one way in which this can be done. During this phase, each concept from each paper is compared with all the other papers to check for the presence or absence of commonality. Doing this highlights the similarities and differences between the concepts and metaphors and allows the

researcher to organise them into further conceptual categories, which results in the development of the higher third order constructs.

This phase is approached by arranging the studies either chronologically (Campbell et al., 2011) from the highest scoring paper to the lowest scoring paper (where the scores are generated during the quality appraisal process (Scott & Grant, 2018). Arranging the studies chronologically is advised when you are including a large number of papers over a large time span (Atkins et al., 2008; Cahill et al., 2018). The order in which studies are compared may influence the synthesis, as earlier papers will have a strong influence on the subsequent development of ideas (Campbell et al., 2003). The reviewer first starts by summarising the themes and concepts from paper 1. Summarising involves comparing and contrasting the concepts taking into account study contexts. They then summarise the themes and concepts from paper 2, commenting first on what is similar with paper 1 and then what paper 2 may add to paper 1 or where its findings diverge from paper 1 (Atkins et al., 2008; Cahill et al., 2018). Next, paper 3 is summarised, considering what is similar to papers 1 and 2, and then noting any areas of divergence and anything that paper 3 adds to the knowledge offered in papers 1 and 2. This process continues until you have synthesised all the papers and produces a synthesis of the primary author interpretations (see figure 4) which are useful in aiding with the development of the third order constructs in the next stage.

Examining the key concepts within and across the studies is similar to the method of constant comparison (Cahill et al, 2018). During this phase, it is important to refer back to the table of study characteristics you recorded earlier, (country, sample, recruitment method, gender, publication date etc.) to use as a context for the comparisons (Scott & Grant, 2018) as well the full papers. This process can also be supported by creating a translations table (see figure 5 for an example of a translations table), as this is a useful way to display this level of synthesis (Coventry Small, Panagioti, Adeyemi & Bee, 2015). Maintaining a personal journal during this phase of the analysis can help to ensure that the researcher is aware of their position from a theoretical point of view (Doyle, 2003). Discussing the key concepts and their meanings with team members can result in collaborative interpretations.

Example

Two separate syntheses were conducted; one for the views of patients and one for healthcare professionals, and conducted a line of argument synthesis of all the included studies, therefore it was found to be useful to have two separate translation tables; one for

each group. Part of the translation table for healthcare professionals is shown in Figure 5 (see example of table below).

The type of information provided/what information is provided during disclosure
Synthesis of papers 1, 2, 3, 4 & paper 5:
Findings from paper 1 show that providing an explanation including a description of the incident was supported by both healthcare professionals and participants from the general public. Participants from the general public required a description even if the error was ambiguous. Similarly, findings from paper 2 show that patients described that receiving information about what had occurred was important to them. Similarly, in paper 2, acknowledgement of the event was also important to patients. Findings from paper 3 also show that patients want to know what happened and why it happened, and preferred this basic information to be provided to them rather than having to ask their physician numerous questions. In paper 3, some physicians also agreed with patients ideas of how errors should be disclosed and agreed to tell them what they knew immediately.
Similarly in paper 4, healthcare professionals believed it was important to have the sufficient information on the event On the other hand, in paper 3 some physician's spoke of 'choosing their words carefully' when talking to the patient about the error, and although the adverse event would be mentioned, they would not explicitly state that an error took place. These physicians believed if patients would ask follow up questions if they wanted more information; contradicting patient's perspectives. Similarly, findings from paper 5 suggest that one physician provided enough information for a clinician to understand the relationship between the error and the outcome, however the causal connection was not obvious and would be lost to a patient/family. This again falls under the category of the physician not disclosing an error upfront but being open to answer any questions that may emerge, with this being especially true for 'near misses'.

Figure 4: Primary data synthesis of the primary author interpretations

Descriptor (Groups of similar concepts clustered together/ broad thematic headings)	First order data (participant quotes/ primary data from studies)	Second order themes (Themes developed by primary authors)
Acknowledging responsibility and apology	'If I'd made a mistake I've got to go and see that person and say look I am sorry, it was my fault. I am not saying it was right, you know it was me that did it and I did it and it was an error and I apologise. And if they then want to take that further, well that is their prerogative' (Harrison et al, 2017); 'I made an error. I discontinued a medication that I shouldn't have-by accident. You know, I picked up the error, presented it to the family. You know I tried to make it a system thing because the reason I did it was not because I'm a dummy. I'm sure it could have happened to the next guy in my shoes (Coffey et al, 2010); 'But I felt it was my responsibility to tell the family and I did' (Coffey et al, 2010); 'If I made a mistake, then it would be my responsibility to tell them [patient or family] (Shannon et al, 2009); 'No matter what happens in the care of the patient…I am the one who is responsible for that patient' (Fein et al, 2005); 'It is your obligation to do so' (Fein et al, 2005); ' I really don't know what happened. I really can't explain what happened, but it shouldn't have happened, and I have to take the responsibility for it' (Iedema et al, 2008b); 'I don't literally bring up the word regrettable but I do it eventually…it's a Korean thing that you don't really need to put it into words to…the biggest problem is when you're about to discharge your patient after stitch removal, the last step of the surgery, the wound starts to open up. It'll drive you crazy and what can you say to the patient? Seems like you can't go home today…that's the Korean way of saying sorry…you don't really need to say it through words' (Ock et al, 2016); …And if somebody has made an error or I've made an error then I'm going to apologise (Harrison et al, 2017)	Open disclosure as a moral and professional duty (Harrison et al, 2017); Responsibility (Coffey et al, 2010); Social context in which the participant observed or experienced the error (Coffey et al, 2010); Who should tell the patient? (Shannon et al, 2009); Influences on the decision to disclose a medical error (Fein et al, 2005); Support for open disclosure (Iedema et al, 2008b); How should open disclosure be carried out (Ock et al, 2016); Clarity (Harrison et al, 2017)

Figure 5: Example of a translations table

Phase 6: Synthesising the translations

This phase is described by Noblit & Hare (1988) as 'making the whole into something more than the parts alone imply'. However, similar to Phase 5, there has been no clear

guidance on how to carry out this phase. During this phase, the studies are now viewed as a 'whole' with the aim of developing a framework (Toye et al., 2014; Cahill et al., 2018). When writing about how the studies are related, reviewers can present this in a narrative and/or diagrammatic form (Toye et al., 2013). Phase 6 can be broken down into the following two stages; (a) reciprocal and refutational synthesis and (b) line of argument synthesis.

(A) Reciprocal and refutational synthesis

This stage of the synthesis involves deciding whether the studies are sufficiently similar in their focus to allow for a reciprocal translation synthesis. Alternatively, the studies may refute each other in which case a refutational synthesis is conducted. It is possible to conduct both types of synthesis to discuss similar accounts (reciprocal translation synthesis) and also explore any contradictions between the studies (refutational synthesis) (France et al., 2019b). Generally, reciprocal translation syntheses are conducted more frequently in reviews than refutational syntheses and guidance on how to conduct a refutational synthesis is currently limited (France et al., 2019b). Below we first discuss how to carry out a reciprocal translation and then describe the way a refutational synthesis can be conducted. Referring to the translations table of data developed in the stages above allows reviewers to establish the relationship between the studies and consider how to approach a reciprocal and refutational synthesis.

Reciprocal translation

It is during this phase where the shared themes across the studies are summarised by juxtaposing the first and second order constructs. This leads to the generation of new concepts which provide a fuller account of the given phenomenon and resolve any contradictions. These are known as the original third order constructs developed by the review authors and provide a new understanding of the phenomena (Scott & Grant, 2018). To put briefly, this can be achieved by reading the primary data synthesis (figure 4) alongside the translations table (figure 5) and drawing out the main points to form the reciprocal translations and therefore developing the third order constructs. It is important to constantly check the summary and third order constructs you are developing against the translations table to ensure it is consistent with the original data.

Refutational synthesis

There are limited published examples of refutational synthesis (France et al., 2014; France et al., 2019b) as reviewers often focus on reciprocal translations (Thorne et al., 2004). Also reviewers may conduct a refutational synthesis, but not label it as such (France et al.,

2019b). There are two published examples of refutational synthesis (Garside, 2008; Sleijpen, Boeije, Kleber & Mooren, 2016).This is not surprising given the lack of guidance available on how to conduct a refutational synthesis. The purpose of a refutational synthesis is to explore and explain the differences, exceptions, incongruities and inconsistencies in concepts across the studies (Barnett-Page & Thomas, 2009; Booth et al., 2013). Refutational synthesis focuses on identifying, understanding and reconciling the contradictions, rather than developing concepts around the similarities. Similar to reciprocal translation, reviewers are required to refer back to the primary data synthesis and translations table in order to develop third order constructs. The contradictions between the concepts across the studies may be explained by differences in participants, settings or study design. During this phase, it is helpful to refer back to the study characteristics table as this can help provide context for interpretations and explanations (Feast et al., 2018). It has been suggested that a refutational translation can be approached by placing two refutational concepts at either end of a continuum and proceed by analysing the differences between the concepts [23, 66]. In order to express the refutational findings, a narrative can be created so that the findings 'are placed into context' **(**Finfgeld-Connett, 2014).

(B) A line of argument synthesis

A line of argument synthesis can then be created from the third order constructs, which involves 'making a whole into something more than the parts alone imply' (Noblit & Hare, 1988). A line of argument synthesis means that there is an 'interpretation of the relationship between the themes, which further emphasises a key concept that may be hidden within individual studies in order to discover the whole from a set of parts' (Noblit & Hare, 1988; Feast et al., 2018). This is classed as a further higher level of interpretative synthesis, and provides scope for developing new insights.

A line of argument synthesis is achieved by constant comparison of the concepts and developing a 'grounded theory that puts the similarities and differences between the studies into interpretative order' (Noblit & Hare, 1988). Practically, reviewers can approach this phase by reading through the reciprocal translations and noting down the similarities and differences between each of the third-order constructs. These notes can then be used to construct interpretations of how each third order construct relates to the others in the analysis. These relationships can then be represented using a diagram to aid understanding. Each of the reviewers can carry out this stage independently, and merge their findings as a team to produce the final line of argument synthesis. Diagrams can be used to develop the line of argument synthesis and it is suggested that discussions

between team members are vital to this process (Toye et al., 2013; Cahill et al., 2018). A line of argument synthesis can be a useful way to bring together and explain the perspectives of two or more different groups and interpreting the relationship between the themes. This is particularly relevant for research in healthcare, where often the views of one or more groups are examined on a phenomenon (e.g. patients and healthcare professionals). An example of a line of argument synthesis from the worked example is presented in figure 6.

Example

Separate reciprocal translations were conducted for the first- and second-order constructs relating to patients and healthcare professionals, resulting in third order constructs which related to solely either patients or professionals. Therefore, the synthesis process for this review consisted of three steps- (1) reciprocal translations of the patient studies to understand patients' views and experiences of disclosure, (2) reciprocal translations of the healthcare professional studies to explore healthcare professionals views and experiences on disclosure and (3) a line of argument synthesis which contributed to the identification of both the key elements of an ideal disclosure desired by patients and the facilitators for healthcare professionals which can increase the likelihood of this taking place. Initially, a refutational translation instead of a line-of-argument synthesis, but it was apparent during the synthesis that the concepts from the patient and healthcare professional studies were not contradictory in nature; rather they described alternate perspectives of the same phenomenon. Therefore it was agreed that a line of argument synthesis was the most appropriate for the aim of our synthesis. During this stage of the analysis, it was found to be useful to place all the third order constructs in a table to enable visual comparison (see table 2 below). The third order constructs should be theoretically rich. In the synthesis of this review, although it was found that the data that was being dealt with was descriptive, it was rich descriptive data. This therefore provided sufficient detail to further interpret this and develop third order constructs (France et al., 2019b). The third order constructs we developed reflected the data that was being dealt with, but allowed the production of higher levels of analysis. Reviewers should take caution when dealing descriptive data. They need determine whether it is 'thin descriptive data' which could be problematic to further interpret due to lack of depth, or 'rich descriptive data' which can provide sufficient detail to be further interpreted (France et al., 2019b).

Table 2: Examples of third order constructs

Third order constructs- Patient studies (views on disclosure process)	Third order constructs- Healthcare professional studies (views on disclosure process)	Third order constructs- Healthcare professional studies (barriers to disclosure)
Need for information	Sometimes economical with the truth	Difficulty of disclosure in a blame culture
Importance of sincere regret	Owning up without saying 'I'm sorry'	Avoidance of litigation
Promise of improvement	To tell or to not tell? *-When anxiety may cause unnecessary anxiety* *-Outcome determines disclosure*	Disclosure is a learned skill
		Inconsistent guidance

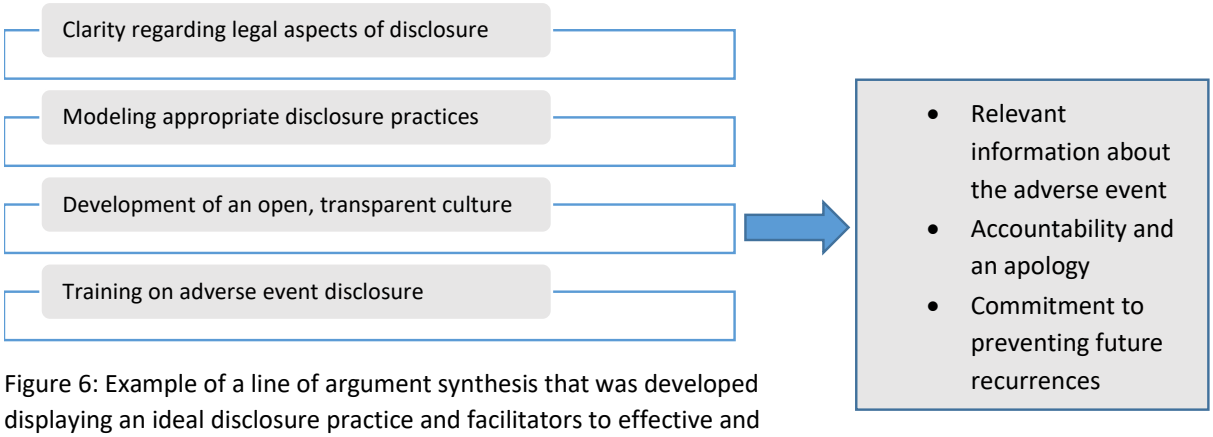


Figure 6: Example of a line of argument synthesis that was developed displaying an ideal disclosure practice and facilitators to effective and practicable disclosure for healthcare professionals.

Phase 7: Expressing the synthesis

Reviewers should follow the eMERGE reporting guidance when writing up the synthesis (France et al., 2019a) and the PRISMA guidelines may be used alongside this if systematic searches are conducted as many journals may require a PRISMA diagram (Moher, Liberati, Tetzlaff & Altman, 2009). In addition to these standard reporting methods as described by the eMERGE guidance (France et al., 2019a), the final phase can be broken down into the following three stages; (a) summary of findings, (b) strengths, limitations & reflexivity and (c) recommendations and conclusions (refer to (France et al., 2019a) where this phase is described in further detail).

Discussion

Meta-ethnography is an evolving approach to synthesising qualitative research and is being increasingly used in healthcare research (Cahill et al., 2018). Although this approach is being used by numerous reviewers, transparency on how each of the stages should be conducted is still poor and there is a lack of clarity surrounding the exact stages reviewers utilise to reach their final synthesis (France et al., 2019b). The ultimate aim of qualitative research synthesis in healthcare is to contribute towards improvements in patient care and experience, as well as improving the processes for healthcare professionals involved (Atkinson & Cipriani, 2018). In order for a meta-ethnography syntheses to be considered to be of high quality and useful, the meta-ethnographic approach needs to be rigorous and consistent. Therefore, a clear understanding of the steps included in a meta-ethnography is vital to produce a synthesis which is rigorous and comprehensive. Poorly reported methods of meta-ethnography can also make it challenging, particularly for early career qualitative researchers to conduct this synthesis. High quality qualitative research synthesis should not end with the final write up and further research needs to focus on how the impact of qualitative research can be maximised to improve healthcare.

Conclusions

There was previously a lack of step-by-step guide to meta-ethnography conduct. This guide has filled this gap by providing a practical step-by-step guide for conducting meta-ethnography based on the original seven steps as developed by Noblit & Hare (1988). Adaptations have been incorporated and developments by recent publications and detailed annotations have been provided, particularly for stages 4-6 which are often described as being the most challenging to conduct, yet the least amount of guidance is provided for conducting these stages. Each stage has been described in detail and in relation to a previous meta-ethnography that has been conducted to aid understanding, and allows the reader to follow on from one step to the next easily.

Appendix 5: Participant information sheet (for interview study)

Information sheet for participants

Study title: Exploring the views and experiences of maternity staff on disclosing adverse events to patients.

You are being invited to take part in a PhD research study. It is important for you to understand why this research is being carried out and what it will involve. Before you decide to take part, please take your time to read the following information carefully, and if there is anything which is not clear, or if you would like more information, please contact the researcher, Raabia Sattar at ps15rs@leeds.ac.uk.

A recent legislation known as the Duty of Candour (2014) now states it is a legal duty to disclose to patients any adverse events which have caused them harm during their care. However, little research has been carried out in relation to disclosure of such events in maternity services.

What is the purpose of this study?

The purpose of this study is to explore and understand your views and experiences regarding the disclosure of adverse events and complications to patients, in maternity services. This study also aims to explore how the disclosure of such events affects the mental well-being of maternity staff. However, with the limited research available in this area, it is not clear what process staff follow in order to disclose these events and how this disclosure affects the well-being of staff. Understanding your views and experiences can allow an insight into what training should be provided to support staff with these disclosure processes. This research is funded by the University of Leeds and NIHR CLAHRC.

Why have I been chosen?

You identify as a maternity health care professional and therefore you have been identified as a potential participant.

It is up to you to decide whether or not you wish to take part in this study. If you do decide to take part in this research, you are free to withdraw your data from the study up until a month after the interview has been conducted.

What will happen if I take part?

If you agree to take part in this research, you will be asked to take part in a telephone interview, which will last approximately 40 minutes. The interview will consist of questions related to your personal views and experiences related to the disclosure of adverse events and complications to patients in your unit. Whilst taking part in this study, you have the right to refuse to answer any of the questions given by the researcher. Within this interview you will also be asked to state how long you have worked in your profession.

To thank you for taking out your time to take part in this research, you will receive **£20 Amazon shopping voucher** from the researcher.

What will happen to the information I provide in the interview?

All interviews will be recorded, however all information which is collected from you will be kept secure and your identity will remain anonymous at all times. This research will be written up into a thesis, and may also be published at some point in the future. However, all information received from you will be anonymised, with any potentially identifiable information being changed, including the use of pseudonyms for the name of people and places. Confidentiality would only be broken under the following conditions:

1. If you provide information which indicates perceived significant and immediate risk of harm to self or others. E.g. if you provide information which indicates intended harm to patients, or others in your workplace.

All recordings will be password protected and stored securely. Data will only be accessible by the researcher and supervisors for a period of five years, after which the data will be destroyed, where all copies of the data will be deleted.

You have the right to withdraw your data from the study without having to provide a reason, until a month after your interview has been conducted. If you wish to withdraw

from the study, or you have any other questions regarding the study please contact the researcher by email at ps15rs@leeds.ac.uk.

In order to ensure confidentiality, you will be asked to generate a code. . E.g. by using your day of birth, last 2 digits of your phone number and first 2 letters of your favourite colour. If you would like to withdraw your data, you will be asked to provide this code.

Who has reviewed the study?

This study has received ethical approval from the School of Psychology Research Ethics Committee at the University of Leeds on 27/04/2017, Ethics Reference No: 17-0128. This study also received HRA approval on 28/07/17, Ethics Reference No: 229238.

What if there is a problem?

The study researcher will be available to resolve any minor problems (contact details below).

Researcher: Raabia Sattar- ps15rs@leeds.ac.uk
Based at: University of Leeds, School of Psychology &
Bradford Institute for Health Research

Study supervisors:

Dr Judith Johnson- j.johnson@leeds.ac.uk
Professor Rebecca Lawton- r.j.lawton@leeds.ac.uk
Based at: University of Leeds, School of Psychology &
Bradford Institute for Health Research

If you are unhappy about any aspect this study and you do not want to discuss this with the researchers, you can contact the School of Psychology Ethics Committee: ips.ethics@leeds.ac.uk.

If you are interested, we will be happy to provide you with anonymised feedback about the findings of this study. Thank you for taking the time to read this information sheet.

Appendix 6: Participant consent form (for interview study)

Appendix 6: Participant consent form (interview study)

UNIVERSITY OF LEEDS

NHS National Institute for Health Research

YQSR Yorkshire Quality and Safety Research Group

Consent form

Study Title: 'Exploring the views and experiences of maternity staff on disclosing adverse events to patients'

Please carefully read the following statements and highlight your response for each of them. The reasoning behind this form is so that you have an understanding of the purpose of the study and that you are giving your consent to take part. (*This consent form will be read out to participants verbally over the telephone, and consent will be recorded. Participants will also be sent this consent form via email).*

1. The aims and purpose of this study have been explained to me at least 24 hours in advance of being asked to sign the consent form. Also, I have had the opportunity to ask questions about the study.	YES	NO
2. I understand that participation in this study is voluntary and it is up to me to decide whether I would like to take part or not.	YES	NO
3. I understand that I can withdraw from the study up until a month after the interview has been conducted without having to provide a reason. I also understand that if I wish to withdraw, my data will not be used in the study.		
4. I understand that the telephone interview will be audio recorded and I have given my consent for my interview to be recorded.	YES	NO
5. I understand that any parts of the recording may be used in the final report and these recordings will be available for others to read.	YES	NO
6. I understand that if any parts of the recording are to be included in the final report, information which identifies myself, others and places will remain confidential and all efforts will be made to achieve anonymity via a process of random name assignment. I also understand that any information in these recordings that	YES	NO

exposes my identity, identity of others or identity of places will be removed.		
7. I understand that only the researcher and supervisors will have access to anonymised data sets.	YES	NO
8. I understand that some questions are related to personal experiences and may cause short term distress.		
9. I understand that I have the right to not respond to any question asked by the researcher.	YES	NO
10. I agree to take part in this telephone interview.	YES	NO

The study researchers will be available to answer any questions related to the study or resolve any minor problems (contact details below).

Researcher: Raabia Sattar- ps15rs@leeds.ac.uk

Study supervisors:

Dr Judith Johnson- j.johnson@leeds.ac.uk

Professor Rebecca Lawton- r.j.lawton@leeds.ac.uk

Based at: University of Leeds, School of Psychology &

Bradford Institute for Health Research

This study has received ethical approval from the School of Psychology Research Ethics Committee at the University of Leeds on 27/04/2017, Ethics Reference No: 17-0128. This study also received HRA approval on 28/07/17, Ethics Reference No: 229238.

Appendix 7: Detailed descriptions of each study including participants, intervention & components, outcome measures & main findings.

Author/Year/ Country	**Participants**	**Intervention & components**	**Outcome measures**	**Main findings**
Gunderson et al (2009)	Students (*n* = 18) from the six health sciences colleges	Educational module on full disclosure. This was conducted as part of a 30 hour, 2 week patient safety elective in 2006. The module consisted of the following: 1. Pre-reading 2. Large group interactive lecture with facilitated discussion and training DVD 3. Small group practise of full disclosure using	1. Perceived patient safety self-efficacy: 19-item instrument (four domains specific to full disclosure: understand full disclosure, do a full disclosure, admit an error to a supervisor, admit an error to a patient). 2. Standardised	Confidence among students improved significantly after taking part in the module.

		case scenarios 4. Reconvened as a large group for discussion and debriefing 5. Learning acquired reinforced throughout remainder of the elective	patient case: standardised patient encounters were observed and subjectively evaluated by the course directors	
Halbach et al (2005) Country: USA	Third-year medical students (*n* = 572) attending 4-week family medicine clerkship in years 2000–1, 2001–2	4-hour curriculum to raise awareness about medical errors and patient safety. This included the following components: 1. Brief required reading 2. Introductory 1-hour	1. Self-awareness about patient communication and safety: seven-item questionnaire 2. Evaluation of the curriculum: 13-item	89% of students reported that the opportunity to present an error to a patient increased their confidence about discussing this issue with patients. 94% of students reported

	and 2002–3	lecture/discussion 3. Videotaped simulation with a standardised patient. Three-hour exercise including orientation to case material, review of skills required, videotaped encounter with standardised patient and small-group feedback session.	evaluation 3. Students' experience with medical errors since their clerkship: 12-item anonymous follow-up questionnaire 4. Confidence regarding error in medicine: Graduation Questionnaire of the Association of American Medical Colleges given to fourth-year	that they strongly agreed or agreed that the standardized patient and feedback exercise was a useful learning experience. A comparison of before and after questionnaire data revealed statistically significant increases in the self-reported awareness of students' strengths and weaknesses in communicating

			students.	medical errors to patients.
Kiersma (2009) Country: USA	First-year pharmacy students (*n* = 160)	1. Didactic instruction. Received instruction on strategies for medication error reduction 2. Completed a community based pharmacy observation assignment 3. Participated in a skills-based laboratory. Three laboratory activities: (i) dispensing and counselling simulations; (ii) medication error	1. Students' knowledge of medication safety: 16 open-ended items and true/false questions 2. Students' confidence in medication safety: 10 questions based on laboratory objectives	Students' awareness of the pharmacist's role in medication error reduction improved and confidence in their ability to recognize, prevent, and communicate medication errors increased.

		scenario- role play scenario on how to manage and communicate errors; (iii) feedback session on pharmacy observation assignment.		
Madigosky (2006) Country: USA	Second-year medical students (*n* = 92)	Patient safety and medical fallibility curriculum (10.5 contact hours). Addressed the following components: 1. Patient safety overview, error reporting systems, vs. human approach, safety tools and ethics/ disclosure.	1. Knowledge, skills and attitudes: 28-item questionnaire. 2. Assessment of self-reported behaviours: % of yes or no responses to questions about whether or not they used what they learned	One skills item evaluated comfort with skills disclosing an error to a patient Pre-test to post-test mean change 0.79 (95%CI0.48to1.10) 56%(of participants

		2. Involved a mixture of lectures, panel discussion, demonstration and interactive forums. 3. Disclosure techniques involved role play disclosing an error to an attending, supporting a peer who experiences an error and assuming role of an attending to disclose an error to a patient.	(at 1-year follow-up). 3. Curriculum evaluation: five-point scale to rate the curriculum, and invited students to describe the most important thing they gained, plus suggestions for improvement.	reported having used what they learned from the curriculum. 73% of participants agreed or strongly agreed that it was useful in their medical education. Suggested improvements included changes in the timing, shorter sessions, less lecture and smaller group sessions.
Moskowitz (2007)	Third-year	1-day programme on	1. Attitudes and	Item for disclosing

Country: USA	medical students (*n* = 229)	patient safety. This included two plenary sessions and two 1-hour workshops selected from a list of nine topics (one topic was discussing medical errors with patients).	beliefs: Survey: two open-ended items related to a specific medical error observed by the participant.	error to a patient: 'offering an apology to a patient is unwise because it implies negligence'. Percentage of students (n=124) who agreed: pre=5, post=3 (p=0.04).
Paxton (2010) Country: USA	Intervention group (n=51) including medical students and physician assistant students. Control group (n=24) medical	Intervention: Medical Errors Educational Intervention. 2-hour session consisted of small-group discussions with slide presentation. Slides covered six major medical errors subjects including	Study provided no clear statement about the outcome measures. 12 multiple choice questions on medial error disclosure were provided. This may have	This brief educational intervention led to statistically significant improved performance in general understanding of medical errors.

	students.	error disclosure. Frequent breaks throughout session allowed students opportunity to describe their own experiences with medical errors. Control group received no medical error educational tool.	assessed knowledge about medical errors.	
Posner (2011) Canada	Obstetrics & Gynaecology Medical residents (n=14)	2-hour workshop on disclosure which was facilitated by a physician risk manager. Objectives of the workshop were to review the circumstances when a	1. Were residents able to follow the suggested CMPA guidelines and incorporate the necessary steps that are considered to be integral parts of	Residents' performance in disclosure improved after formal teaching.

		disclosure discussion is appropriate, who should participate in disclosure discussions, when and where disclosure should take place, what to disclose and how to say it, the role of apology and what should be documented. Disclosure in objective structured clinical examination performed by students before and after the intervention.	the disclosure process? Checklist extracted from the guidelines for disclosure of adverse events developed by the Canadian Patient Safety Institute and published by the CMPA.	
Wayman (2007) Country: USA	Registered nurses on a paediatric oncology ward	Simulation-based adverse event disclosure training.	1. Perceived self-efficacy in communication:	A statistically significant increase in nurses' communication

	(n=16)	Three disclosure or adverse event scenarios were developed. Scenarios varied in the level of adverse effects to the patient. Two scenarios involved chemotherapy and the third involved blood transfusion. Instructors from the Centre for Advanced Paediatric Education who were skilled in role playing and debriefing led the training. Trained parents were	14-question self-assessment survey that was developed for the study.	self-efficacy to carry out medical disclosure after taking part in the intervention.

		incorporated as actors in the simulation scenarios.		

Appendix 8: Participant information sheet (for feasibility study)

Participant information sheet

Enhancing skills in disclosure of adverse events

You are being invited to take part in this research study. Taking part in this research study is completely voluntary. It is important for you to understand what the research is about and what it will involve. Please take your time to read the following information carefully.

What is the purpose of the study?

This is a pilot research study which aims to test a training session to enhance confidence in disclosing adverse events to patients. This pilot study will be used to determine if the training workshop is feasible for a wider implementation and whether it is likely to enhance disclosure skills.

Why have I been chosen?

You have been chosen because you are either a midwife or obstetrician. Research shows there is a lack of training available on adverse event disclosure within maternity services.

What will I have to do in the study?

If you choose to take part in this research study, you will be asked to:

1. **Attend a two hour training workshop** that will take place during one of your training sessions at Leeds General Infirmary.

2. During the training session you will be asked to **complete questionnaires** to assess your:

- Confidence in disclosure
- Knowledge of disclosure practices within the UK
- Feedback on the training

3. Following the training session, you have the option to take part in a **brief telephone interview, which will last approximately 25-30 minutes**. The purpose of this is to understand your experiences of taking part in this training workshop. Upon completion of the workshop **AND** telephone interview, you will receive a £25 voucher as an incentive for taking part. Once you have taken part in the workshop, you will receive a certificate to show you have taken part in training for disclosing adverse events to patients.

Do I have to take part?

It is up to you whether you wish to take part. If you decide to take part, you will be asked to read and sign a consent form. You may also choose to not respond to any of the individual questions on the questionnaires without having to provide a reason. You can withdraw at any point from the study and withdraw your data for up to one month after by contacting the researchers, without having to provide a reason.

What will happen to the information I provide in the questionnaire?

All the information you provide in the study will be kept confidential. All data will be stored on secure university computers. All research data will only be accessible to members of the research team. All data will be anonymised and any identifiable information such as contact details will be stored separately from your questionnaire data. Any information which contains your name or email address will be stored for up to 3 years and then disposed of securely. The anonymised questionnaires which cannot be linked to you will be stored safely for up to ten years and will then be disposed of securely.

Who has reviewed the study?

This study has been reviewed by the University of Leeds Research Ethics Committee (Reference number: PSC-415, Approval date: 05/09/18).

What if there is a problem?

The study researchers (contact details below) will be available to resolve any minor problems:

Raabia Sattar: ps15rs@leeds.ac.uk

Dr. Judith Johnson: j.johnson@leeds.ac.uk

Professor Rebecca Lawton: r.j.lawton@leeds.ac.uk

If you are unhappy about any aspect of the research study and you do not want to discuss this with the study researchers, you can contact the School of Psychology Research Ethics Committee: psethics@leeds.ac.uk

Appendix 9: Participant consent form (feasibility study)

Participant consent form

Enhancing skills in disclosure of adverse events

Declaration by the participant

- ☐ I understand I am being asked to provide consent to take part in this research study.
- ☐ I have read the participant information sheet and it has been provided to me in a language I understand.
- ☐ I consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I understand that taking part in this training workshop also involves completing 3 questionnaires.
- ☐ I understand I am able to ask any questions about this study and the study researchers will respond to my questions.
- ☐ I understand that I am free to withdraw from the research study at any time, and able to withdraw my data up to one month after the study has been conducted.
- ☐ I am happy to be contacted for the telephone interview and I provide my contact details below for this purpose only.
- ☐ If I wish to take part in the telephone interview, I agree to audio-recording of the telephone interviews on the basis that no personal identifiers will be used in the reporting of this data.
- ☐ I agree to participate in this research study.

Name:

Mobile number:

Email address:

☐ I understand that I can request a signed copy of this document to keep.

Participant signature:

Date:

Appendix 10: Multiple Choice Questionnaire assessing knowledge of adverse event disclosure (feasibility study)

Please tick only ONE best response to each of the questions below

When should you disclose an adverse event to a patient and/or their family?

- When the patient has become aware of the adverse event through other means
- When the patient enquires about the adverse event
- When the event results in severe harm, moderate harm or prolonged psychological harm to the patient
- Only when the event results in severe harm to the patient

Should you offer an apology when you initially disclose an adverse event to a patient and/or their family?

- Yes, in all circumstances
- No, never at the initial disclosure phase
- Yes, if it seems likely the adverse event was due to the hospital's error
- Yes, but only if you personally contributed to the occurrence of the adverse event

Should you discuss the adverse event with senior colleagues before disclosing the event to the patient and/or family?

- Yes, because it is necessary to have a senior colleague accompany you during any disclosures
- Yes, and this colleague must be a medic
- No, never
- Yes, if you feel this is necessary or appropriate

How much information should you provide during the initial disclosure?

- Provide all the facts as you understand at the time

- Keep information provided to a minimum as the subsequent investigation may produce contrary results
- Only provide information in response to patient questions
- Only provide information about the investigation and actions that will occur subsequently

If the patient and/or their family become angry, what should you do?

- Remind them that all the correct processes and procedures are being followed
- Ask them to put their complaint in writing, as you are not the individual responsible for the adverse event
- Let them know that you understand why they are angry and acknowledge their concerns and feelings
- If your hospital has a counselling service, offer to refer them to this. Provide an information sheet with relevant organisations they can contact

Which of the following should you do after disclosing an error?

- Follow up in writing and provide updates in every circumstance
- Follow up in writing and provide updates if appropriate
- Complete a GCAT form once following the disclosure
- Complete a GCAT form every time there is an update related to the adverse event and the investigation into this

Appendix 11: Self-efficacy questionnaire (feasibility study)

Please circle your ONE response to each question below.

How confident are you in your understanding of the importance of disclosing adverse events to patients/family

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your understanding of the steps that should be included in the adverse event disclosure conversation?

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your knowledge of the professional Duty of Candour?

Not confident at all	A little confident	confident	Very confident
1	2	3	4

How confident are you in your ability to communicate a statement that an unexpected adverse event has occurred?

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your ability to provide an expression of regret/ empathy to the patient (or family)

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your ability to answer questions posed by the patient (or family) about the adverse event?

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your ability to manage emotions (e.g. sadness, anger) that patients (or family) may exhibit when you inform them of the adverse event?

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

How confident are you in your ability to manage your own emotions when disclosing an adverse event to a patient (or family)?

Not confident at all	A little confident	Confident	Very confident
1	2	3	4

Appendix 12: Feedback questionnaire (feasibility study)

Please complete the following:

Age:

Gender:

Profession:

How many years have you worked in this profession?

Please circle your ONE response for each of the following questions

The training:

- Was effective in its delivery

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Was an effective use of time

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Provided adequate time to learn the concepts & skills

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Described skills which will be applicable in my hospital

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

The following aspects of the training were useful:

- Background information on adverse events

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Case-based group discussion

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Guidance document for disclosure of adverse events

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

- Awareness of psychological strategies to reduce emotional distress faced after an adverse event

Strongly disagree	Disagree	Neither disagree or agree	Agree	Strongly agree

Please answer the following questions in as much detail as possible

Q1. What are your overall thoughts of the training workshop?

Q2. What do you think you have learnt from this workshop?

Q3. Were there any aspects of the training which could be improved? If so, please describe in what ways

Appendix 13: Interview guide (feasibility study)

Enhancing skills in disclosure of adverse events
(follow- up interviews with participants)

Provide information on what the interview will involve, the timings and audio-recording.

1. Could you start by telling me about what your profession is?
2. How many years have you worked in this profession?
3. What are your overall thoughts of the training workshop?
4. Since engaging in this workshop, how do you feel about disclosing an adverse event to a patient?
5. Imagine you are involved in an incident which results in harm to patient. Now that you have taken part in this training, how would you approach disclosure?
6. Has your approach to disclosure changed after taking part in this workshop?
   (Probing question= in what ways? Anything you would now do differently?)
7. If you were to now advise a colleague on disclosure after taking part in this training, what would you tell them?
8. What do you think you have learnt from this training?

Workshop delivery

9. What was your overall perception of the training workshop which was provided?
   (Probing questions: Views on the guidance document? (laminated sheet) Did you find it useful? Were you aware of the Duty of Candour principles prior to taking part in this workshop? Would you refer back to the document?)

10. Views on the component which focused on the emotional aspect of disclosure & how this affects you as healthcare professional?
    (Probing questions: What did you think of the group discussions which took place? Midwives & doctors in the workshop together – what did you think of the interdisciplinary nature of this?)

11. What did you think of the psychological strategies which were discussed to reduce your emotional distress after being involved in an adverse event?

    (Probing questions: We discussed ways to reduce threat orientated thoughts, positive self-statements, breathing exercises -Would you use any of these strategies? Do you believe utilising these types of strategies so you can manage your emotions before disclosing an adverse event will help you deliver a more effective disclosure? If so, how?)

12. What did you think of the background information on disclosure that was presented?

13. What are your thoughts on the role play aspect of the training?
    Probing questions: (Were the case studies used appropriate?)

14. Overall, what did you think was useful in the training?

15. What do you think could be improved?

16. Do you think there were any aspects which could be taken out from the training?

17. Overall, would you recommend this training to your peers and colleagues? If so, why?

Thank participant, provide interview closing information

Appendix 14: Comments provided by participants on the feedback questionnaire (feasibility study)

What are your overall thoughts of the training workshop?

- 'It was absolutely useful and should be part of the yearly/2 yearly updates'.
- 'It was completely related…it felt good to know that it is normal to feel awkward/difficult while going through disclosure to a patient'.
- 'Many thanks, it is very important to raise awareness of our feelings, this isn't usually discussed'.
- 'It was a good workshop as adverse events are unfortunately higher in obstetrics and it is good to address emotions around these adverse events'.
- 'Very good workshop, should be happening earlier in the training. I learnt my response to adverse events is normal and everyone feels like this'.
- 'This was a relevant topic and good to see that this training is based on ongoing research'.
- 'It was good to share experiences and expertise, and it is excellent to have the guidance framework to refer to'.
- 'These things don't really get discussed unless a really serious incident happens, thank you covering our feelings and thoughts in this workshop'.
- 'I enjoyed it- it was well balanced and was good to hear how to support us healthcare professionals for once'.

What do you think you have learnt from this workshop?

- 'It was good to know the feelings and thoughts I experience, others also feel this way too'.
- 'It is important to acknowledge these feelings, I know how to rephrase my thoughts now so I feel better emotionally'.
- 'The breathing techniques- I will use these'.
- 'The structure for disclosing, I really like the guidance document and I think it should be widely available for all to access'.
- 'The strategies to reduce emotional distress faced after an adverse event'/ 'Coping strategies in adverse event situations'.
- 'Guidance framework provided is a really good too to use, I will be sharing this with my colleagues'.

- ‘The framework provided was the most useful as it provides a structure to follow. Before I was always unsure what the Duty of Candour stated’.
- ‘Great hearing the research that is currently being conducted and how research your team are doing aims to support us’.
- ‘Group discussions were really useful, it made me realise that everyone has been through these events and feeling worried and stressed is normal reaction to it’.

Were there any aspects of the training which could have been improved?

- ‘Input from the local trust- what support do we have here?’
- ‘More scenarios would be useful’.
- ‘Already aware of the CBT model, less detail on this and more detail on other psychological ways to manage ourselves better’.
- ‘Nil- good training all around’.
- ‘To spend longer on how to change behaviours/thoughts’.
- ‘Some of the slides on CBT could be condensed down as we already cover this in our medical training’.
- ‘More context to the scenarios would be useful’.
- ‘The breathing techniques and changing thought strategies were useful, but could you include some more of these techniques?’.
- ‘Less role play and less discussions, more lecture teaching’.