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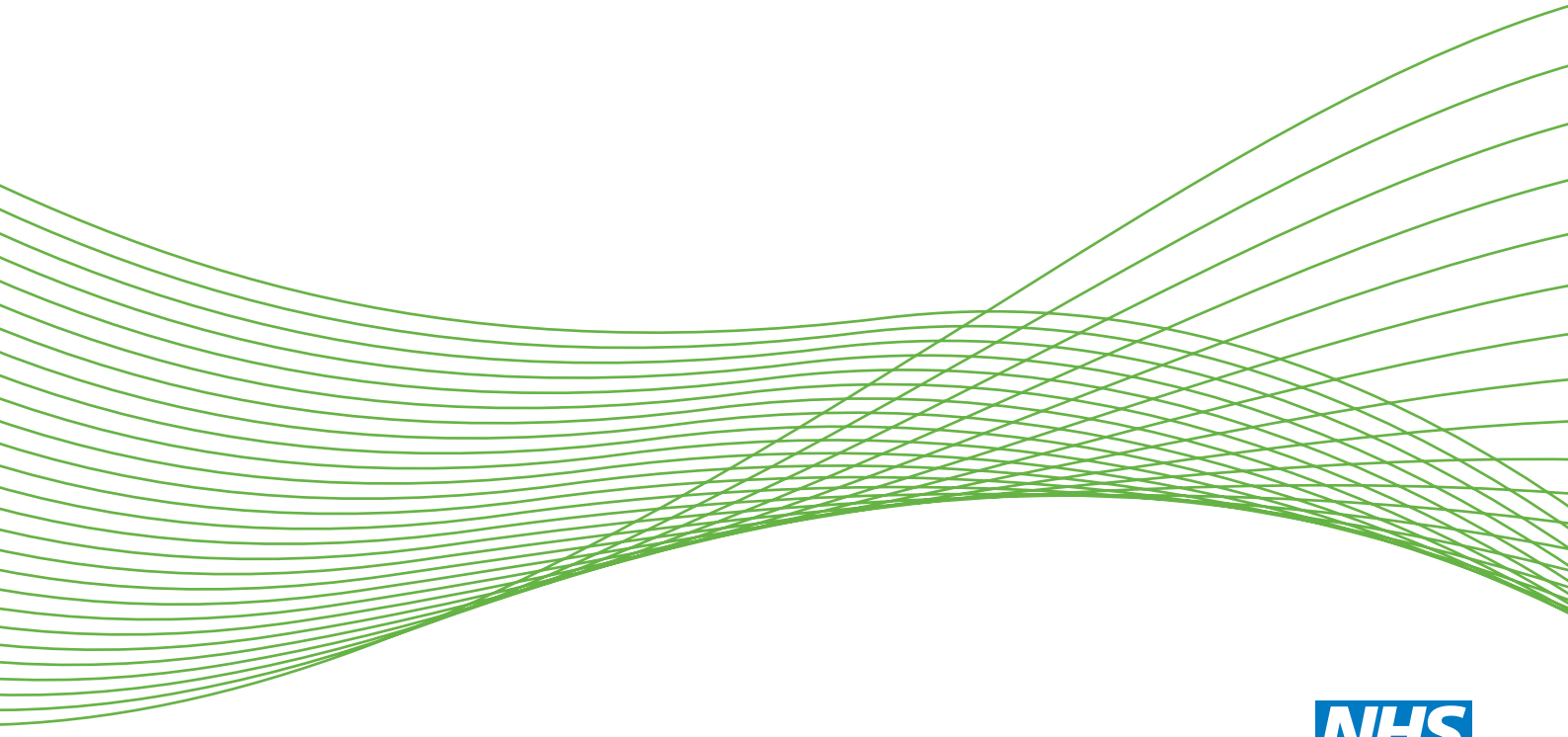

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Abstract

An exploration of the implementation of open disclosure of adverse events in the UK: a scoping review and qualitative exploration

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Background: In 2009 the UK National Patient Safety Agency relaunched its Being Open framework to facilitate the open disclosure of adverse events to patients in the NHS. The implementation of the framework has been, and remains, challenging in practice.

Aim: The aim of this work was to both critically evaluate and extend the current evidence base relating to open disclosure, with a view to supporting the implementation of a policy of open disclosure of adverse events in the NHS.

Methods: This work was conducted in three phases. The first phase comprised two focused systematic literature reviews, one summarising empirical research on the effectiveness of interventions to enhance open disclosure, and a second, broader scoping review, looking at reports of current opinion and practice and wider knowledge. The second phase involved primary qualitative research with the objective of generating new knowledge about UK-based stakeholders' views on their role in and experiences of open disclosure. Stakeholder interviews were analysed using the framework approach. The third phase synthesised the findings from the first two phases to inform and develop a set of short pragmatic suggestions for NHS trust management, to facilitate the implementation and evaluation of open disclosure.

Results: A total of 610 papers met the inclusion criteria for the broad review. A large body of literature discussed open disclosure from a number of related, but sometimes conflicted, perspectives. Evidential gaps persist and current practice is based largely on expert consensus rather than evidence. There appears to be a tension between the existing pragmatic guidance and the more in-depth critiques of what being consistent and transparent in health care really means. Eleven papers met the inclusion criteria for the more focused review. There was little evidence for the effectiveness of disclosure alone on organisational or individual outcomes or of interventions to promote and support open disclosure. Interviews with stakeholders identified strong support for the basic principle of being honest with patients or relatives

when someone was seriously harmed by health care. In practice however, the issues are complex and there is confusion about a number of issues relating to disclosure policies in the UK. The interviews generated insights into the difficulties perceived within health care at individual and institutional levels, in relation to fully implementing the Being Open guidance.

Conclusions: There are several clear strategies that the NHS could learn from to implement and sustain a policy of openness. Literature reviews and stakeholder accounts both identified the potential benefits of a culture that was generally more open (not just retrospectively open about serious harm). Future work could usefully evaluate the impact of disclosure on legal challenges within the NHS, best practice in models of support and training for open disclosure, embedding disclosure conversations in critical incident analysis and disclosure of less serious events.

Funding: The National Institute for Health Research Health Services and Delivery Research programme.

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List of abbreviations

ACSQH	Australian Commission on Safety and Quality in Healthcare
AHRQ	Agency for Healthcare Research and Quality
ASSIA	Applied Social Sciences Index and Abstracts
AvMA	Action Against Medical Accidents
BMA	British Medical Association
CDSR	Cochrane Database of Systematic Reviews
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CPCI-S	Conference Proceedings Citation Index – Science
CPCI-SSH	Conference Proceedings Citation Index – Social Science & Humanities
DARE	Database of Abstracts of Reviews of Effects
GMC	General Medical Council
GP	general practitioner
HMIC	Health Management Information Consortium
HSRProj	Health Services Research Projects in Progress
HTA	Health Technology Assessment
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LILACS	Latin American and Caribbean Health Sciences Literature
LST	large system transformation
MDU	Medical Defence Union
MeSH	medical subject heading
MPS	Medical Protection Society
NHSLA	NHS Litigation Authority
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Agency
NPSF	National Patient Safety Foundation
NRLS	National Reporting and Learning System
NTIS	National Technical Information Service
SCI	Science Citation Index
SSCI	Social Sciences Citation Index
TJC	The Joint Commission
UMHS	University of Michigan Health System
VA	Veterans Affairs
VHA	Veterans Health Administration
WHO	World Health Organization
WHO ICTRP	WHO International Clinical Trials Registry Platform Search Portal

Plain English summary

Open disclosure of adverse events, in terms of health care, refers to the practice of telling people if they have been harmed by a mistake when receiving care. In 2009, the National Patient Safety Agency relaunched its Being Open framework to support open disclosure in the UK. We explored how this guidance has been received, combining the literature on open disclosure with findings from interviews. We reviewed the international literature on open disclosure since 1980, identifying over 600 papers, predominantly from the last 12 years. Simultaneously, we conducted 86 interviews with respondents from a range of stakeholder groups, including policy-makers, health professionals, NHS managers, representatives from professional bodies and patients. Evidence from both the literature and the interviews showed that the principle of truthfulness was widely supported but not always upheld. Many factors seem to create uncertainties over what should be disclosed, by whom, when and how. Being honest and open about mistakes is theoretically supported but seems considerably more difficult in practice. In conclusion, the evidence suggests that open disclosure should be a process and not a one-off event as it is often described. Open disclosure should be a conversation whereby information is shared and the patient is both listened to and responded to. The key message from this report seems to be that while open disclosure is widely regarded as the right thing to do, creating a culture of openness remains challenging, yet necessary, if patients are to be involved effectively in all aspects of their care.

Scientific summary

Background

Estimates suggest that approximately 1 in 10 patients admitted to hospital will experience some sort of unintended harm; approximately half of these cases are thought to be preventable. This represents a significant proportion of patients, and the Department of Health in the UK has identified quality and safety of care as a major concern. The disclosure of adverse events to patients who have been affected or their families is considered to be a central feature of high-quality and safer patient care, but despite this, as few as 30% of harmful errors may currently be disclosed to patients. Advocates of open disclosure propose that failing to communicate effectively with patients following adverse events may have negative repercussions for all stakeholders.

In the UK, after an original launch in 2005, the National Patient Safety Agency relaunched its Being Open framework in November 2009. The framework describes Being Open as being about the way in which health-care organisations and their staff communicate with patients and/or their carers following a patient safety incident, and sets out 10 key principles that underpin the successful facilitation of this process. 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. Being Open suggests that good communication and trust are fundamental to the relationship between health-care professionals and patients, but also that it is the ethical course of action.

A review of the available literature in 2008 revealed increasing recognition of open disclosure as an important issue for both organisations and patients. Although the ethical arguments for open disclosure are strong, there are many stakeholders, and the implementation of any initiative must take all of these perspectives into consideration. A number of barriers to open disclosure have been identified for different stakeholders, such as health professionals' fears of litigation or damaged reputation. If such barriers are not recognised, challenged and addressed appropriately they may cause significant problems for the implementation of a more open safety culture.

Much of the research to date has been undertaken outside the UK. Little is known about how the policy of open disclosure is being, or might be, implemented locally or nationally in the UK and how it is, or will be, aligned with current incident reporting and analysis systems. There is also a lack of knowledge about how open disclosure might best be evaluated and improved. The overall aim of this project was to critically evaluate and extend both the evidence base and practice in relation to the implementation of a policy of open disclosure of adverse events to patients within the UK.

Objectives

The study objectives were to:

- extend a previous literature review of open disclosure conducted in 2008
- identify the strategies considered or used to encourage an open disclosure, and to assess the evidence of their effectiveness
- identify and critique the various ways in which open disclosure has been conceptualised and measured
- determine the understanding of, views on and interpretation of a policy of open disclosure among UK stakeholders

- explore stakeholders' experiences of involvement in the disclosure of adverse events in the UK
- explore how open disclosure might be, and actually is, linked to safety and quality management systems at all levels
- develop a summary of evidence-based guidance for managers to facilitate the implementation of open disclosure in individual trusts.

Methods

Two reviews, a primary qualitative study and a final synthesis of these phases were conducted. The first phase comprised two literature reviews, summarising current knowledge on open disclosure, discussions and debates, and interventions to enhance disclosure. Supported by information specialists, a broad search strategy was developed on MEDLINE (Ovid SP) using the two main concepts of open disclosure and patient safety incident. A range of text words, synonyms and subject headings for each of the two concepts were identified by scanning key papers identified at the beginning of the project, and through discussion with the review team and collaborators, and the use of database thesauri. The terms for open disclosure were combined using the AND Boolean operator with terms for adverse events. The MEDLINE strategy was adapted for use in each database. Details of the documents identified as potentially relevant from the electronic literature searches were entered into bibliographic software. Two reviewers assessed the titles and abstracts for relevance. Full copies of all potentially relevant papers were obtained and assessed.

The second phase involved primary research (individual interviews) to generate new knowledge about stakeholders' views and experiences of open disclosure and the Being Open guidance in a UK health-care context. Study participants were strategically selected from four different groups:

- policy-makers
- professional organisations
- NHS managers and health professionals
- patients and patient organisations.

Eighty-six interviews were audiotaped and fully transcribed. Transcripts were analysed using framework analysis, involving a process of familiarisation with the data, thematic analysis to develop a coding scheme, systematic coding and charting of data. Charts contained summaries of data (supported by references to data points in the original transcripts), and the research team built a matrix to examine data across cases and under themes. Finally, a mapping and interpretation of the data was carried out to explore relationships between the codes.

The third phase involved synthesising the information from the reviews and interviews. This was achieved through charting the data under the headings of the Being Open principles, examining data across the phases and principles to identify the current state of knowledge, gaps in that knowledge and directions for future research.

Results

Reviews

After deduplication, 10,527 records were identified, with 610 papers included in the final review. Review 1 highlighted the volume of literature that discussed or explored open disclosure. Much of this originated from the USA, and much of the evidence was based on expert consensus rather than empirical pieces of evidence. There was broad agreement that open disclosure is the 'right' thing to do. However, justifications often sit within a context of managing risk and reducing legal costs to organisations. There was a lack of evidence to underpin how open disclosure is operationalised in practice and how staff negotiate the systems within which they operate, as well as interactions with patients and explicit links to

related dimensions of quality and safety. Review 2 examined evidence for the effectiveness of open disclosure and interventions to support open disclosure. From an initial field of 21 references, a total of 10 studies (11 publications) fulfilled the eligibility criteria and were included in the review. In two studies the intervention was disclosure, and in eight studies (nine publications) the interventions were intended to promote or support open disclosure. Two studies included a comparator group and eight were uncontrolled before-and-after design. Findings from this review indicated that there was little high-quality evidence for the effectiveness of open disclosure or interventions intended to support or enhance open disclosure.

Interviews

Interviews with 86 stakeholders revealed six primary themes and a number of related discussion points. Primary themes were:

- broad understandings of open disclosure
- motivators
- the framework
- 'good' disclosures
- uncertainty
- professional and organisational context.

A descriptive summary of these data was used to inform a preliminary but more theorised analysis which helps to explain why implementation of the Being Open framework, and the principles of open disclosure more generally, are not consistently evident in practice. The findings illustrated the complexity and uncertainty surrounding many aspects of disclosure experienced by a range of stakeholders. From the interviews, it was also evident that stakeholders converged on the importance of open disclosure as a principle, but that different perspectives were largely related to the translation of the principles in practice. Stakeholders discussed the need for cultural change when considering ways to embed Being Open in health-care practice. It was suggested that intervention is required to address core values focused on 'hitting targets' and following economic incentives, which were viewed as detrimental to the quality of patient care. A need for a cultural change, from the negative associations of reporting incidents to a focus on the positive outcomes of learning from mistakes to improve practice and care, was identified. It was suggested that a key factor in the poor take-up of the Being Open guidance was a lack of awareness of the guidance. However, other factors were also considered important, such as the unique contextual factors of each situation and the multiple value-based and moral factors which are involved prior to any behaviours associated with disclosure. Respondents highlighted the slow pace of change in health care, noting that a change in culture requires active drivers and that best practice would be unlikely to be disseminated without intervention and incentives. Overall, it would appear that the situation does not reflect a picture where health-care organisations and those that work within them are deliberately avoiding disclosure conversations, but one where multiple but defensible values are apparent and may be in conflict at times.

Synthesis

The synthesis of the reviews and interview data highlighted that the principles of acknowledgement, apology, professional support, truthfulness, and timeliness and clarity of communication were widely recognised as critical to disclosure. Although these principles featured heavily in the literature and the interview data, uncertainties around terminology and inconsistent understanding across stakeholders appeared to be the main barrier to their effective enactment. Further principles of continuity of care, multidisciplinary team responsibility and recognising patient and carer expectations were raised consistently by interviewees, but lacked focus in existing literature. Finally, discussions of confidentiality, risk management and systems improvement, and clinical governance lacked representation in either phase of the research, suggesting less awareness of their relationships to open disclosure.

This synthesis highlighted that there is little information about the consistency with which Being Open guidance is being interpreted, implemented or evaluated at a local policy level, or the factors that may contribute to a better or worse quality disclosure process. The links between outcomes of interest for risk managers and those concerned with clinical governance and open disclosure need to be explicit to determine whether or not outcomes relating to safety can be used as proxy measures for successful disclosure process.

Little training is provided for health-care professionals or managers with relation to disclosure. The training that exists is not well known and there is little evidence to underpin claims for any effectiveness of one model over another. Although open disclosure is consistently identified as a positive and morally sound action, there is little understanding of the mechanisms through which open disclosure might address and reduce some of the psychological and health-related consequences of error for patients, their families and the health-care providers involved. Finally, there is little recognition of any role for patients and families in the disclosure process beyond being 'disclosed to'.

Existing theoretical perspectives were explored with a view to a possible future role in structuring examinations of disclosure work, including current theories of quality and safety, ethical leadership and complex adaptive systems theory as applied to large-scale transformational change. However, this is not an exhaustive list and the lack of theoretical underpinning of the area is apparent.

Conclusions

The findings suggest numerous implications for health care in relation to the implementation of open disclosure guidance in the UK. Enhancing stakeholders' understanding of terminology associated with open disclosure may be fundamental to ensuring that Being Open is delivered consistently across health-care organisations and that health-care providers feel able to translate the principles in a diverse range of circumstances that may arise in practice. The provision of professional support and training may contribute to health professionals' desire to be open and their ability to do this effectively. Consideration of patients' needs and perspectives regarding adverse events may also provide some useful insights.

The following recommendations for research are proposed:

1. Future studies may explore the mechanisms through which open disclosure might address and reduce some of the psychological and health-related consequences of error for patients, their families and the health-care providers involved.
2. Little is known about the effect of training models designed to support disclosure. Future research may seek to determine whether or not educational and institutional interventions reduce the influence of impeding factors or enhance the influence of facilitating factors.
3. The importance of context in examining efforts to improve disclosure practice is an important and challenging task for future work. More focus on direct observational methods is required.
4. Further examination of patients' perceptions of particular disclosure styles, and the impact of these on objective and relational disclosure outcomes, may be of interest.
5. Most of the work looking at disclosure takes place in secondary care. There is a notable lack of work from the UK in the areas of general practice and private health care or in relation to social care. Further study may be directed to these contexts.

Funding

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Chapter 1 Background

> *. . . there are no easy answers when it comes to making mistakes. That needs to be said outright lest someone, especially someone in training who is less experienced, think that admitting a mistake stops at quality control or sharing responsibility, and that there is then some way around the difficult task of actually taking responsibility for the mistake. Within the culture of medicine and even more broadly in modern society there seems to be a drive for finding the easy way out. In this case there is none, and it needs to be made very clear that this is a defining moment in the life of a physician with regard to integrity and professionalism*
>
> *Reproduced from* Medical Errors and Medical Culture. There is no Easy Way Around Taking Responsibility for Mistakes*, Lyckholm L, Vol. 323, p. 570, 2001*[1] *with permission from BMJ Publishing Group Ltd.*

Estimates suggest that approximately 1 in 10 patients admitted to hospital will experience some sort of unintended harm; approximately half of these cases are thought to be preventable.[2,3] In a recent review of prevalence studies, between 3% and 16% of hospitalised patients were found to have suffered harm from medical care.[4] This represents a significant proportion of patients, and the Department of Health in the UK has identified quality and safety of care as a major concern.[5] The recent publication of the Francis report has brought this into even sharper focus.[6] Internationally, other agencies are dedicated to co-ordinating improvement efforts [e.g. the Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission (TJC) – formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) – in the USA, and the Australian Commission on Safety and Quality in Healthcare (ACSQH)]. A central component of a just patient safety culture is thought to include the disclosure of serious medical incidents to patients who have been affected or their families, often termed *open disclosure*.[7] The concept of openly disclosing the details of medical incidents has been adopted by several organisations, including ones in Canada,[8] New Zealand,[9] the UK,[10,11] the USA[12] and Australia,[13] which implemented a national open disclosure policy in 2003. However, it is estimated that as few as 30% of harmful errors may currently be disclosed to patients.[14]

Historically, the disclosure of adverse events to patients was neglected. Prior to the 1970s there was a general acceptance of medical expertise; medical notes were rarely seen by patients or families and, if required, often had to be obtained through a legal process. Discussions recognising this as problematic appear to have emerged during the 1970s and early 1980s, when it was identified that patients suffering from 'medical mishap' were often unable to find out who was responsible for an error or whether or not anyone had been at fault.[15] The importance of transparency in relation to improving quality and safety in health care became increasingly discussed in the wake of seminal documents such as *To Err is Human*[16] in the USA and *An Organisation With a Memory*[17] in the UK. Standards that promote open communication with patients following events where errors have occurred are rapidly emerging in both the UK and a wider international setting.[4,17–19] Advocates of open disclosure propose that failing to communicate effectively with patients following errors could reduce patient trust in health services, perhaps with negative consequences for future care, and may increase the likelihood of litigation. Patient trust may be diminished if they consider that their health service provider has not honoured their commitment to care for patients by apologising. There is some evidence, mainly emerging from the USA, to support such concerns.[20,21]

In the UK, the National Patient Safety Agency (NPSA) relaunched its Being Open framework in November 2009.[11] The framework describes Being Open as being about the way in which health-care organisations and their staff communicate with patients and/or their carers following a patient safety incident, and sets out 10 key principles that underpin the successful facilitation of this process. 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.

An apology is described as different from an admission of liability, and though an apology may be referred to in legal proceedings, the NHS Litigation Authority (NHSLA) stresses that this should in no way deter those involved from providing explanations and apologies following adverse events.[22] Being Open suggests that good communication and trust are fundamental to the relationship between health-care professionals and patients, but also that it is the ethical course of action. The Being Open framework was part of a broader NPSA initiative in the UK to create an open and fair culture in the NHS. The NPSA stressed that open disclosure should be explicitly linked to systems of incident reporting and analysis in health-care organisations.[23] Reorganisation within the NHS meant that on 1 June 2012 the key functions and expertise for patient safety developed by the NPSA transferred to the NHS Commissioning Board. It was anticipated that this would ensure that patient safety remains at the heart of the NHS and builds on the learning and expertise developed by the NPSA in driving patient safety improvement. The Board will continue to use the National Reporting and Learning System (NRLS) to identify important patient safety issues at their root cause. Health-care organisations are expected to report patient safety incidents to the NRLS as previously. The approach to monitoring safety within UK NHS trusts is therefore unchanged, and the stance that disclosure should be part of safer patient care remains.

Despite limited empirical work assessing the effectiveness of implementing open disclosure policies (largely undertaken in the USA, Australia and New Zealand), a review of the available literature in 2008 revealed increasing recognition of open disclosure as an important issue for both organisations and patients.[24] The review also highlighted key debates around the ethical principles of 'being open' versus the legal liability and economic risk involved. The absence of investigation into non-hypothetical scenarios and individuals' actual experiences of open disclosure was also noted. With growing acknowledgement of the challenges associated with open disclosure, the literature in this field has rapidly expanded, and there is now a need to update the synthesis undertaken in 2008 to identify a point from which to move forward, particularly in relation to the UK. Further work undertaken by Iedema *et al.* includes the assessment of open disclosure in terms of the impact on patients and health-care staff in Australia.[25–27] Qualitative analysis of interviews with 131 clinical staff and 23 patients/family members indicated that, despite some uncertainty surrounding the use and consequences of open disclosure, the system was strongly supported.[24] Further work has examined 119 patients' and family members' responses to questions about whether or not, and how, they experienced disclosure.[27]

Complementary work by Gallagher *et al.* has conducted an investigation into patients' and doctors' attitudes towards the disclosure of medical errors, which highlighted the need for doctors to meet patients' expectations of an apology following medical errors and also to provide information about the error.[28] Further work by Gallagher *et al.*,[29] in line with findings from other studies,[30,31] has discussed the increasing need and desire for open disclosure of medical errors.

Although the ethical arguments for the open disclosure of adverse events to patients are strong, there are many stakeholders (e.g. patients and clinicians, hospital managers, health policy-makers, unions, equipment companies, insurers, legal advisers and indemnifying organisations) involved in the delivery of such a framework at a variety of levels. (Future reference to stakeholders will include the aforementioned groups, although this is not intended as an exhaustive list.) The complexities of the differing perspectives of all of these stakeholders means that implementation of any initiative is challenging. Embedding incident disclosure into national and local culture within the NHS is a substantial challenge for NHS managers, as well as for the individuals involved in direct patient care. It has been suggested that this is due to a culture that favours risk aversion over patient-centred disclosure, despite the suggestion that the latter produces better financial and relational outcomes.[32] Current barriers to disclosure, such as fear of litigation or damaged reputation, can obstruct clinicians in maintaining good relationships with patients and becoming more open to learning from error or mistakes. If such barriers are not recognised, challenged and addressed appropriately and overtly, they may cause significant problems for the implementation of a more open safety culture.

There appears to be a small but significant literature within the area of patient safety which looks at the open disclosure of adverse events, including the important area of the impact of open disclosure on the

health professionals involved in the error and the link between disclosure and systems improvement.[33] However, this research is almost exclusively grounded in contexts outside of the UK, and much of the empirical work is based on training scenarios rather than in situ practice. We know little about how the policy of open disclosure is being, or might be, implemented and applied locally or nationally in the UK and how it is, or will be, aligned with current incident reporting and analysis systems in health-care organisations. As is the case with many patient safety outcomes, there is also a lack of knowledge around how open disclosure might best be evaluated and improved. In addition to examining the current breadth and quality of the literature in the area of open disclosure to date, this research will provide information about the implementation and current stakeholder perceptions of open disclosure within the UK.

Aim

The overall aim of this project was to critically evaluate and extend both the evidence base and practice in relation to the implementation of a policy of open disclosure of adverse events to patients within the UK.

Objectives

1. To extend a previous literature review of open disclosure conducted by one of the applicants in 2008.
2. To identify the strategies which have been considered or used to encourage an open disclosure culture, and to assess the evidence of effectiveness of such strategies.
3. To identify and critique the various ways in which open disclosure has been conceptualised and measured.
4. To determine the understanding of, views on and interpretation of a policy of open disclosure of adverse events among a variety of UK stakeholders.
5. To identify specific situations and ways in which the various stakeholders have been involved in the disclosure of adverse events in the UK, and their experiences of this.
6. To explore how open disclosure can be linked effectively into safety and quality management systems at all levels.
7. To explore the extent to which disclosure activity is actually linked in practice to safety and quality management.
8. To develop a summary of evidence-based guidance for managers to facilitate the implementation of open disclosure in individual trusts.

The objectives were addressed in three main phases, each of which built on the previous work. The first phase comprised a focused literature review, summarising current knowledge on different stakeholder roles, current interventions and proposed interventions, underpinning theory and the ways in which current strategies feed into established reporting systems. The second phase involved individual interviews, with the objective of generating new knowledge about UK-based stakeholders' views on their roles in and experiences of open disclosure of safety incidents in health-care settings. The third phase involved the development of a set of short pragmatic suggestions aimed at NHS trust executives and managers, to facilitate the implementation and evaluation of open disclosure in UK NHS trusts.

The main product of this research was intended to be new information which can be used to:

1. identify areas where current evidence and knowledge remain sparse
2. supplement the current guidance on implementing open disclosure
3. inform training and support for organisations and individuals in this area
4. identify continuing barriers to the implementation of open disclosure
5. identify well-developed models for open disclosure.

We also aimed to produce a series of short and pragmatic guidelines for NHS trust managers to facilitate the implementation and evaluation of open disclosure initiatives.

Chapter 2 Methods

This study addressed the objectives via three main phases of work. A review phase and a qualitative phase directly contributed to a synthesis of the information, to address specific issues in relation to delivery of the Being Open guidance in the UK in the final phase of the study.

Phase 1: reviews

The reviews were conducted to capture data from a diversity of sources, in a systematic way, to identify how open disclosure (an openness with patients about avoidable potentially harmful incidents) has been conceptualised, the key ethical and legal debates associated with the process, the roles of the different stakeholder groups and the outcomes that have been used to assess its impact.

A more focused review of the effectiveness of open disclosure interventions to date was carried out to sit within this broader conceptual synthesis.

Two previous reviews have been conducted, both of which involved one of the current project team (RI). The authors of these reviews planned to search five electronic databases using terms related to open disclosure, as well as the websites of health and government regulatory bodies in a number of countries.[34,35] Although both of these reviews are seminal pieces of work and comprehensive, the authors adopted a less standard systematic search strategy than the strategy presented in this work. In the previous work, searching was stopped after three databases had been searched as it was considered they had 'reached saturation' (the same articles began to appear), whereas all literature identified will be considered in this work. This makes the current work the most comprehensive exploration of previous literature to date.

Objectives

Review 1: scoping review

The aim of this review was to identify and critique the literature around open disclosure, including (i) the ways in which it has been conceptualised and discussed within current systems of quality and safety, (ii) the wider debates around legal and ethical issues in open disclosure, (iii) the outcomes used to explore its impact, (iv) the roles of stakeholder groups, (v) the relationship between open disclosure policy and systems of reporting and monitoring adverse events worldwide and (vi) the extent to which open disclosure policies appear to have been informed by research evidence.

Review 2: effectiveness review

This review was carried out to identify, assess and summarise the effectiveness of open disclosure and strategies/interventions that have been explicitly used with the intention of promoting and supporting open disclosure of patient safety incidents in a health-care context.

Definitions

Patient safety incident

The term *patient safety incident* refers to any unintended or unexpected incident which could have, or did, lead to harm for one or more patients.[23]

Open disclosure

There is no agreed international definition of open disclosure, but its underlying principle involves clinicians informing patients and/or family members when a safety incident has occurred. Many policies describe the use of an honest and consistent approach to communication which should happen as soon as possible

following the incident (e.g. Canadian Patient Safety Institute,[8] New Zealand Health and Disability Commissioner,[9] NPSA,[10,11] Joint Commission Resources Inc.,[12] ACSQH[13]). Elements of such policies, including that of the UK, commonly include saying sorry for what has happened; keeping patients and/or their carers informed about the progress of the incident investigation; reassuring patients and/or carers that the incident is being taken seriously; and ensuring measures are taken to prevent the incident from happening again.[11]

Search strategy

The aim of the search was to systematically identify literature on the open disclosure of adverse events in health care to inform both systematic reviews. A broad search strategy was initially developed on MEDLINE (Ovid SP) using the two main concepts of open disclosure and adverse events. A range of text words, synonyms and subject headings for each of the two concepts were identified by scanning key papers identified at the beginning of the project, and through discussion with the review team and collaborators, and the use of database thesauri. The terms for open disclosure were combined with those for adverse events using the AND Boolean operator (see *Appendix 2* for the full search strategy). The MEDLINE strategy was adapted for use in each database. These searches are considerably more detailed than those adopted in the previous literature reviews.[34,35]

Retrieval of studies was restricted to those published after 1980 as little literature appears before this date. The early reports which reinvigorated the drive for higher-quality and safer patient care began to appear from the early 1990s, and a period of 10 years prior to this was felt reasonable to capture the vast majority of the literature. No language restrictions were applied to the search strategy, to ensure that non-English-language papers were retrieved. Study design filters were not applied to the search strategy, so that any literature – including papers about the effectiveness of specific open disclosure interventions, reviews, opinion pieces, policy documents and discussion articles – was identified by the search.

A wide range of electronic resources were searched, including databases, research registers, trials registers and other internet resources, to retrieve both published and unpublished literature, grey literature and ongoing research. The resources searched covered literature from the medical, health, nursing, social science and legal fields. The full list of searched databases can be seen in *Appendix 3*.

The above searches were supplemented by searching key patient safety organisation websites and government agency websites to identify reports, policy documents and grey literature not indexed in the electronic databases. Further references were identified by scanning the reference lists of key papers and reports identified during the searching process, from the personal collections of the review team and consultations with key personnel from patient safety organisations, and by hand-searching the reference lists of key seminal papers.

Records were managed within an EndNote library (EndNote version X3; Thomson Reuters, CA, USA). After deduplication, 10,527 records in total were identified.

The literature search was designed and carried out by an information specialist from the Centre for Reviews and Dissemination, University of York, with input from the review team. Peer review of the search strategy was undertaken by a second information specialist at the Centre for Reviews and Dissemination. Searching of the legal databases was carried out by an information specialist from Capsticks (a specialist health and social care law firm), using a search strategy adapted from the initial MEDLINE strategy.

Inclusion criteria

Review 1: scoping review

Types of literature included

(a) Available in English.
(b) Produced after 1980 following the rise of patient safety/medical error research.

This could be any of the following:

(a) policy documents
(b) opinion pieces
(c) research that has investigated
  – perceptions or experiences of open disclosure
  – ethical or legal issues in open disclosure
  – the process or outcomes of open disclosure
  – the role of any stakeholder in open disclosure
(d) accounts of stakeholders' experiences of open disclosure, including those of patients, patient support groups, health professionals, health-care managers and litigation services
(e) literature developed to guide patients, health-care providers or litigation services about open disclosure
(f) grey literature reporting activities/initiatives/research that focuses on open disclosure.

Types of participants included

Participants could be stakeholders in open disclosure from any health-care context in any location, including:

(a) health service users who may have been affected by safety incidents (patients, relatives, carers)
(b) potential health service users
(c) representatives or members of support groups for health service users
(d) health-care professionals
(e) health-care managers
(f) representatives or members of medical litigation services
(g) professional/regulatory bodies such as the General Medical Council (GMC) or Nursing and Midwifery Council (NMC).

Nature of content

The content of the literature could be any of the following:

(a) conceptualisation of open disclosure
(b) discussion of the principles or implementation of open disclosure
(c) discussion of the ethics of open disclosure
(d) discussion of legal issues relating to open disclosure
(e) reporting or describing criteria for assessing quality and/or consequences of open disclosure
(f) reporting the implications of open disclosure for health services
(g) discussion of the roles of any of the stakeholders in the open disclosure process
(h) discussion or development of open disclosure policies or experiences of its use
(i) professional expectations from bodies/regulatory bodies.

Exclusion criteria

Documents were excluded if they:

(a) did not include stakeholders in open disclosure from a health-care context, i.e. none of the types of participants described above
(b) described/discussed/reported disclosure relating to deliberate acts of harm
(c) were not available in English
(d) were produced before 1980.

Additional criteria for the effectiveness review

Population

These could be stakeholders in open disclosure from any health-care context in any location, including health service users, potential health service users, representatives or members of support groups for health service users, health-care professionals, health-care managers and representatives or members of medical litigation services.

Intervention

We included open disclosure as an intervention. Interventions that were explicitly intended to promote, enhance or support open disclosure were also included.

The following comparisons were included:

- Open disclosure *versus* against non-disclosure. Any intervention which involved an act of informing a patient and/or family member or representative that a patient safety incident had occurred. Characteristics of open disclosure interventions were likely to differ, however seemed likely to include elements commonly identified in open disclosure policy (see definition above).
- Interventions to promote or support open disclosure in combination with open disclosure versus *against* open disclosure alone.

Any intervention that was explicitly intended to promote, enhance or support open disclosure of patient safety incidents in a health-care context was included. It was anticipated that candidate interventions would be, for example, training or education in communication techniques and peer support groups.

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 ('bad or sad news'), such as diagnosis of cancer or terminal illness, were excluded. Studies of interventions relating to deliberate acts of harm were also excluded.

Outcomes

Outcomes included (but were not restricted to):

- patients' and/or health professionals' attitudes relating to the intervention
- rates and patterns of uptake of the intervention (among patients and/or health professionals) and of any behaviours/practices it was designed to promote
- other behaviours relating to health service delivery or use
- patients' assessments/evaluations of health-care quality, including their perceptions of involvement, of the quality of their interactions with health-care professionals, and of their safety
- patients' health status and sense of well-being
- psychological effects on staff.

Study design

The following study designs were included:

- Randomised controlled trials (including cross-over trials and cluster trials). Investigators allocated participants to groups using randomisation.
- Quasi-experimental studies (non-randomised controlled studies, before-and-after studies and interrupted time series). Investigators allocated participants to groups using a non-random method.

It was not anticipated that many studies of these designs would be available. Therefore, observational data were included if there was a comparison group, as in the following studies:

- *Cohort studies* A defined group of participants is followed over time and a comparison is made between those who did and those who did not receive the intervention.
- *Case–control studies* Groups from the same population, with (cases) and without (controls) a specific outcome of interest, are compared to evaluate the association between exposure to an intervention and the outcome.

Case series and case reports were excluded.

Study selection

Four reviewers screened citations of the title and abstract for potential relevance, with all citations being viewed by two reviewers. Full papers were obtained for citations judged potentially relevant. On receipt of the full paper, one reviewer applied the inclusion criteria for all papers to identify material of relevance. A second reviewer screened a random subset (10%) of the sample to ensure that no potentially relevant papers were missed and that the inclusion/exclusion criteria were applied consistently. Where decisions were unresolved, the two reviewers discussed the decision, and a third party was consulted if agreement could not be reached.

Information extraction

Review 1

Given the complexity and variety of literature explored, we specified that data extraction would be based on the study objectives to ensure that the review had a clear and consistent focus and was carried out in a systematic way.

Given the ultimate aim of developing current guidance on open disclosure in the NHS, we extracted data from the reviewed papers that related to any of the 10 principles of open disclosure described in the Being Open framework. These were:

1. acknowledgement
2. apology
3. truthfulness, timeliness and clarity
4. professional support
5. recognise patient and caregiver expectations
6. risk management and systems improvement
7. individual/multidisciplinary team responsibility
8. clinical governance
9. continuity of care
10. confidentiality.

It was anticipated that this would provide an idea of those aspects of the framework for which there was currently supporting literature and those that had been implemented in health care, and the extent to which implementation had been perceived as successful. It would also highlight the areas of the framework for which

there was less evidence or support, that were less clearly defined or enacted or that had been less successfully implemented to date. Both intended and unintended outcomes were documented during this process.

On this basis we extracted:

(a) author/investigator
(b) date
(c) location
(d) type of literature
(e) population
(f) study design (if applicable)
(g) outcomes/arguments/guidance, which were summarised in relation to
  – acknowledgement
  – truthfulness, timeliness and clarity of communication
  – apology
  – recognising patient and carer expectations
  – professional support
  – risk management and systems improvement
  – multidisciplinary responsibility
  – clinical governance
  – confidentiality
  – continuity of care.

There were two stages of information extraction: in the first stage, a basic extraction that provided an outline of the paper, and in the second, a more detailed extraction in which particular aspects of the work were drawn out, depending on the type of material and its salience to the review objectives and domains outlined in the Being Open guidance.

Review 2

The following data were extracted from included studies (where available):

- general information (author, article title, type of publication, country of origin, source of funding)
- study characteristics (aims and objectives, study design, inclusion/exclusion criteria, recruitment procedures, unit of allocation)
- participant characteristics (of both health-care workers/managers and patients, including age, gender, ethnicity, profession/position of health-care worker, disease or condition/adverse event details of patient)
- intervention and setting (setting where the intervention was delivered, description of the intervention and comparator)
- outcome data (for intervention and comparator groups the following were reported: number enrolled, number included in analysis, number lost to follow-up, withdrawals and exclusions. For each reported outcome the following were extracted: definition of outcome, measurement tool used, length of follow-up, results of study analysis).

Data collection and analysis

In the larger primary review (review 1), each included paper was summarised to provide an overview of research, discussion and policy or guidance documents relating to open disclosure of error.

In the smaller systematic review of interventions (review 2), no formal pooling of data was appropriate owing to a lack of studies with a comparator group and uncontrolled before-and-after designs. Findings were grouped into two sections:

1. studies where disclosure was the intervention
2. studies where interventions were intended to promote or support disclosure.

In each of these sections the included studies were described in terms of their setting, participants, methods, intervention, outcomes, outcome measures and reported findings, and linked to tabulated descriptions of studies.

Phase 2: interviews

Ethical approval

Ethical approval for this phase of the project was obtained from the Bradford NHS Research Ethics Committee (ref. 10/1007/47). Research governance approval was obtained from the relevant NHS trusts (see *Appendix 4*).

In-depth individual interviews were used to describe, explore and explain stakeholders' views and experiences of open disclosure in health care. The rationale for selecting a qualitative approach was threefold. Firstly, little research has been conducted in the UK in this area to date; qualitative methods are ideally suited to reveal the range of views or practices and key issues that might be missed through the use of more structured data collection instruments. Secondly, in-depth interviews are the most effective and valid way of exploring people's experiences, beliefs and meanings, from the perspective of the respondent, in order to provide a 'rich' data set which is grounded in the experiences of the interviewees themselves. Thirdly, one of the strengths of qualitative research is that it can identify the complex ways in which particular beliefs or experiences are likely to influence behaviour.

Perspectives were likely to vary according to stakeholder, health-care setting and participant demographics; therefore, we employed sampling strategies and data collection techniques that allowed for an inductive, hypothesis-generating approach to interpretation of the data.

Populations studied

In order to explore the views of a range of stakeholders who might contribute to open disclosure, with diverse clinical backgrounds and differing degrees of patient contact in a variety of health-care contexts, study participants were strategically selected from four different groups:

- *Policy-makers* Individuals with a current or previous position of responsibility for developing health policy, and in particular the Being Open guidance.
- *Professional organisations* Individuals from professional organisations that represent or regulate the health professions.
- *NHS managers and health professionals* Health-care managers included members of the senior management team, some of whom had dual clinical and management roles. Health professionals were staff who carried out work on the 'shop floor', from matron and consultant level to junior doctors and nurses (from band 5 up).
- *Patients and patient organisations* Participants were approached through national patient groups. Participants could include patient advocates and those with experiences of disclosure or a lack of disclosure.

Details of the original sampling framework and the planned participant numbers in each group are shown in *Appendix 1*.

Recruitment and consent

Recruitment procedures were tailored according to the stakeholder groups. Policy-makers, leaders of professional and patient organisations and senior managers were contacted in the first instance by a targeted letter from the research team. All other participants were contacted, in the first instance, by an appropriate member of the identified organisation. In all cases, potential participants were sent information about the study and asked to return a short slip (or contact the research team by e-mail or telephone if preferred) to discuss participation.

A member of the research team then contacted respondents to explain the nature and purpose of the study. In the case of patient participants, we emphasised that the research would not directly help them to seek a remedy or redress for any problems they may have experienced related to the disclosure of adverse events. Where people expressed willingness to participate, the researcher made arrangements to hold an individual interview at a time and place convenient for the respondent. A small number of interviews were conducted over the telephone if specifically requested by the participant.

Prior to the commencement of interviews, the researcher reminded participants of the purpose of the research; asked respondents if they had any further questions; checked that they were still happy to take part; and reminded them that they could stop the interview or withdraw from the study at any time.

Data collection

The aim of the interviews was to explore:

- stakeholders' general awareness and understanding of open disclosure
- their personal experiences and perceptions of both the principle of openness in relation to disclosure of adverse incidents and the Being Open guidance, in the context of their own position in relation to health care
- their views on the contribution that they might make to promote and enhance open disclosure
- their thoughts about the Being Open guidance.

Although all interviews shared these aims, the emphasis in the interviews varied by stakeholder group. Interviews with policy-makers focused on the development of the Being Open guidance and perceptions of its current use. With professional organisations, the translation of national and local guidance into practice was emphasised, along with the perceived contribution that such organisations can make to support health professionals in delivering open disclosure. Interviews with NHS managers and staff explored experiences of open disclosure and of implementing the Being Open guidance specifically. We also explored the challenges of discussing adverse events with patients. Representatives from patient organisations were asked about their perceptions of open disclosure in the policy context and from a broader patient perspective, and patients were asked to share their individual experiences and beliefs.

A core topic guide (see *Appendix 5*) covering these investigative areas was developed and piloted. This was refined before interviews commenced with the target populations. Interviews opened with questions exploring respondents' broad understanding of the term 'open disclosure', the reasons for implementing open disclosure, experiences or beliefs about the Being Open guidance and, finally, where the challenges lie. Modified versions of the topic guide were developed for use with each stakeholder group. After initial interviews, some minor alterations were made to the wording of the guide to be used with NHS managers, to make it more sensitive to exploring the experiences of this group.

Data analysis

Interviews were audiotaped and fully transcribed. Transcripts were analysed using framework analysis.[36] This approach was selected for several reasons. Firstly, it is especially well suited to applied qualitative research, in which the objectives of the investigation are typically set a priori, and shaped by the information requirements of the funding body, rather than wholly emerging from a reflexive research process. Secondly, framework analysis provides a visible method which can be scrutinised, carried out, and discussed and operated by individuals in a team. Lastly, the approach lends itself to reconsidering and reworking ideas because the analysis follows a well-defined procedure, which can be documented and accessed by several members of a research team.

Framework analysis comprised the following steps:

- Familiarisation with the data, sometimes referred to as 'immersion'.
- Thematic analysis, carried out in order to develop a coding scheme.

- Systematic coding of the data.
- Charting of data using a Microsoft Excel 2010 spreadsheet (Microsoft Corporation, Redmond, WA, USA). Charts contained summaries of data (supported by references to data points in the original transcripts), so the research team was able to build a matrix to see across cases and the range of data under themes.
- Mapping and interpretation of the data in order to explore relationships between the codes.

Each of the three researchers (YB, RH, KB) most involved in fieldwork took a sample of interviews, and initial data were open coded. The coding framework emerged from a focus on the questions posed by the research document, but at initial stages was also open to emergent codes. The coding framework was further developed through discussions with members of the wider research team with extensive qualitative (VE) and clinical (IW) experience, to discuss emerging codes and categories, the interpretation of key texts and potential new lines of enquiry. The coding framework is included in *Appendix 6*.

Data sampling

Sampling decisions always fluctuate between the aims of covering as wide a field as possible and conducting analyses which are as deep as possible.[37] A strategic decision was made to aim for depth in analysing the qualitative interview data, as we sought to present findings which were 'rich' in relevant information. All interviews were coded, and 33 interview transcripts were selected for in-depth analysis, to represent diversity in the total data set of 86 interviews. The interviews were selected strategically from the complete data set using maximum variation sampling;[38] that is to say, they included 'typical' cases (reflecting the views of the majority of respondents), 'deviant' cases (extreme cases of the phenomena under investigation) and 'critical' cases (those that appeared to be especially information rich and thus particularly illuminating). These 33 interviews related to 33 participants (four policy-makers, four professional organisations, 10 health-care managers, 12 health professionals and three patients/family members who had experienced error). Although these transcripts formed the basis of the analysis, data from across the whole sample contributed to the analysis. The selected transcripts included interviews with males and females, who had wide-ranging views and experiences of open disclosure (see *Appendix 7* for a detailed participant breakdown).

Rigour and transparency in the analytic process

Analytic rigour and accurate interpretation of data were promoted and enhanced in a number of ways. The three team members most closely involved in fieldwork (YB, RH, KB) met frequently to discuss data collection and analysis. At regular intervals, meetings were held with members of the wider research team with extensive qualitative (VE) and clinical (IW) experience, to discuss emerging codes and categories, the interpretation of key texts and potential new lines of enquiry. In this way, the combined insights of those 'handling' the data closely and members of the team with a wider perspective of methodological and open disclosure issues could be incorporated into the coding framework to be used for all data analysis (see *Appendix 6*). In addition, a small subsample of transcripts coded using this agreed framework ($n = 5$) were examined by a member of the wider research team (VE) as an independent check on the assignment of codes to data.

The framework approach to data analysis allowed data to be compared within cases, facilitating the exploration of contextual meaning; comparing cases across the data set facilitated the search for regularities (key themes) and exceptions (negative cases). The use of memos during initial stages of analysis provided a visible 'audit trail' as the analysis moved from 'raw' data, through interpretation to the production of findings. A reflexive approach has been taken throughout the entire research process, from the initial development of the research questions, through data collection and analysis (for a full statement on reflexivity see *Appendix 8*).

Chapter 3 Results

Phase 1: review 1

The searches identified over 10,000 pieces of literature. Of these, 1435 full copies were retrieved and 610 pieces of literature were included in the final review. Full details of the literature selection process are illustrated in *Figure 1*.

A broad description of the literature

Literature published over a 22-year period was examined, with the majority of papers published from 2001 onwards. A broad description of the literature is presented below. We were interested in capturing the volume and type of literature and the pattern of publications over time, which has been little discussed in previous reviews.

The majority of literature discussing open disclosure is from the USA (65.1%). A further 20% is from Canada, the UK and Australia. The remainder consists primarily of single publications from a range of countries, and in just under 7% of papers the country of origin was not clear. Further details are shown in *Figure 2*.

The literature search was restricted to 1980 onwards as previous work had demonstrated a surge in safety literature in the 1990s,[39] and this was felt to be an appropriately sensitive time frame in which to capture the main body of literature. *Figure 3* demonstrates that until 2000 there were few publications per year relating to open disclosure. From 2001, the number of publications suddenly increased to an approximate average of 50 publications per year. The rise in publications is likely to reflect the increased awareness of patient safety issues and the publication of articles now regarded as seminal pieces in the safety literature, such as *To Err is Human* in 1999;[16] this article drew attention to the consequences and cost of medical error in the US health system and other health systems worldwide.

The majority (just over two-thirds) of the literature comprised opinion or 'think' pieces, journalistic-type articles and a variety of articles containing reports of other (previously published) publications and guidelines. Thirty-five per cent consisted of either primary research or papers which were judged to be of seminal importance to the topic, largely based on authorship by well-published or well-cited figures in the open disclosure field. There were small pockets of literature emerging from Europe, Asia and sub-Saharan Africa, as well as the better-known literature from North America and Australia, where discussion of the area of disclosure of adverse events is well established. Largely, this consists of descriptive literature outlining what clinicians feel about disclosing error and harm and what they report that they do in relation to disclosure, as well as descriptions of patient preferences and experiences in the context of open disclosure. There is little primary research and referencing back to early publications is common, with key messages largely unchanged. Clinicians, in principle, and for the most part, agree that patients should be informed of errors in their care that cause harm but are challenged by mixed messages from their institutions about what they perceive to be their legal status in this context. This is further exacerbated by concerns about their skills in disclosing error, due to a lack of specific training or exposure to this kind of communication. Additionally, the literature includes inconsistent terminology and ideas about which events should be disclosed, which adds further confusion.

Patients unequivocally report that they want disclosure of all unanticipated events and errors that occur during care. In some literature, the barriers to disclosure are explored more deeply and there are some in-depth critiques of what 'telling the truth' means. Although a good understanding of the concepts that underpin openness is valuable, such theoretical accounts may have limited application in changing the current culture in health care or persuading the NHS to fully implement the policy of open disclosure

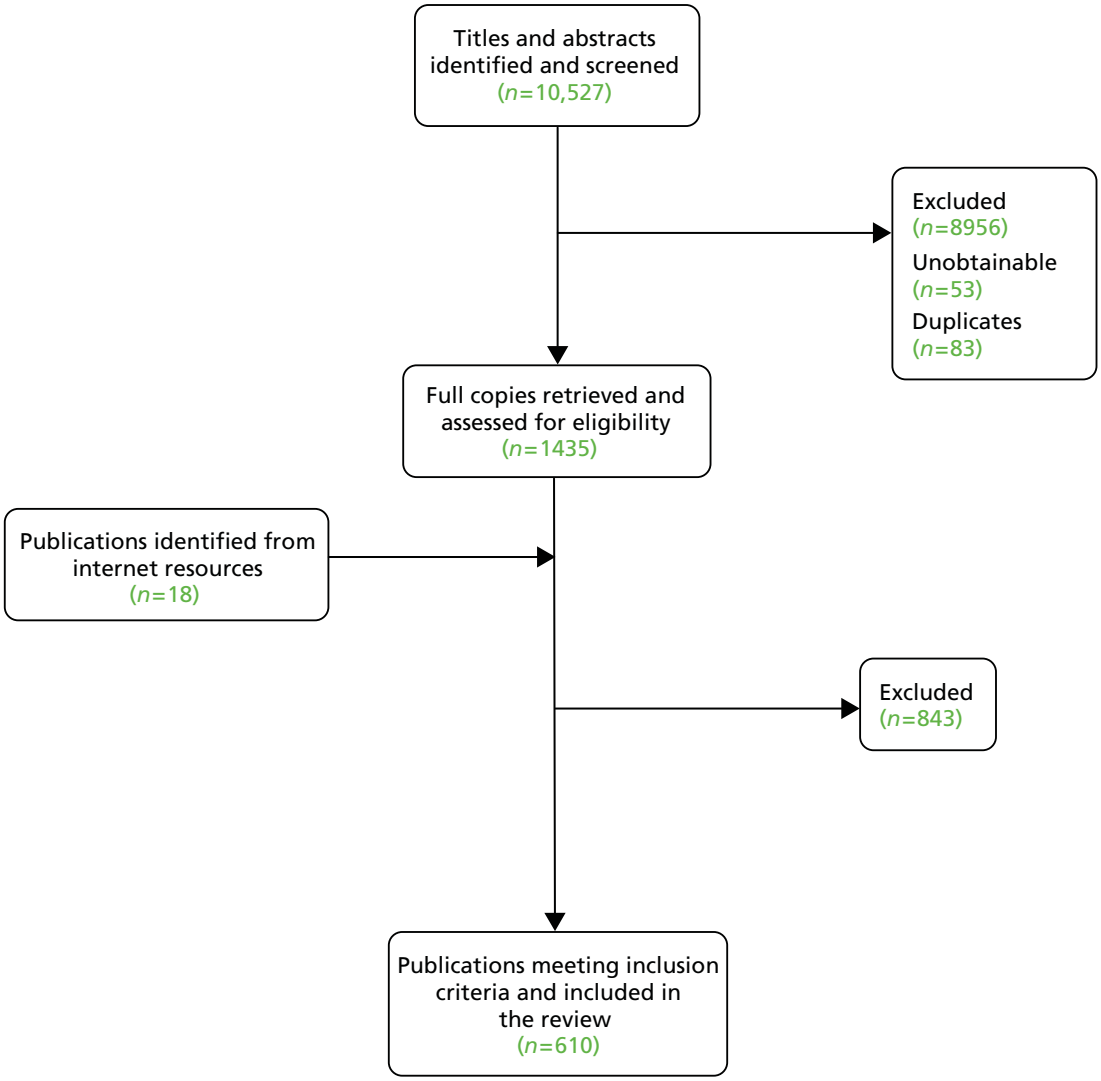

FIGURE 1 Selection of literature.

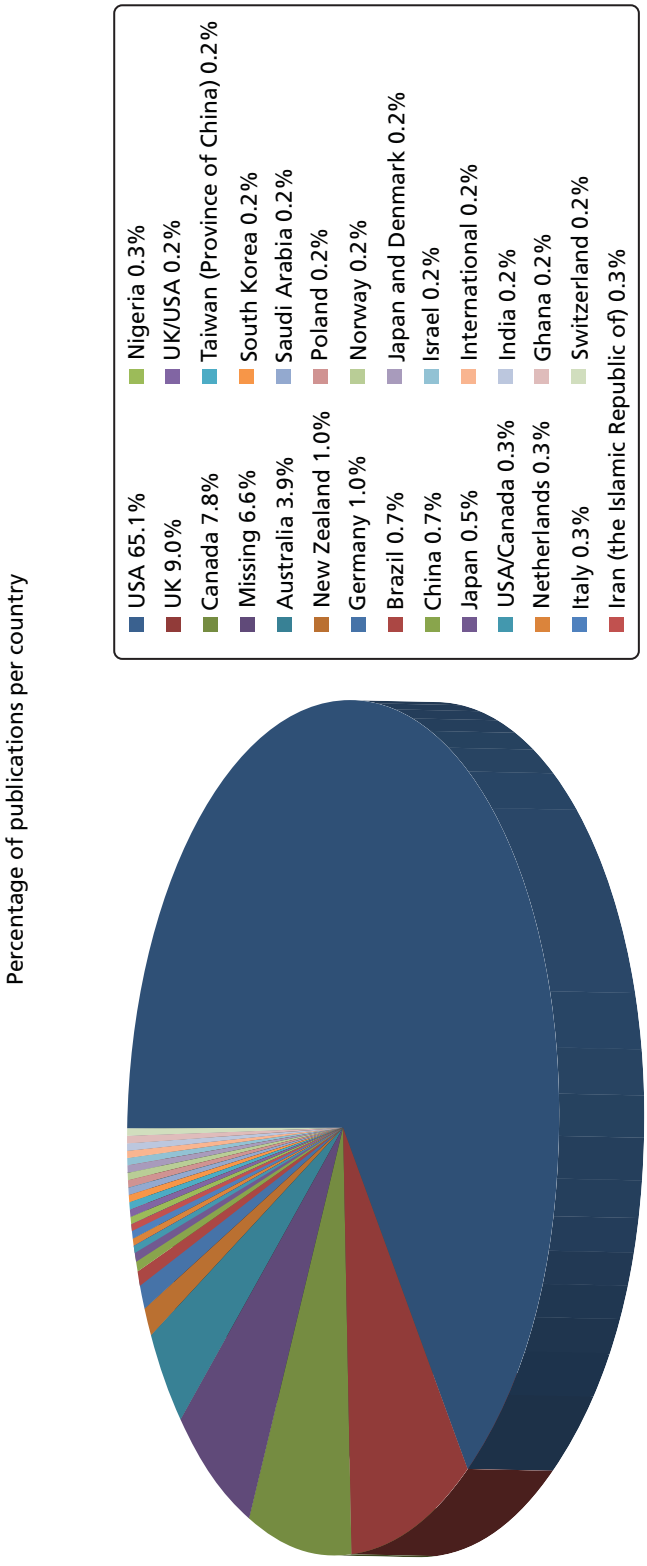

FIGURE 2 Countries of origin of the literature.

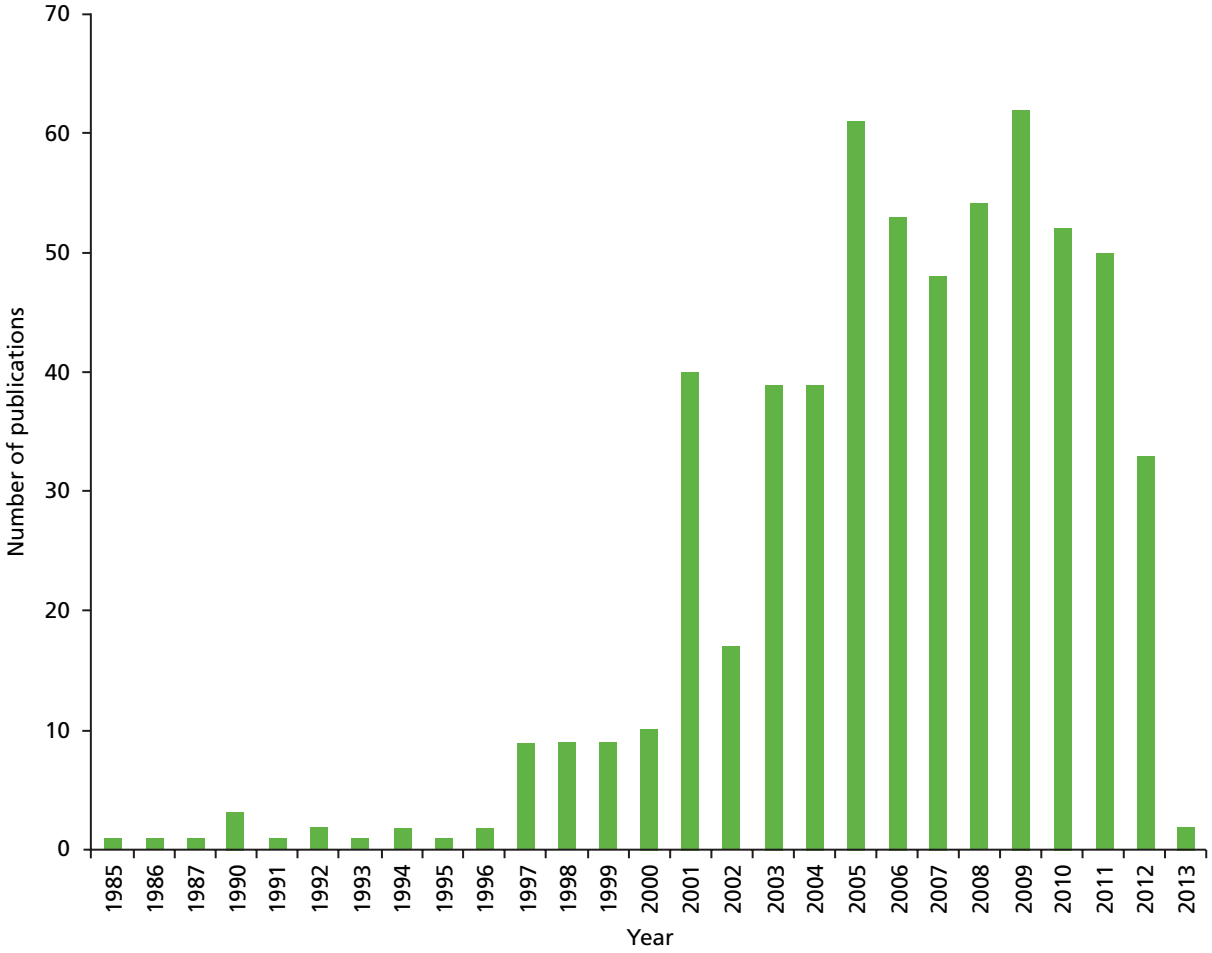

FIGURE 3 Number of publications per year.

rigorously and consistently. However, these accounts have been included alongside more practical accounts and primary research to fully illustrate the types of literature available to inform each principle.

Main findings

Given the challenges which open disclosure appears to present for some individuals and health-care organisations, it is surprising how little attention the topic has received in the UK. There is good reason to think that open disclosure may be different in different contexts.[40] In the limited evidence available, UK doctors were more likely than US doctors to agree that significant medical errors should always be disclosed to patients, and more US doctors reported that they had not disclosed an error to a patient because they were afraid of litigation.[40] The context of care may influence both how professional values are expressed and the extent to which behaviours are in line with stated values. Lessons may be learned from the largely US and other literature about the implementation of a policy of open disclosure, but the clinical negligence contexts in each country may have implications for how open disclosure is perceived locally. A large and growing body of literature exists in relation to open disclosure. Much of this is in practice journals and summarises a small number of frequently cited pieces of original research in the area. Thus, although there appears to be a great deal of activity in this field, there is limited underpinning primary research to substantiate conclusions; received truth is perpetuated from past references often based on small before-and-after studies or single cases.

Following detailed data extraction and appraisal of the literature, the results were synthesised under the specific principles of Being Open. Although there are vigorous and ongoing debates within the literature related to open disclosure, the nature of the UK health-care context, and in particular the NHS, means that some of these debates have less relevance than in other countries. This is reflected in the attention

afforded to some of the areas presented in this review and we did not seek to capture the very valid but less applicable areas within State and Federal statute in other international contexts. The large volume of literature on this topic has been surprising, but the aim of this project was to examine open disclosure specifically in a UK context. The legal frameworks and statutory requirements differ in various contexts and therefore some of the literature is less applicable to the UK. The review will address the international literature but focus on its applicability to a UK context, concentrating on lessons which can be learned to specifically address the implementation of open disclosure policy and duty of candour in relation to unanticipated outcomes in the UK.

A complete list of included literature sources is included in *Appendix 9*.

Acknowledgement

The Being Open guidance[10] states that all patient safety incidents should be acknowledged and reported as soon as they are identified. In cases where the patient, or his or her family and carers, inform health-care staff that something untoward has happened, this must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all health-care professionals. However, the literature suggests that defining the events that warrant disclosure presents a fundamental challenge for organisations, managers and clinicians. Although a number of definitions of what constitutes an error or an adverse event exist, there is much less clarity about what should be disclosed. Often the need to disclose has been associated with whether or not an event is classed as an error or constitutes harm. This is further complicated by an abundance of diverse error definitions in the literature. The terminology used to describe and categorise errors is also complex and includes an array of synonyms such as 'bad outcome', 'sentinel event', 'adverse event', 'mishap', 'mistake', and 'untoward incident'. All are used as synonyms or (partial) explanations of the word 'error'.[41] Additionally, errors can occur through acts of commission or omission; that is, not only as a result of what is done, but also as a result of what is not done.[41] The guidance suggests that 'error' refers to 'any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare'.[10] 'Error' seems to be problematic in its definition, and although harm, certainly in a biomedical context, may be easier to define, it does not address issues of culpability. Although this appears to be a well-defined principle, the discussions in the literature reflect continued ambiguity about the events that individuals feel are covered by any principle of openness.

Definitions of error or harm

Patients and clinicians appear to define error differently.[42] From the patient perspective, the distinctions between the terms 'error', 'adverse event' and 'unexpected outcome' seem relatively unimportant. Such definitions are largely constructed from the systems perspective and may be at odds with the way in which patients interpret harm. In the patient experience, harm is perceived, and regardless of how members of the health-care community and legal profession wish to classify this harm, patients who perceive that they have suffered as a result of their treatment feel that they deserve a timely, supportive and informative conversation about their concerns. In 2003, the College of Physicians and Surgeons of Ontario recognised this with the publication of its policy on disclosure of harm.[43] This describes a definition of harm as a concept which is not always preventable nor necessarily an indicator of substandard care. According to this definition, harm refers to any unintended outcome arising during the course of treatment, which may be reasonably expected to negatively affect a patient's health and/or quality of life. Such outcomes may occur as a result of individual or systemic acts or omissions, and include adverse events related to the care and/or services provided to the patient rather than to the patient's underlying medical condition. This is a considerably broader definition than many and has the potential to address the broader nature of patient concerns which are often raised but not addressed.

What should be disclosed?

The definitions of which events should be disclosed have subtle differences but there are common recommended elements of disclosure including 'an expression of sympathy or regret',[10] as well as the provision of practical and emotional support for the patient. Most guidance is keen to stress that disclosure

discussions should ensure that no speculation, opinion or attribution of blame occurs and that an apology to patients by health-care providers is not taken as an admission of liability. The Canadian Patient Safety Institute[44] has non-binding disclosure guidelines for adverse events which state that all harm must be communicated to patients, irrespective of the reason for the harm. There does not appear to be any consensus about the obligation to disclose adverse events with minor consequences,[16,20,21,28,45–48] despite the fact that most patients express the desire to be informed of these types of errors. It is proposed that the need for disclosure is proportionate and increases as the harm or risk of harm to the patient increases.[49] Others have proposed the 'view from below', putting oneself in the patient's position to determine how he or she would want the situation to be handled.[50] Disclosure should be the norm, with practitioners expected to justify why there should be any exception to this rule. The 2008 Veterans Health Administration (VHA) directive, *Disclosure of Adverse Events to Patients*,[51] is one of the few policies which has been explicit about its stance on serious and minor errors and events, stating that even when a near miss occurs, disclosure of such 'close calls' is recommended if the patient may have become aware that something strange had occurred.[52,53] One account describes the useful role lay members can play in informing decisions with regard to disclosure. Even in well-motivated organisations which try to implement openness, it can be useful to have lay members as part of a review board to ensure decisions remain patient centred.[54]

Truthfulness, timeliness and clarity of communication

Being Open guidance[10] stresses the three principles of truthfulness, timeliness and clarity, mentioning specifically an 'appropriately nominated person', a step-by-step explanation which is timely and based on fact and that patients and families should be kept up to date with the progress of any investigation. Additionally, communication should be clear and unambiguous with a single point of contact.

Why is truthfulness important?

There are a number of involved critiques of why disclosure should occur, which refer to philosophical underpinnings. The most powerful argument in favour of disclosure is deontological in nature. This deontological perspective, which is the perspective of duty-based ethics, is largely attributed to German philosopher Immanuel Kant and suggests that, in principle, all errors must be disclosed.[55,56] In this argument, truth-telling is not mandated by the specific detail of the situation. Therefore, factors such as whether or not an error is serious, or does or does not cause harm, or indeed whether or not an institution or practitioner is liable for harm, are not relevant. The duty is simply one of honesty. The same ethical principles insist that any proposed ethical rule must be universally applicable; it must bind everybody in all situations or else individuals are unable to know if they are bound by it or not. An in-depth but accessible critique of this perspective as it applies to disclosure is presented by Scheirton.[41] In this critique, the reader is asked to imagine that we propose a rule that therapists, nurses, pharmacists and physicians should generally tell the truth but that sometimes it may be acceptable to hide the truth or even lie (for example, in the case of an error). The outcome for patients in this scenario, as soon as they learn about this rule for health-care practitioners, is likely to be suspicion. One family member's account of non-disclosure refers to the fact that they 'know of no other industry where honesty is optional'.[57] A practitioner may be telling the truth, but the patient knows this may not be the case, as the practitioner is ethically allowed not to tell the truth sometimes. Therefore, in this paradigm the practitioner's moral duty to tell the truth cannot logically accommodate exceptions for errors.

Scheirton also describes patient rights as the other side of a similar argument, as the flip side of duties.[41] Laws, professional bodies and institutions agree that patients have a right to be informed about their own medical situation and health care. This right is not conditional upon the individual qualities of the patient or their condition. It is argued that any information is the patient's and it does not matter whether the particular condition or intervention is the result of an error or some other cause. The patient's right is to be informed, and this should be honoured by the health-care practitioners who have entered into a therapeutic relationship with the patient.

The picture of disclosure and non-disclosure

A recent paper looking at error and disclosure in emergency care in the USA has outlined the scale of non-disclosure,[58] at least in one context. A large number of medication errors (13,932) from 496 emergency departments were analysed. Physicians were responsible for 24% of errors, nurses for 54% and most occurred in the administration (36%). Although 3% of the errors resulted in harm, in only 2.7% of these cases were patients or family members notified. Other work[59] indicates that willingness to disclose was related to the severity of the error, with the majority of near misses not even reported to the head of department or the hospital error committees. Such studies indicate that health professionals still hesitate in their reports of many errors or adverse events unless serious harm occurs. A small number of papers have looked at the kinds of factors which may affect whether or not a patient or his or her family experiences disclosure.[60–63] These tend to be conducted in survey work directed at either clinicians or patients. One study[60] conducted with patients who had experienced error suggests that patients were less likely to report that disclosure had occurred if they were older than 50 years, did not generally report good health, experienced preventable events, or were still affected by the event at the time of the interview. Disclosure seems to have been more likely to occur when events required additional treatment and among patients who reported good health.[60] This suggests that disclosure occurs when individuals and organisations feel compelled to do so because the error is more visible.[61] Although there is little work directly addressing attitudes to and rates of disclosure in Britain, one paper looking at trainee anaesthetists as recently as 2009 reported that, although 57% had made an error which caused harm, only 68% of these had informed the patient. In the 32% of cases where the patient had not been told, a number of reasons, including negligible perception of patient harm, fear of litigation, fear of organisational or professional reprisal, and the patient having moved, died or remained unconscious were cited as reasons for non-disclosure.[62] This highlights the need for further training among this group of clinicians in relation to both current duty of candour and also medico-legal aspects of care. Other work in the UK[63] has demonstrated norms of selective disclosure in medical trainees whereby errors were disclosed informally to colleagues, particularly when teams were seen as supportive, but formal reports and disclosures to patients were rare.

The disclosure gap

There is an increasing literature stressing the importance of disclosing health-care errors, but the available, largely USA-based evidence suggests that this enthusiasm for what is seen by many as the moral imperative may not be reflected in practice.[60,64–66] Disclosure still remains an elusive concept for some and the evidence from a number of surveys points to a marked difference between what patients want from their health-care provider, in terms of honest conversations about mistakes and errors, and what clinicians (doctors in particular) say they would provide.[67,68] This term has been referred to as the 'disclosure gap'.[69] Several sources give a number of well-cited reasons to explain this mismatch between patient expectations and health-care provider practice, which are discussed at length in a wide variety of outputs from academic papers to short journalistic pieces. However, they seem to fall into four main areas.[69]

1. Truthfulness requires an admission of a mistake. For clinicians, admitting that they have harmed a patient is psychologically difficult. As well-trained and compassionate individuals they have a professional and often personal commitment to helping patients. The challenge to this identity posed by unanticipated outcomes and errors in particular is uncomfortable. Many physicians are upset by an allegation that they have been negligent, even if this turns out not to be the case.[70] This is further complicated by a culture of self-regulation and one where the belief is that health-care professionals heal rather than harm.
2. Health-care professionals undergo extensive training, both initially and as part of continuing professional development. However, this rarely extends to conducting the challenging conversations that are required by disclosures of errors or mistakes.[71,72] US work by Gallagher revealed that only 9% of physicians reported receiving any training in disclosing medical errors.[71] Where work has used standardised patients to explore skills in error disclosure, current evidence suggests that doctors are relatively lacking in such skills.[73,74] There is no literature to support training input in the UK.

3. It seems likely that health-care organisations and the individuals who work within them may not fully appreciate how important full disclosure is to their patients, and thus make interpretations about what it is important to disclose. In fact, many examples are given where individuals argue that they are protecting patients from difficult information. A number of studies show that physicians are less likely to tell patients about errors if the error is not obvious to the patient.[67,71]
4. In the extensive literature from the USA, one of the arguments is that the biggest barrier to full disclosure is fear of litigation.[75] Risks and costs associated with malpractice are high, and physicians and institutions are worried that admitting an error will increase the likelihood that patients will sue them. The emphasis on this has changed with a number of reforms in state law and in the policy adopted by a number of large insurers, but physicians remain sceptical about the power of such 'apology clauses' to protect them in practice. Additionally, most clinicians do not understand the law or update themselves, as they are too busy with clinical decision-making and practising medicine.[70]

Delaying disclosure or non-disclosure

Common objections to open disclosure policies suggest that disclosures may not always be in the best interest of the patient. Some work suggests that even if many physicians are perceived to prefer to limit disclosure for their own rather than patients' interests, or that as a society we believe paternalism is no longer acceptable, there may still be good reasons not to inform a patient of an error, or at least not to disclose immediately.[41] The idea that information conveys power to the patient is sometimes questioned in relation to whether or not such information may also harm them. Does the patient's right to information always trump emotional well-being? It has been suggested that if an error has no consequences for the patient's well-being and disclosure does not empower the patient, but is more likely to cause distress or reduce the patient's trust, then non-disclosure for the sake of sustaining the therapeutic relationship may be the ethical course.[76] However, this rule of therapeutic exception means that the burden of proof is on the one who wishes to use the exception.[41] At this point, proving that full disclosure will create an unreasonable risk of serious harm to the patient before the patient has the information is impossible. Unless research could demonstrate that patients would like clinicians to judge whether or not information relating to an error would be more distressing than non-disclosure, this reasoning ultimately fails. Largely, the limited literature suggests that the opposite appears to be the case, as patients have indicated when surveyed that they would prefer to be told about errors.[28] However, a patient can only judge how distressing the conversation might be after the event, and often such surveys are conducted in patients who have not experienced error and, as such, lack ecological validity. Even bearing this in mind, the best argument for non-disclosure of errors may be difficult to navigate with conviction. Aside from the well-intentioned motive of protecting the patient from what might be judged to be additional distress, the decision not to disclose for whatever reason may backfire. Another member of the team may (inadvertently) disclose the error, the patient may request copies of his or her records, or the error may be discovered during another procedure or even at post-mortem.

The literature here highlights the consistent findings in relation to the disclosure gap. This work comes largely from the USA, but some UK evidence also exists which indicates that disclosure policy is at best inconsistently applied.[28,41,76] There remain considerable challenges for and barriers to the principles and enactment of any policy of open disclosure, which range from a well-intentioned but paternalistic view of protecting patients and families from additional distress to a self-preserving strategy based on fear of reprisals from a legal or professional perspective.

Apologies

Being Open guidance[10] stresses that patients and families should receive a sincere apology and this may include expressions of regret for the harm. The wording of the apology should be agreed as early as possible and a decision about who should apologise and how would be based on local circumstances. Characteristics of the person to apologise may include judgements of seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. The role of both verbal and written apology is stressed and the time frame suggested is 'as soon as possible'. The purpose of the verbal apology is stated as allowing face-to-face contact between the patient/family and the

health-care team. It is stressed that an apology should not be withheld on the basis of setting up a more formal enquiry, organisational apprehension or staff availability. The guidance also relates evidence from focus groups that families are more likely to seek legal advice if apologies are not forthcoming.

The issue of an apology is related to, but distinct from, openness. The decision about whether or not and when to give an apology, and about what an apology is, seems to be complicated in the literature by the open disclosure process. Individuals often feel they are unable to apologise as this may be construed as an admission of fault or negligence, or that a full investigation has to have been completed before an apology can occur; that is, that an apology can only occur once fault has been determined. A key recommendation of the various global policies on medical error disclosure is to apologise to the patient, which is thought to reduce anger and increase trust.[77] Apologies are recommended elements and processes of all disclosure policies, which generally include who, when, where and what to disclose, as well as how disclosure should be conducted. In a number of descriptive accounts from patients, the concept of an appropriate and sincere apology is often raised as a key element of the perception of an adequate or inadequate disclosure. There are often repeated and strong claims for the power of disclosure and apologies in a number of contexts. Allan suggests that apologies are powerful factors in the healing of harmed patients.[78] This may or may not be the case, but there appears to be little evidence to support this belief. Although a lack of openness, accompanied by little information and no apology, often causes a prolonged and distressing period for patients or their families, we know very little about what 'good' disclosure conversations might look like from the patient perspective beyond some common-sense recommendations. The fact that an apology is made does not necessarily make a situation better for the patient who has been harmed and there is little to substantiate this claim. It has been articulated that some feel that the ability of current laws to protect against use of apologies in legal proceedings is perceived as inadequate in the US and Australian contexts.[79]

What is an apology?

An apology refers to an encounter between two parties in which one party, the offender, acknowledges responsibility for a harm or grievance and expresses regret or remorse to the aggrieved party.[80] Building on this core definition, Lazare, who has published extensively on the concept of apology,[80] outlines the vital components of an apology to include:

1. acknowledging offence
2. providing an explanation for committing the offence
3. expressing remorse
4. offering reparation.

However, it is thought that an apology may have a number of functions. For patients an apology can restore self-respect and dignity, facilitate forgiveness and provide the basis for a reconciliation with an individual health-care professional or institution; for the physician, it is thought to moderate feelings of guilt, shame and fear of retaliation. For both parties, it may strengthen a previously satisfactory relationship, or restore one that has been damaged.[80] However, reassuring though these statements are, there is currently little empirical evidence which can support these claims beyond expert opinion.

What do apologies achieve?

Zammit[81] suggests that although people often fear giving an apology as it implies an admission of guilt, the reality may be that the courts have a certain respect for apologies; apologies may actually be viewed favourably. However, this work also suggests that there is little evidence that apologies reduce malpractice claims, as the studies cited in support of this claim are often based on scenarios and have little ecological validity. Additionally, the dangers of unskilled apologies, or weak and insincere apologies made by clinicians who are unsure whether an apology may be protected or not, may actually inflame rather than calm an angry patient or family. This point relates specifically to training in open disclosure conversations, which will be followed up in a section addressing training (see *Professional support*).

Recognising patient and caregiver expectations

Being Open recognises the need to fully inform patients and families and to attempt to ensure that the process of disclosure meets their expectations. Although there are some practical suggestions for an appropriate attitude from the health-care organisation reflecting sympathy and respect, addressing additional support needs and informing the family of any appropriate support networks is less well reported; we know relatively little about the patient experience of disclosure.

What do patients and families say they want?

Since 1996 there has been some evidence that patients report a wish for an acknowledgement of even minor errors, that they may wish to be referred to another doctor if other treatment is required and that they are more likely to litigate if they have not had an error disclosed.[21] Since this paper, there has been a limited amount of work exploring how patients feel after an error and exploring their responses to disclosure. In survey work the majority of patients clearly indicate that they would want full disclosure of medical error and wish to be informed of error immediately upon its detection.[82] Patients also clearly support reporting of errors to government agencies, state medical boards and hospital committees focused on patient safety. Patients also indicate that they support teaching health-care professionals error disclosure techniques, with honesty and compassion endorsed as a priority for educators who teach clinicians about error management.[83] Patients are clear that, as the person who has experienced harm, they are important, and if apologies are perceived to be driven by regulatory standards and institutional policies alone, and are felt to be insincere and purely managing risk to the organisation, then this may well carry its own risks in terms of the subsequent patient or family response to any apology. One study which explored how patients had experienced disclosure and error described patients reporting that the actual error was less concerning than the continued relationship with their health-care provider.[84] These individuals described being treated not as experts in their own experience of care, but as outsiders. The authors described this as patients feeling like a foreigner in a strange land experiencing a different culture and language, and highlight how poor communication suggests a conflict between a model of person-centred care, with the patient–provider relationship at its heart, and the business or corporate model of health care. A number of other studies have suggested that when poor communication occurs, it can be perceived as medical error by the patient.[28,85]

Patients are known to value apologies and expressions of remorse, empathy and caring. They indicate that what they want from disclosure is an explanation of any potential harm and an acknowledgement of responsibility, and they need to see efforts to prevent recurrences; however, these are often reported as missing elements in the disclosure process.[82,83] For many patients, actions and evidence of learning were most important. Current reports of patients' accounts of apology and disclosure suggest that clinicians' and organisational responses continue to fall short of expectations.[86]

These accounts of what patients seek from open disclosure and apologies largely emanate from the US literature, often from surveys where it is unclear whether or not the population has experienced harm or error. However, from the few findings available from other contexts, these desires would seem to be relatively consistent. Okamoto,[87] for example, found that individuals in Japan reported that after the immediate disclosure of a medical error by senior medical personnel, medical providers should create an environment where communication is repeated and continuous to accommodate the shifting nature of the perspectives of those who have experienced the error. Although the severity of the outcome remains the most important single factor in a patient's choice of actions following an error, the professional's approach to the error is regarded as essential in the overall evaluation of consequences. In errors with a severe outcome, an honest, empathic and accountable approach to the error decreased the probability of participants' support for strong punitive action against the physician involved by 59%. These judgments in this scenario study were only marginally affected by respondents' characteristics.[88]

These findings are consistent but come from a context which is quite different from the UK and the NHS in particular. Though it seems unlikely that UK participants would expect different standards in relation to open disclosure or apology, we know little about this.

Real accounts of disclosure by patients and families

There is still relatively little work exploring real accounts of disclosure and error, what worked well and what was less successful from either a clinical or a patient perspective. A number of individual accounts of what non-disclosure or poor disclosure feels like from the patients' perspective are reported, often by the individuals themselves,[57,89] but few accounts exist in the academic literature.

One of the few pieces of work exploring this directly is a focus group study with patients who had been subject to iatrogenic harm.[85] This paper describes how trauma as a result of harm developed in two ways, from the incident itself and/or from the manner in which the event was subsequently handled. This has been previously described by Vincent.[90] Those who experienced what they felt had been skilled communication (demonstrable respect, active listening, caring) with their provider reported less emotional trauma. The medical error literature has often ignored financial trauma but the participants in this group all mentioned the devastating impact of financial problems following an incident; this may be from bills for health care but also from loss of income, either temporarily or permanently. This paper also identified a cycle where patients tried to work out what happened, what would happen next and finally whether or not they would ever be the same. Often patients reported working through the process, feeling very alone. Participants pointed out the importance of having information to help them cope, but also reported having great trouble obtaining it. There were reports of frustration resulting from poor information about their situation causing anger and a perceived need for battles or conflict. The provision of adequate information was often accompanied by relief. Patients reported a perceived need to 'threaten' to get action. Some of the group reported that apologies did not routinely happen, but an apology remained important to their ability to resolve their situation and was associated with organisations or individuals taking responsibility for the harm that occurred. Where the communication process was seen as satisfactory, the patients were usually able to continue their relationship with the provider. Those patients who experienced a 'good' communication process with their provider also perceived a 'no fault' event. These patients were more likely to call these events 'mistakes or complications'. Conversely, those patients who were dissatisfied with their communication with the provider had a tendency to see incompetence or malicious intent. Most patient anger was directed at the way in which they were treated rather than at the event itself.[91]

The 100 Patient Stories project[27] is the most comprehensive attempt to date to gather the accounts of patients and relatives of patients who have experienced harm in their health care. From this work, so far, the investigators have been able to gather that most individuals appreciated the opportunity to meet staff and have the adverse event explained to them. There were a number of concerns about how disclosure took place, including disclosure not occurring promptly or being conducted too informally; disclosure not being adequately followed up with tangible support or change in practice; staff not offering an apology; and disclosure not providing opportunities for individuals who have experienced error or harm to meet with the staff originally involved in the adverse event. This work suggests that the practice which is likely to best represent how individuals would prefer to experience disclosures is likely to consist of a combination of formal open disclosure, a full apology and an offer of tangible and material support.[25]

There is little to suggest that the experiences of patients who have experienced harm and/or disclosure in the UK are likely to be more or less positive than those described so far in other contexts. Although financial issues are often overlooked, as health care is usually free at the point of care in the UK, the subsequent financial burden for some patients is likely to be substantial if their ability to work is affected or ongoing care is required for a member of their family. The majority of accounts raise the challenges associated with obtaining accurate and timely information, and the frustration, anger and sense of having to engage combatively with an organisation. Another strong account directed towards health-care providers summarises messages from three individuals who had experienced error, either as individuals or to a family member.[92] These accounts leave the reader in no doubt as to the profound effects that poorly conducted disclosure or non-disclosure has on patients and their families. They describe a sense of betrayal and abandonment, likening their experience to a 'hit-and-run health care accident' where they were abandoned by a clinician who was both personally afraid and worried about the legal implications of the error. The non-disclosure of medical error is described as 'the most destructive phenomenon in health

care', eroding trust and confidence and reflecting an 'intolerable lack of integrity' which was perceived to be the result of poor leadership. One relative described knowing that something had gone wrong, and that the outcome of the given explanation did not fit that explanation, but experiencing being faced with 'stonewalling, lack of empathy, and lack of information that would have been helpful'. She perceived this as 'emotionally and viscerally insulting' to her intelligence, and believed that if disclosure had occurred and the organisation had given an expression of regret and instigated an investigation, this would have made a great deal of difference to the following period in her life – a period she goes on to describe as '2 years of solitary confinement in a prison of inconsolable pain'. The silence is not perceived as passive by these individuals; it is perceived as an active and abusive strategy by individuals and organisations. In contrast, one account describes a senior clinician coming to a child's home, taking responsibility for the error and maintaining a relationship with the child's family all through the process of investigation. This was interpreted as a courageous act by the family and they reported this as directly influencing their decision not to litigate.

The perception of some commentators is that organisations and the individuals who work within them have a general lack of knowledge of the suffering inflicted on patients and families when they do not disclose. One participant in the work by Sheridan *et al.*[92] stated: 'When they harm us, it is typically a passive event. When they consciously withhold information, cover up what happened, or seek to discredit us in courts of law to preserve their precious financial resources, they are actively harming us'. This US article also points out that consumers do not wish to litigate for monetary gain for the sake of it. Rather, they suggest that people may risk their homes because they cannot pay medical bills and that medical error expenses are an additional harm to the patient and his or her family. The accounts conclude that if hospitals disclose errors and adverse events and work with the patient and/or family to improve the system, they may well eliminate many lawsuits and at the same time continuously improve the system so that the same errors do not repeat themselves. The strength of these accounts may reflect a situation where the consequences for individual families of ongoing medical costs can be more catastrophic than is common in the UK, but this should probably not be based on an assumption and requires more examination in the UK context.

Professional support

The relevant literature and guidance for UK clinicians and managers would seem to be clear and originates from a number of sources including the Being Open guidance itself.[10,11,22,23] In the UK, open disclosure and appropriate apologies or expressions of regret are not the same as admitting legal liability or negligence. Openness and honesty towards patients are supported and actively encouraged by many professional bodies, including the Medical Defence Union (MDU), the Medical Protection Society (MPS) and the GMC for doctors, and the NMC for nurses and midwives.

The MDU advises that, if something goes wrong, patients are entitled to a prompt, sympathetic and, above all, truthful account of what has happened, and it encourages its members to apologise where appropriate.[93] This approach has been given legislative support in section 2 of the Compensation Act, which reads: 'An apology, offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'.[94] Doctors' ethical responsibilities are also clearly set out in guidance from the GMC, which states:[95]

> *If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects. Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not allow a patient's complaint to affect adversely the care or treatment you provide or arrange.*

However, this statement is framed in the context of harm or complaints rather than being aimed at a more overarching spirit of openness. The GMC has also indicated that saying sorry and providing an explanation to a patient or relative seldom does any harm and can often avoid a complaint.[96]

The role of training and support has been identified by a number of sources as fundamental to the success of any open disclosure policy. Leape[97] believes that hospitals must expand the training of physicians to ensure that patients are treated with openness, honesty and compassion, and, when indicated, are given an apology and compensation. Most physicians and other health-care professionals have little or no training in the communication skills required for effective disclosure of adverse events or errors but there are increasing efforts to teach these skills.[69] Recent studies have used standardised patients and role play to teach practising doctors, surgeons and medical residents these skills.[73,98] As well as providing a relatively safe environment in which to practise, this approach also allows individuals to receive feedback to improve their communication. This method could be used for any training, from the highest level of management to risk managers and front-line clinicians. Although the majority of training is directed at medical professionals, a number of barriers to nurse involvement in disclosures have been identified, principally in the area of training and knowledge of how to disclose incidents,[99] alongside uncertainty around the information that they could and should reveal.[100,101]

The evidence for the effectiveness of such interventions has been captured in detail in the second, more specific review addressing effectiveness specifically (see *Phase 1: review 2*).

It is thought that patients often litigate to get information after failing through their routine contacts with professionals and organisations. Doctors are often more likely to explain than admit errors.[102] There are a small number of accounts in the literature by health-care professionals discussing cases where they (or one of their colleagues) have made an error, often accompanied by their account of disclosure or, in some cases, no disclosure.[103] There are big challenges in terms of addressing difficult concepts such as guilt and shame in the professional education and continuing professional development of health-care professionals. However, one suggestion is that a more candid discussion of such issues from senior members of professions may help junior staff to talk publicly about their own errors and address the associated emotions that arise as a result of error. Ofri[104] suggests that, for junior staff, witnessing the fact that these professionals continue to practise successfully despite their errors may be an important lesson, demonstrating that it is possible to survive the distress associated with error and not be defined by it. Making an error has been highlighted as a defining moment in the life of a physician with regard to integrity and professionalism.[1] A number of accounts have reflected on this, and the way in which a senior physician deals with a more junior colleague who has made a mistake may be crucial in the way this situation is modelled for trainees in any profession.[105,106]

An overview of the literature suggests that though professional, regulatory and indemnifying bodies support professionals to be open, the norms within practice seem somewhat removed from this. Discussing a change of 'culture' seems overly vague but there is a sense that medical societies, certifying boards and accrediting bodies all play a role in integrating this into practice alongside institutions and professionals, and a more consistent and joined-up approach to education needs to be undertaken. Whether or not this requires statutory support is unclear, but it is likely to require to tackle the issue of openness within health care using both bottom-up and top-down approaches which are reinforced throughout career pathways. Information on the educational approaches which are most effective is lacking.

Risk management and systems improvement

The importance of investigation of adverse events is emphasised in the Being Open guidance,[10] which stresses the need to embed this within a process which aims to improve systems of care. Local Being Open policies should be integrated into local and national incident reporting and risk management policies. The framework is aimed at boards and health-care staff responsible for clinical governance infrastructure rather than front-line clinicians, with the emphasis on systems rather than individual failures.

No-blame culture

Although the general thrust of patient safety literature is directed towards the promotion of what is often termed a 'no-blame' culture as encouragement to promote the reporting of error, the idea of 'no-blame' is questioned by some as being misdirected.[107] Robinson[107] suggests that this focus will only lead organisations to identify patterns of risk, but stop short of investigating primary causes. This may feel like a safe climate for professionals, but it is unlikely to address the fears around damaged reputation. However, the assumption that removal of penalties will automatically create a climate of honesty is unproven. Occasionally the source of risk is the individual personality, not the system, and those people have to be identified if they falsify documentation or are dishonest. It is important that institutions do not defend their own staff against a patient or family in the name of a 'no-blame' culture.[107]

Learning from mistakes and error

Part of the rationale for disclosure is to allow learning to occur. This is obvious when disclosure occurs to the system and to colleagues, but is perhaps less recognised in terms of the potential contribution of the patient and family perspective to enhancing learning. Firstly, some valuable lessons may not be learnt if disclosure does not occur for all patients for the majority of events. Secondly, the process of disclosure is often one of information-giving rather than a dialogue around issues. A number of individuals highlight the role that patients and families may have.[84] Patients and their families often have a unique perspective on their experiences and can provide information and insights that health-care providers and systems administrators may not appreciate or know.[108] Allowing patients and families to engage in a dialogue as part of disclosure allows them to describe what may be important insights into factors leading up to and following health-care incidents, and emotional harms that occur when these incidents are inadequately communicated or responded to, and to make a potential contribution to patient safety.[109]

Evidence for the effect of disclosure on risk management outcomes

Calvert *et al.*[110] have explored the strength of evidence around a number of common statements concerning the belief that disclosure of a medical error improves a patient's confidence in the physician and leads to improved outcomes, and conclude that they are based on expert opinion rather than concrete evidence. The idea that physicians and other staff may experience a resolution of anxiety and guilt that can improve their well-being after an error may be true, but in terms of quality of evidence this is based on survey data.[110] There is limited evidence that disclosure increases assessments of quality by patients.[111] Mazor has conducted a number of manipulated scenario and other studies in an attempt to build what we know about how patients may respond to disclosure.[13,20,47,86] Some of her work suggests non-disclosure increases the likelihood of swapping to a new clinician and leads to reduced satisfaction and trust in clinicians.[112] Her work suggests that non-disclosure increases the likelihood of seeking legal advice and is associated with a more negative emotional response in one experimental condition, although this was not consistent across conditions.[113] Interestingly, neither the existence of a positive relationship nor an offer to waive health-care costs had a significant impact on outcomes.[113]

A current study[114] to look at the effect of medical liability reforms and patient safety initiatives is under way and may be able to answer the questions surrounding the effect on liability of offer with disclosure. The experience of a number of US providers has pushed the perspective that open disclosure can be a useful risk management strategy. It is suggested and borne out by some patient accounts that litigation is often initiated by an injured patient in order to get the answers that they feel unable to get from their health-care provider.[41] Practitioners and organisations, when they fear litigation, may avoid open and honest discussion with the injured patient. However, the widely described experience of the Veterans Affairs (VA) Medical Center in Lexington, KY, has not resulted in higher liability as might be suspected.[52] The VHA is not generally representative of the US health-care system,[41] but many authors have remarked on the low rates of litigation.[115–117]

In 2005, the Sorry Works! Coalition was formed to promote an approach to medical and surgical errors that incorporates full disclosure, apology and reparation.[48] However, a number of papers suggest that there is little evidence to support the perspective that disclosure or apology will deter patients from seeking

litigation,[117,118] even if disclosure meets the patients' expectations.[20] Early adopters of this approach have reported reduced liability costs, but the extent to which these results stem from effective disclosure and apology practices, versus compensation offers, is unknown. A survey study[119] using vignettes examined the effects of different compensation offers on individuals' responses to disclosures of medical errors compared with explanation and apology alone. Although two-thirds of these individuals wanted compensation offers, increasing the offer amount did not improve key outcomes. Full compensation offers did not decrease the likelihood of seeking legal advice and increased the likelihood that people perceived the disclosure and apology to be motivated by providers' desire to avoid litigation, which suggests this relationship is complex. Conversations with patients may benefit from separating disclosure conversations and compensation offers and from excluding physicians from compensation discussions.[119] However, Boothman, a well-known advocate of moving compensation discussions away from the courts, has said it is important to move discussions of compensation into the hands of physicians, hospitals and patients in an attempt to defuse the adversarial nature of the process.[120]

Systems for compensation

A number of health-care systems have adopted different ways of addressing compensation for error. New Zealand, Sweden and Denmark have replaced litigation with administrative compensation systems in which patients who sustain an avoidable medical injury can apply directly, without any legal representation, for compensation. However, fear of discipline arising from complaints and threats to reputation remain a concern for doctors and are factors that are still thought to be a factor in inhibiting disclosure.[121,122] Suggested advantages of this system are a focus on compensation and learning from system errors rather than attributing blame, as well as allowing injured patients to access compensation for their injuries quickly without the additional stress and cost of the legal system. However, upper limits attached to claims may not adequately compensate over time for care costs. It has been suggested that many of these early compensation mechanisms which occur in the disclosure with offer programmes, particularly in the USA, are capable of causing patients to reach a financial settlement before considering their future medical costs or the need for non-economic damages.[123]

Apology laws

An admission of error to a patient is not the same as the admission of liability for the damages the patient has suffered. In the USA this is the basis of a series of 'apology laws' that prohibit or limit the use of an apology in the case against a health professional or organisation in litigation.[124–126] At least 36 states have passed, and others are considering passing, immunity for apology laws and five states have passed mandatory disclosure laws.[127] However, there continue to be a number of authors who warn individual clinicians to be wary of making an admission of liability during the open disclosure process.[128–130] Professional journals sometimes carry 'health warnings' which highlight the problems associated with saying 'sorry'.[131] Although litigation is feared by clinicians, most patients do not bring a legal challenge to court and physicians substantially overestimate the risk of being sued. When a clinician has apologised to a patient, the legal case against him or her is likely to viewed differently by a jury, who will be more likely to concern themselves with establishing just compensation rather than negligence in the face of an honest clinician who has apologised.[132]

Apology laws emerged in the USA in the 1990s as part of efforts to enhance medical error reporting and patient safety. As outlined earlier, it is thought that more disclosures and apologies, combined with early settlement offers by hospitals, has led to a dramatic decrease in claims of malpractice in the USA. However, the actual impact of apologies and of apology laws on litigation is less clear because both are components of broader regulatory and institutional efforts to overcome the complex problem of resistance to disclosure. Early settlements may well drive down the cost and number of claims with or without an apology.[133] Some consider that apology laws are unnecessary for the open disclosure of adverse events and that they will make it more difficult for individuals to pursue negligence claims.[134] But others suggest that apology laws are unlikely to shield people in the case of gross negligence.[135] The most important distinction among apology laws is whether or not admissions of fault are protected. However, there are many variations in these laws between states. Some protect oral, but not written, statements;[46] some

mandate that hospitals or their physicians notify patients of medical errors leading to adverse outcomes, moving beyond voluntary disclosure[52–54,57] with laws to protect the required disclosure from being used as evidence of fault in any legal action. Some have suggested that apology laws usually do not protect physicians who expressly admit fault or use explanations or statements that can be interpreted as admitting fault, and that in such cases physicians could find themselves in difficulty regarding explanations and disclosure of error.[136] The perception of a lack of explicit legal protection for the admission of faults and the fear that an apology will expose physicians to higher risk of litigation certainly causes concern in the USA. If this is the perception of clinicians in the UK then it is likely to have a similar effect. However, the NHSLA, which indemnifies NHS trusts for claims in England, stresses that apologies and explanations should be provided and to do so will in no way affect the availability of the trust's indemnity.[22] However, although risk managers in the USA tend to support disclosure, they are much less enthusiastic than physicians about offering an overt apology.[61,137] We have little evidence that would allow us to determine the position of risk managers in the NHS.

Dissenting views on the need for apology laws do exist[138] although they seem to exist in a Canadian rather than a US context. Objections seem to rest on the premise that whereas apology laws exist to protect admissions of liability, a better course is to express sympathy, discuss the facts and promise investigation, followed up with further disclosure after a review has determined the most likely causes of the situation. If an error has occurred and physicians or institutions admit an error that caused harm, then they should encourage their liability insurer to negotiate reasonable compensation without requiring their patient to sue them.

Consistency of patient experience

Some take a broader view of the culture in relation to apologies, looking at smaller steps leading to culture change. If the broader approach of health care were to apologise for relatively minor violations like being late or forgetting to do things, then apologising for bigger things should be easier. Woods[139] discusses this idea and points out that it seems convenient for organisations to believe that litigation is driven by opportunistic solicitors and patients who see a way to profit from error in a way that seems to be beyond the control of clinicians and organisations. However, she suggests that this may not be so if people feel they have been treated honestly, and that if information has been shared perhaps people will sue less.[139] Nonetheless, she cautions against the use of apology and openness as a risk management strategy in itself, something that is seen as out of keeping with the rest of the patient experience. Patients are perceptive to change. If no trust has been established by offering apologies and courtesy throughout care, then any perception that an organisation is offering one up after a poor outcome to lower liability may well make them angry.[139] These suggestions link to the observations of others who have pointed out that there is a general failure of openness across information-giving to patients, which means they are often unprepared for what the system might consider disappointing, but not unexpected, outcomes. As such, informing and managing expectations before, during and after treatment should always be part of decision-making, ensuring that all possibilities have been discussed.[140] Difficult and possibly adversarial situations can arise when anxieties during care and then afterwards have been ignored, and defensive and/or slow responses will cause problems. Others have observed that apologies might be easier if patients are better prepared for complications or poor outcomes as a possibility.[141]

The responsibility/role of the patient and family

A slightly different perspective discusses patients having rights in relation to disclosure, but on the basis that with rights come responsibilities.[142] The emphasis here is that patients cannot expect the right of disclosure without taking an active role in making challenges and information-giving in relation to safety. The examples given in this work sit within a previously described literature in which patients are expected to contribute their knowledge and input for the greater safety good. However, other work has demonstrated how challenging these kinds of roles can be for patients and families who experience this process as outsiders to a system in which they only know what the system chooses to disclose to them, and where the implications and assumptions underlying roles are often not well thought through.[39]

There appears to be little work exploring the roles that patients might play in informing disclosure policy and in directly informing improvement after errors.

Liang[143] suggests the patient/family should be asked to assist in the error investigation by the error disclosure team during the initial contact, if appropriate, or by the patient care liaison at a later time. It is proposed that this could range from discussion of any factor, problem and/or witnessed error that may or may not have contributed to the negative outcome to a full debriefing on all stages of care, from before admission to the event itself and even the time following the event. This kind of approach is consistent with the systems nature of error and outcomes and is indicative of a more equal partnership approach between health-care providers and patients. Additionally, the patient and/or family have a vested interest in corrective action at the facility, which may allow something constructive to emerge from an otherwise destructive situation. Perspectives gathered in the 100 Patient Stories work support the view that patients and families feel they have a valuable perspective to contribute.[27]

Implementing disclosure policy

Sorensen *et al.*[144] examined the implementation of open disclosure policy and concluded that health service managers must formulate their own local approaches. This would include identifying 'the circumstances under which open disclosure is conducted, who should be involved, where and when discussions take place and how patients are informed of the process, the plan of remedy and the means for feedback of investigative results' (p. 231). They too identify a gap where open disclosure policy fails to be applied by those who have to undertake the process, and find that the necessary links between policy-makers, those who have to conduct disclosure conversations and those who hold knowledge that may improve the process remain unconnected. The organisational components required to improve practice include improved competence at both the organisational and individual levels, but also the removal of barriers such as the covering up of errors and a lack of commitment to disclosing error. The identification of this organisational competency, they propose, would link the two currently predominantly discussed areas of policy development and clinician–patient communication. On a practical level, it is proposed that this would consist of networks where good practice can be shared, allowing managers to examine models of care and appraise their possible implementation within their own local context. This would allow more support for managers to move beyond what is referred to as a complacency which talks about principles but fails to support their enactment in practice.[145,146]

There is little knowledge of how open disclosure policies are being implemented in the UK, but one recent cross-sectional survey of UK risk mangers[147] identified that 98% of the participants reported that they were familiar with the Being Open guidance and 82% stated that they implemented it more than half the time when incidents occur. However, provision of timely information was not reported as routine, with two-thirds of the discussions taking place 3–6 weeks after the investigation. The frequency of taking responsibility for harm was low for incidents of different severity levels but significantly lower for less serious ones. Long-term follow-up of patients and ex-gratia payments to patients occurred less than half the time. The most highly rated barriers to being open were reported by risk managers as clinical staff's fear of negative reactions from patients or their families and anxiety about litigation. Support practices for staff, such as debriefing and training on being open, were acknowledged as highly important but not always available. The authors concluded that though awareness of the importance of open disclosure appeared to be high in their respondents there was still considerable scope for improvement in the consistent application of the guidance.

Accounts of open disclosure policy perceived as successful

Instances where local policies of open disclosure have been successfully implemented do exist and are frequently cited moving through the chronology of the literature. Such examples of implementation are rarely discussed in the academic literature and are often limited to risk management conferences and professional journals. There are a number of examples of individuals from practice who talk persuasively for the power of disclosure of adverse events in terms of institutional learning and patient- and clinician-centred outcomes, but a substantial evidence base has yet to be established. These individuals are

often interviewed as part of more journalistic literature discussing the challenges they experienced in implementing disclosure policy within their organisation. Often these policies emerged from serious errors within their organisation. Such accounts must be taken at face value but have strong messages for the UK in terms of how implementation may be able to succeed in the face of the barriers that are frequently cited in literature from all contexts. It seems to be agreed that a number of key actions and individuals need to be mobilised. Disclosure needs to take place systematically and based on agreed protocols, with tangible support in the case of psychological health-related problems, accompanied by clear and demonstrable efforts to learn from events and make the system for providing health care safer. Much more could be done relatively quickly by hospital management and department leaders, who are identified as key in implementing such comprehensive incident management approaches, educating staff in collaboration with professional organisations and professional curricula and promoting an organisational culture that supports open communication and learning from critical incidents.[148] Although the principles espoused in policies such as Being Open seem simple, operationalising these locally is often the point at which a number of questions arise.[149] All accounts stress that a focus on the patient perspective, not that of the organisation, is key to making implementation credible. Resistance from the system to disclosure should be expected and will need to be overcome.

Julie Morath from the Children's Hospitals and Clinics of Minnesota describes the commitment required to change and describes a 'wholesale revamping of philosophy at the hospital, not just the implementation of a new policy handed down by risk management'.[150] She has also highlighted that a focus on limiting organisational liability does not fit well with full disclosure and should not compromise the philosophy. Jo Shapiro from Brigham and Women's Hospital, Boston, MA, describes the use of Boothman's principles as the basis for the hospital's process and describes having to convince her institution that it was the right thing to do.[151,152] The approach at Brigham is grounded within the Center for Professionalism and Peer Support, which is able to offer a support hotline 24 hours a day and uses a 'train the trainer' model to engage all staff with the principles of and skills need for disclosure. She credits the success at Brigham to the joined-up approach between risk management, human resources, patient safety, and senior clinicians and managers. There are monthly symposia and staff evaluate the effectiveness of full disclosure with patients and families. Families continue to seek care, and safety is reported to have improved, as have attitudes.

Richard Boothman is another well-known individual within US health care who has disseminated his practice from the University of Michigan Health System (UMHS). Boothman describes what started out as an effort to save money changing into a major patient safety and patient communication agenda, and describes the issue of claims as 'background noise'.[153] As soon as UMHS learns of an error, risk management staff are assigned to talk to patients. They apologise, letting the patient and/or family know that UMHS will investigate the error and that whatever is learned from the investigation, as well as any new practices to prevent the error in the future, will be shared with them. If UMHS has made an error, compensation will also be offered. They will, however, vigorously defend their organisation if no error is identified. Another initiative involves a team in risk management which supports doctors who find themselves in difficult positions, helping them decide on an honest approach with patients. Sincere apologies are encouraged, with support given to help clinicians make sure their conclusions and evaluations are sound, that the event is discussed in context and that disclosure and follow-up plans are supported. As with the approach described by Shapiro, the emphasis is on the whole team. Additionally, Boothman describes the way in which the publicity of UMHS's success has led to more reports of near misses and patient injuries.[153]

In 2003, Trillium Health Centre in Toronto, ON, identified the need to develop a disclosure protocol as part of its risk management approach. Key to this was training provided through a 'train the trainer' model and this account also stresses the need to address and change norms which happened slowly over time.[154] Sisters of Mercy Health System in St. Louis, MO, has described the questions it asked itself in developing a policy for open disclosure.[155] The process was clearly iterative and took a great deal of negotiation in defining the policy; however, the advice from this risk management system was to begin a defined output

and to choose a strong facilitator and multidisciplinary team members. Further steps involved looking at the process and policy of other successful organisations and examining how these might apply to this organisation in light of current guidance and statute. A number of other accounts of the application of policies with the support of insurers can be drawn upon to examine concrete suggestions for change, at least from the US literature.[156–160] Common to these accounts is a sense of enthusiasm, but also often a charismatic individual driving the process forward. There seem to be fewer of these accounts outside of the US context and we found only one in the UK, which described Liverpool Women's NHS Foundation Trust's approach to embedding quality improvement and patient safety in the organisation.[161]

In a recent critique of the Consultation Draft of the Australian Open Disclosure Framework, Parker[162] suggests that there appears to be movement towards ethical practice being prioritised over organisational and individual learning from error, rather than an organisational risk-management approach. However, a note of caution is stressed with the emphasis still being one of stating regret rather than accepting responsibility. As has been pointed out previously, expressions of regret are not apologies, as an apology presupposes the fault that health professionals are advised to avoid admitting. A criticism levelled by Parker is that this may represent a continuing insincerity on the part of health professionals and their institutions regarding the kind of apologies that patients look for, and suggests that though open disclosure policies and practices are inconsistent and unclear about complete disclosure, admission of fault and genuine apology, they will continue to lack respect for and empathy towards patients harmed by health care. Finally, it is suggested that the National Open Disclosure Standard should be revised to encourage and support full disclosure and genuine apology, but that if this fails, statutory reform should be considered. This would chime with the recommendations of the Francis report[6] in the UK.

Individual/multidisciplinary team responsibility

The Being Open framework[10] stresses the role of all staff and suggests that this should be reflected in the way that communication occurs when things go wrong. Multidisciplinary involvement is specifically drawn out. Much of the literature is focused on the role of doctors in the disclosure process; however, there is recognition that a number of other people may be involved in this. A small number of papers discuss a multidisciplinary approach but most argue for the role of an individual profession, usually a physician or a risk case manager.

Some argue that disclosure should be conducted by someone who is one step removed from the error; that contact between the family or patient and those directly involved in an adverse outcome undermines the systems approach. The delivery of health care is conducted in teams and errors typically involve several members of the team, including nurses, physicians, pharmacists and others. When an error occurs, there needs to be communication between the team members to discuss not only what went wrong but who should tell the patient or family. These interprofessional team conversations can be challenging and most team members are not experienced in conducting this type of conversation about a difficult issue such as disclosing an error. Given the complexity of these conversations and the need for consistency, there is a lack of research about how team members should participate in the disclosure process. Who should tell the patient: one individual or several team members?[69]

Whereas some suggest that disclosure should be undertaken by the clinician with responsibility for the patient's care, or a delegated representative, others warn that delegation of this responsibility to a member of the team who does not have sufficient knowledge to answer all the patient's questions may be problematic. Some policies specifically assign this task to the clinician who has overall responsibility for patient care,[163] but in certain settings other health-care professionals and/or senior administrators may be better placed to disclose, particularly if they are more knowledgeable about the consequences of the error. The same policy[163] also recommended that at least one other member of staff is present during the disclosure process. The VHA suggests that in instances with minor harm, an informal process is indicated involving the clinical team, but in more serious cases of harm the institution should be represented by one or more of its leaders in a more formal approach.[51] The Australian Council for Safety and Quality in Health Care stipulates clear guidance for the qualities and skills of the individuals involved in disclosure,[164] stating

that the individual making the disclosure should be the most senior health-care professional who is responsible for the care of the patient. In serious incidents that person should have the support of a senior staff member with good communication skills. The Council goes on to describe an individual who should be known to the patient; familiar with the facts of the incident and care of the patient; senior enough to be credible; trained in open disclosure; in possession of good interpersonal skills and the ability to communicate clearly in everyday language; able and willing to offer reassurance and feedback to the patient and family; and willing to maintain a medium- to long-term relationship with the patient where possible.

However, a contrary view[142] suggests the practitioner should not initially participate as a member of the disclosure team because the emotional stress generated from the error could result in ineffective communication or conflict. Liang[142] argues for an objective approach which is characterised as calm, non-reactive, caring and honest, and composed of senior institutional representatives such as a risk manager. Although concern for distress in clinicians is valuable, others observe that health-care practitioners who make an error may need to personally make amends and, hopefully, be forgiven by the patient. It is their therapeutic relationship with the patient that may need to be maintained to rebuild trust and preserve continuity of care where possible. Thus, others view delegation not as the rule, but as the exception.

A large body of publications comes from a risk management perspective in literature from the USA, and many of the most vocal and proactive proponents of open disclosure, with or without compensation, are from a risk management perspective. The role of risk management in the UK is less discussed and possibly less defined than in the USA. In the UK, who risk managers are and what they do may differ from trust to trust. Risk managers usually work away from front-line care. Their focus is on service quality and safety, and they occupy an important position in the handling of incidents. They assist clinicians and patients in resolving incidents, and they guard the service against undue risk. Their perspective is often couched in terms of operating a policy of disclosure while keeping liability minimised.[165] The role of clinicians involved in error disclosure, and the personal nature of their involvement, is seen as a disadvantage in some accounts, where they are perceived to weaken the approach to dealing with incidents, disclosure and blame. Risk managers may regard themselves as less personally implicated and therefore more able to be proactive about disclosure and incident investigation; however, with this comes a less pressing perception that an apology may be required. In a critique of the role, Iedema suggests that the current stance adopted by risk management dilutes the function of the role in avoiding simplistic assumptions about incident causality, service responsibility for an error and disclosure.[33] He also suggests that clarity of role remains ill-defined for risk managers and health-care professionals over the main components of patient safety related to systems thinking and just culture.[166] Other work suggests that risk managers have more favourable attitudes towards disclosing errors to patients compared with physicians, but are less supportive of providing a full apology. These differences may create conflicts between risk managers and physicians regarding disclosure. If clinicians are to be clear about the nature of disclosure conversations and encouraged to disclose then greater collaboration between risk management and clinicians needs to take place.[137] Certainly, in the USA, where communication after an event can be viewed as evidence, it is likely that risk managers will be keen to promote expressions of empathy but guard against full apologies.[167] There appears to be no exploration of whether or not such a divergence of views exists among risk managers in the UK context.

Although historically the role of discloser has often fallen to the doctor, there appears to be an increasing awareness of the role that nurses may have to play. Nurses are intimately involved in patient care and, inevitably, in the patient safety incidents that occur. This may create additional dilemmas for nurses when faced with the responsibility of disclosure and has been identified as posing challenges when continuing to provide day-to-day care.[100,168,169] Though a small number of papers make comment on the potential role of the nurse,[170,171] empirical literature exploring nurse disclosure is limited. The literature suggests that while nurses are confident in reporting safety incidents through organisational mechanisms, feelings about the contribution of nurses to disclosing those incidents are more varied. Nurses expressed a desire for a more

senior member of staff, such as the lead physician or nurse manager, to be primarily responsible for the disclosure of more serious events[99] but reported discontent with exclusion from the planning and delivery of such disclosures.[100] Uncertainty around what and how to tell patients about issues arising in their care appears to leave nurses feeling that they cannot freely address patients' queries about their care, which may result in inaccurate, incomplete or ill-timed disclosures.[100]

Disparity between the perceived potential contribution that nurses can make to disclosure and their current contribution was evident. For example, in an emergency care setting nurses reported much lower rates of disclosure conversations than physicians.[172,173] Furthermore, in simulated error disclosures nurses expressed a lack of clarity about the nature of their input and expressed fears around overstepping professional boundaries.[174] A secondary, supportive contribution was apparent across the reviewed papers, whereby nurses balanced being the patient's advocate and supporting doctors; this meant offering additional explanation and comfort to the patient, or contributing detail to the knowledge of the medical team about the circumstances of the incident or the patient involved.

Recent studies described facilitating a more active contribution for nurses in accounts of training for multiprofessional teams.[174,175] Nurses described this as a valuable opportunity to explain their contribution to an incident and be apportioned blame fairly when the patient was in contact with a number of health-care professionals, but the tendency for lead physicians to drive and manage the process of disclosure in practice was identified as a key limitation.

A hierarchical structure within health care has been highlighted in relation to junior and senior doctors and medical students, and in relation to nurses. Ineffective team working, specifically with regard to exclusion of nurses from decision-making processes, has been cited as an obstacle to nurses ensuring that events are disclosed.[100,168,174] Even when empowered to disclose an event, the likelihood of a nurse challenging the decision of a physician or taking the lead for the disclosure was perceived to be rare.[174] Nurses often perceive more than medical staff that they will be punished or treated unfairly by managers or the organisation, supporting the notion that a fair blame environment that encourages consideration of systems factors in patient care may foster a more open and honest culture.[100,169,176,177] Nurses perceive that exclusion from disclosure planning or delivery may expose them to disproportionate blame for an incident, especially where an error was made.[175,178]

Although the majority of literature within this review came from or was directed towards doctors, nurses and risk managers, a number of outputs were seen in journals specifically addressing dentists, podiatrists, pharmacists, physiotherapists, laboratory-based health professionals and general practitioners. However, there was notable bias towards secondary care literature and primary care was identified as an area that required further work.

Clinical governance

Being Open stresses the support of quality and improvement processes and the importance of disseminating lessons learned to health professionals, alongside implementation of learning and subsequent monitoring of change.

The application of this approach is articulated in the seminal documents relating to patient safety, *To Err is Human*[16] and, in the UK, *An Organisation with a Memory*.[17] The Joint Commission, one of the most influential organisations to develop patient safety-related standards for hospitals, explicitly links disclosure of errors and adverse events to hospital accreditation. They require that a 'responsible licensed independent practitioner or his or her designee clearly explains the outcomes of any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes'.[179] However, many hospitals in North America had developed error disclosure protocols addressing the patient's right to be informed some years before these documents existed, for example the Royal Victoria Hospital in Montreal, QC,[180] Minneapolis Children's Hospital and Clinics, MN,[181] and the Dana-Farber Cancer Institute in Boston, MA.[163] More recent model disclosure

programmes and policies are those of the University of Illinois Medical Center, UMHS, Kaiser Permanente, Catholic Health Initiatives and COPIC Insurance Company, which covers a number of Colorado providers.[151,152] However, the best-known examples are probably the VA medical centres.[52] In each of these examples, a set of policies and procedures has been developed to address medical errors committed while caring for patients. In the case of the VA it is required that a mistake be disclosed to the patient, usually by the leader of the treatment team. The 2008 policy of the VHA on Disclosure of Adverse Events to Patients starts out by emphasising that:

> *VHA facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future.*
>
> *VHA 2008*[51]

Litigation

One way of measuring disclosure of medical error might be supposed to be examining litigation activity. The most commonly asserted claim for the advantages of disclosure is the link between disclosure, apology and reduced litigation or malpractice activity.[52] There are number of problems with assuming this link, and indeed there is disagreement in the literature about the strength of this assertion. There is an extensive body of literature which discusses the advantages of disclosure in terms of reduced litigation. It is argued that patients who feel that they have been deprived of full disclosure and, if required, an appropriate apology may be more likely to pursue malpractice litigation.[52] Some evidence (controlled and uncontrolled) suggests that full disclosure, apology and fair compensation may result in lower litigation costs arising from medical error. The University of Michigan has reported that since it adopted a policy of full disclosure of medical error in 2001, a marked reduction in claims and decrease in legal expenses has occurred.[182] A similar experience has been reported by the Lexington VA Medical Center in Lexington, KY. After it adopted a full disclosure and fair settlement approach, the hospital had more settled claims, fewer plaintiffs' verdicts and reduced payments per claim,[183] and subsequently adopted a full disclosure policy across all hospitals in the VA system.[52] The remainder of the literature in this area tends to cite these two papers as evidence of the link between disclosure and reduction in litigation (the publication regarding VA centre experience has been cited by 399 related articles to date). However, in both of these studies disclosure was combined with financial settlement and hence it is impossible to disentangle the effects of the two. We would argue that no clear link has been established between disclosure and reduction in litigation. A review by the Canadian Patient Safety Institute in 2007 also came to similar conclusion.[184]

Advocates of a fault-based civil compensation system suggest that the award of damages is not only intended to compensate the patient but to act as a deterrent, reducing medical error and resulting injury to patients.[185] Negligence law is generally treated with suspicion by health-care professionals but is viewed by others as one system to promote the implementation of mechanisms to improve care to patients.[186] This is unlikely to persuade individual practitioners who have committed an error to disclose it to the patient, but there may be good legal reasons for disclosing error even in the face of an increased risk of litigation.[41] Although the error itself can instigate legal action, failing to disclose may deprive the patient of a timely opportunity to receive treatment for the injury, thus potentially increasing the amount of damages awarded.[187]

Few cases are resolved through a trial; many are resolved through negotiations following an assessment of risk by both parties. As a result, using reported court cases is unlikely to be useful as a way of examining disclosure effectiveness. However, fear of litigation continues to be cited as a reason preventing disclosure. Lord Woolf,[188] with reference to the UK context, has alluded to a role for lawyers with regard to their primary responsibility to facilitate a settlement rather than to encourage litigious exchanges, and has promoted better co-operation and understanding between the courts and the medical profession. Barach[189] has suggested that if the fear of litigation continues to undermine the efforts to improve patient safety through disclosure as a mechanism for learning, then transforming the present unsatisfactory situation into a culture promoting safety for patients may never be fully realised. This said, current

evidence, albeit further survey work, suggests that full disclosure seems to have little effect on the likelihood that an injured patient will seek legal advice, and although the positive results of individual systems, such as the one in Michigan, are able to describe a decrease in malpractice suits, even the most enthusiastic supporters such as Boothman suggest that it is probably overstating the case to directly link the policy to fewer claims for compensation.[190] The effect of disclosure practice on litigation in terms of numbers and value of claims is by no means clear. Studdert *et al.*,[191] in a somewhat controversial mathematical modelling study, concluded that the number of malpractice lawsuits is likely to rise if and when full disclosure occurs. However, the literature is vocal on the benefits of disclosure in reducing litigation and the size of settlements.[52,124,153,192,193] Hickson *et al.*[194] concluded that nearly half of all perinatal injury actions were motivated by parents' suspicion of a cover-up. Another study suggests that patients are significantly more likely to sue if their physician failed to disclose an error.[21] Patients want to know the facts when an injury has occurred as a result of medical error.

Scheirton[41] suggests that law follows ethics, and that as more and more hospitals adopt policies on error disclosure, and professional associations and quality assurance organisations insist on such policies, the courts may start to adopt these standards as normative. The MPS argues for changes whereby health-care managers facilitate and encourage organisations to develop policies and processes to support open disclosure alongside notification of both adverse events and near misses. Crucially, it envisages that this will include strategies which provide ongoing support, training, mentorship and investment in leadership by example. It feels that this will allow staff to be effective in participating in open discussions in health care and will allow them to fulfil their professional obligations.[195]

Duty of candour

As early as 1995, a discussion around a duty of disclosure highlighted that doctors suggested they did not have time to disclose, that they had not done so in the past and were unlikely to start without some kind of professional obligation to do so.[196] This was proposed as a measure to increase trust in hospitals and doctors and possibly defuse negligence cases. Some have observed that there may be many incentives to conceal an error when we compare the possible consequences of concealment with those of disclosure. If a clinician or organisation does not disclose an error in particular, this might never be discovered and there may be no legal sanctions or negative effects, including any impact on reputation. If the error is discovered and the patient actually sues, some have argued that the legal consequences seem very similar to those that would occur if disclosure had occurred right from the start.[197] Thus, the current sanctions for non-disclosure would seem to some to be inadequate.

The codes of a number of professional bodies and indemnifying bodies advocate openness as a professional obligation, including the British Medical Association (BMA), the GMC, the NMC and the MPS. However, in response to a persisting lack of consistency in openness with patients over error, there have been calls to introduce a statutory duty of candour in the UK. Others argue that openness should be encouraged through supporting a culture of change rather than a change in the law.

After much lobbying and debate, the UK introduced a contractual duty of candour for health-care institutions which came into effect in April 2013. This duty is imposed by the NHS Commissioning Board on all contracts with NHS providers. The Department of Health suggests this will cost £130M over a 10-year period, the cost being incurred by clinical commissioning groups taking over the contracts in breach of duty and costs associated with the disclosure of events to patients. However, it is also thought that savings will be in the region of £541M over the same period.[198,199] An amendment to the Health and Social Care Bill was rejected, meaning that no law would be enacted to require the NHS to be open with patients about errors that cause harm. A coalition of patients' charities and health organisations had lobbied for the amendment and a further new report has stressed the importance of transparency.[200] Critics argued that the measure would be woefully inadequate to protect patients' rights because it would lack statutory force and would not apply to non-hospital care providers such as general practitioners (GPs) and dentists.[201] A compromise was introduced: a 'contractual' duty of candour, a standard clause to be included in hospitals' contracts. Recent events related to the questioning of the quality and safety of care

in the NHS, and the Francis report[6] and most recent report by Berwick *et al.*,[200] may lead to this being reviewed with a view to mandating statute; however, it is to date unchanged.

Confidentiality

There was very little literature specifically addressing the area of confidentiality within disclosure of adverse events to patients. As the review concerned itself with disclosure to patients rather than the broader topic of whether or not events are disclosed to systems either local or nationally, this may be one area of the Being Open guidance which requires further examination specifically. Similarly, we did not approach whistleblowing as an area within this review. The area of confidentiality with respect to patients did raise one interesting account, which to some extent addresses how confidentiality may be more difficult to manage once the error has been disclosed to a patient or family. In one disclosure scenario where the parents of a baby had been alerted to an error while their baby was still in the care of the unit, the family alerted other families within the same neonatal unit to be vigilant about the care of their babies following this disclosure.[202] Staff described the dilemma their unit faced as they had to talk to many families as a result of one disclosure discussion, and the time this took. The implication of this did not seem to be that the parents should not talk to other patients but they did seem to be arguing that the disclosure should have been delayed until the parents did not have 'access' to other parents. However, that parents should be vigilant about the care of their children, and that they should question it, seems to be exactly the message given in the pamphlets and books produced around the world to encourage patients to contribute to the greater safety agenda. There is a real question about what harmed patients may do with disclosed information, and it seems impossible to control who patients choose to discuss their error with once it has been disclosed. The Being Open guidance[10] seems more focused on ensuring confidentiality within the organisation to protect the no-blame systems approach, but how and whether or not it applies to patients and families is less clear.

Continuity of care

It is well established that patients and families wish to have early, and complete, information wherever and whenever possible. However, what is often lacking is an understanding of the ongoing nature of the disclosure process. If patients are alerted to an error or adverse event as soon as it becomes apparent then it is likely that there are a number of facts to be established and that an ongoing discussion will be required. Further information will emerge, and in time the nature of any further treatment or compensation will need to be discussed alongside any system learning.[203] The literature suggests that it is still common for medical organisations to approach open disclosure with less than a high-level commitment and belief in the process.[27] Disclosure should begin shortly after a medical incident is recognised, and not when all the internal fact-finding and analysis are complete. Those affected need specific and timely information and the use of any generic approach is unlikely to be helpful. Clinicians require support to effectively deliver an apology and demonstrate empathy for the patient and family. In some situations this may require coaching and role playing before the first disclosure meeting.

As part of a continuing package of care and skilled disclosure process it is crucial that the care team does not abandon patients or families when something goes wrong. Disclosure needs to be viewed as a process, not a single meeting.[31] It is unlikely that affected people will understand all the components or complexities of an incident in one meeting. Organisations should expect a multivisit process, even if the clinicians are involved only in the initial meeting. A single meeting often cannot deal with more than reviewing the event, expressing an apology or expression of regret and answering questions. Subsequent meetings allow for additional questions, further information disclosure, discussion of steps taken to lessen the chance of a recurrence and possibly financial discussions. Any attempt to define a number of meetings in advance is unlikely to be helpful as different individuals and different errors will require a flexible approach. Those affected need someone who can help them collect information, find answers to questions, provide updates and help complete any financial support arrangements.[85] This person must be seen as someone who is supportive of those who have been affected, not someone who is seeking to play down the incident, obscure the content of information, or protect the medical system or clinicians involved.[156]

Amori and Popp[203] suggests that the role of a skilled risk manager who is committed to effective disclosure is in determining where the family is in the process of coming to terms with an adverse outcome. This allows both coaching and support for the staff involved, ensuring the proper timing and mechanisms for the various conversations that need to take place.[203] Whoever leads the process must be available when needed by the patient or family, even when the timing is inconvenient.

Summary

A huge body of work exists which discusses open disclosure of adverse events; however, key messages, although useful and positive, are often handed down as received wisdom on the basis of little theoretical underpinning or research. There seems to be broad agreement that open disclosure is the 'right' thing to do. However, justifications often sit within a context of reducing costs to organisations in terms of lawsuits. If being open is the right course of action, and in some contexts the legal one, then perhaps it does not require such evidence and the focus of research should lie more within implementation and monitoring and the most effective and acceptable models of training. Gallagher *et al.*[204] have identified that more work is needed to examine how open disclosure is operationalised in practice, and how staff negotiate the systems within which they operate as well as interactions with patients. Research needs to focus on how we can best capture dimensions of quality in relation to disclosure conversations and whether or not these are measurable.

Phase 1: review 2

Results of the search

After deduplication, 10,527 records were identified. Screening of the titles and abstracts identified 21 references that potentially fulfilled the inclusion criteria for this review and copies of the full papers were sought. A total of 10 studies (11 publications) fulfilled the eligibility criteria and were included in the review.[52,205–214] In two studies the intervention was disclosure (combined with another intervention)[52,208] and in eight studies (nine publications) the interventions were intended to promote or support open disclosure.[205–207,209–214] Two studies included a comparator group[52,212] and eight were uncontrolled before-and-after design.[205–211,213,214] Two literature reviews were identified[117,215] and one of the included studies[52] was identified from the reference list of the review by Kachalia *et al.*[117] Three references to completed research funding grants were identified.[216–218] Authors identified as the award holder were contacted but we were unable to identify any publications for inclusion. One ongoing study was identified.[219] *Figure 4* explains the study selection process.

Excluded studies

Eight studies were excluded after reviewing the papers.[98,220–226] Seven studies were excluded on the basis of the study design. One study[225] was excluded as the intervention was not open disclosure or an intervention to support open disclosure. A list of the excluded studies detailing the reason(s) for exclusion is available in *Appendix 10*.

Ongoing studies

One ongoing study was identified. Researchers in the USA are undertaking a randomised controlled study of training physicians in disclosure.[219] The intervention includes a disclosure training webcast, practice and feedback with standardised patients, and a refresher training webcast. The primary outcome is patient satisfaction with a disclosure that they experience, measured using the Patient Assessment of Disclosure Quality. The project was due to complete in 2012.

Included studies where the intervention was disclosure

Two studies included disclosure as an intervention,[52,208] combined with another intervention; in both cases this was an offer of financial compensation (*Table 1*).

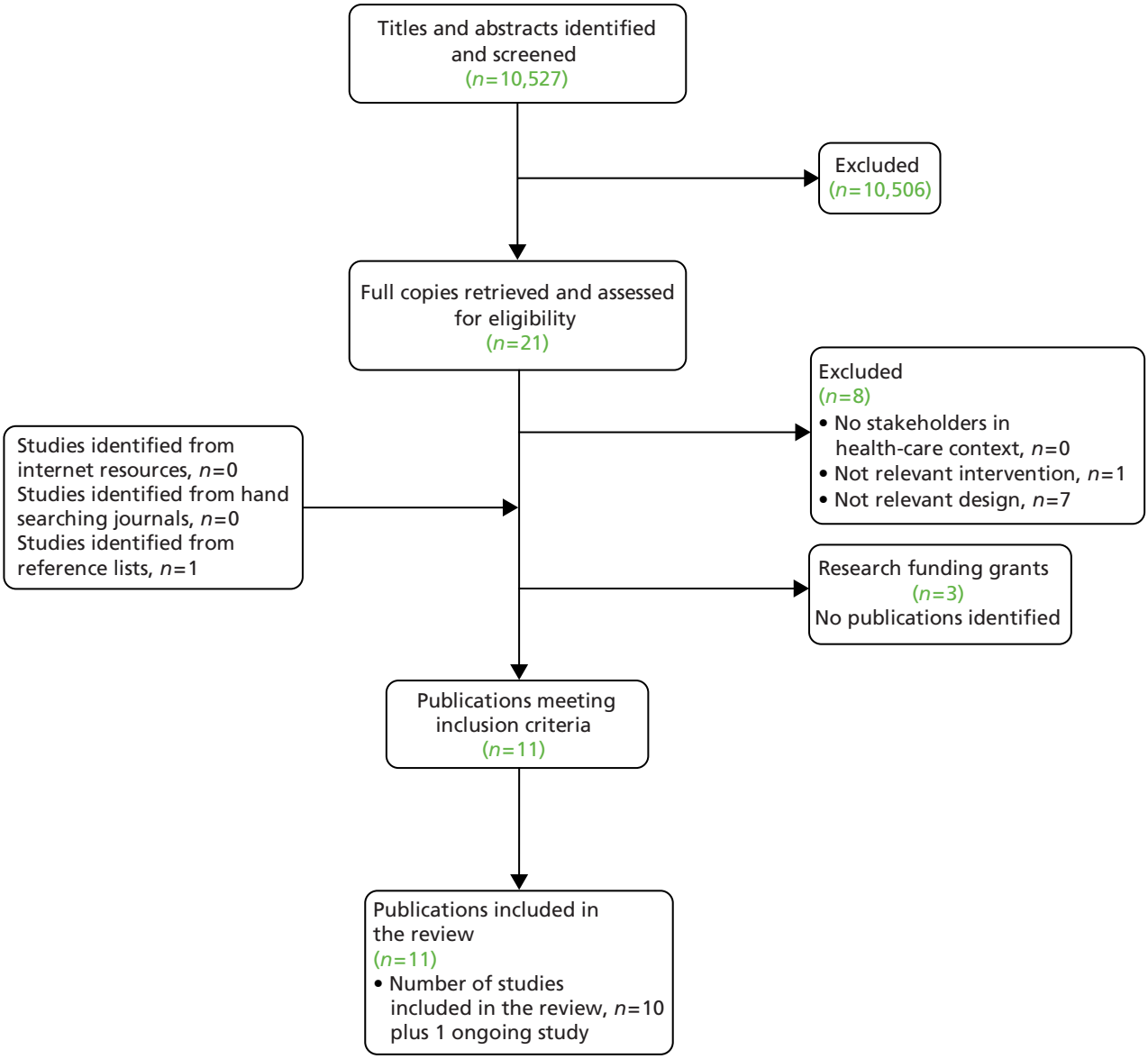

FIGURE 4 Study selection flow chart.

TABLE 1 Included studies where the intervention was disclosure

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Kachalia 2010[208] USA	Uncontrolled before-and-after	Public academic medical centre and health system (UMHS)	Disclosure-with-offer programme Programme first introduced in July 2001, and by February 2003 disclosure programme fully integrated with patient safety efforts. Identifies patient injuries through various means. Experienced risk managers lead investigations and mediate patient concerns as facts are collected and conclusions are disclosed. Settlements, if made, generally occur in the institution's name, not those of individual caregivers	1. Number of new claims: new claims before and after implementation	1. 633 claims before, 498 claims after. Total claims: before 7.03 (95% CI 5.98 to 8.08) claims per 100,000 patient encounters; after 4.52 (95% CI 3.96 to 5.08) claims per 100,000 patient encounters [RR 0.64 (95% CI 0.44 to 0.95)]. The changes in rate were only significant for claims which resulted in lawsuits. Lawsuits: before 2.13 (95% CI 1.58 to 2.67) lawsuits per 100,000 patient encounters; after 0.75 (95% CI 0.47 to 1.03) lawsuits per 100,000 patient encounters. (Annual lawsuits 232 before, 106 after.) (Assuming open cases resulted in a lawsuit: before 233, after 1410.) Claims that did not result in a lawsuit: before 4.90 (95% CI 4.17 to 5.63) claims per 100,000 patient encounters; after 3.77 (95% CI 3.27 to 4.26) claims per 100,000 patient encounters [RR 0.77 (95% CI 0.52 to 1.14)]
				2. Number of claims receiving compensation	2. Before: 632 closed and 319 compensated (50.5%, 95% CI 46.5% to 54.5%); after: 463 closed and 198 compensated (42.8%, 95% CI 38.2% to 47.4%), $p = 0.012$. Average 53.2 paid claims per year before and 31.7 after
				3. Time to claim resolution	3. Median time to claim resolution was 1.36 years (IQR 0.72–2.44 years) before initial implementation and 0.95 years (IQR 0.55–1.96 years) after initial implementation. Rate of resolution increased after programme implementation with an adjusted hazard ratio of 1.27 (95% CI 1.11 to 1.45, $p < 0.001$)

continued

TABLE 1 Included studies where the intervention was disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
				4. Liability costs	4. Median and mean total liability costs decreased after full programme implementation (RR for mean costs 0.41, 95% CI 0.26 to 0.66, $p < 0.001$), attributable to decreases in both legal and patient compensation costs. After initial programme implementation, total cost rates significantly decreased (difference in trend –0.449, 95% CI –0.806 to –0.092, $p = 0.014$) as did legal (difference in trend –0.066, 95% CI –0.111 to –0.022, $p = 0.004$) and patient compensation (difference in trend –0.383, 95% CI –0.715 to –0.050, $p = 0.024$) costs In a sensitivity analysis excluding outliers, results were qualitatively similar for claims overall, type of claim (lawsuits and non-lawsuits) and type of costs (legal costs and patient compensation).Total costs associated with lawsuits decreased after full implementation (RR 0.27, 95% CI 0.13 to 0.54). Total costs for non-lawsuit claims did not decrease (RR 0.81, 95% CI 0.47 to 1.38)
Kraman 1999[52] USA	Retrospective cohort	Intervention ($n = 1$): VA medical centre, Lexington, KY Control ($n = 38$): VA medical centres located east of the Mississippi River between 1990 and 1996	Intervention: risk management policy Where patient injury is caused by accidents or negligence the following procedure is followed: • notifying a patient of negligence • face-to-face meeting • claims assistance Control: no organised effort to standardise or track the notification of affected patients	Tort claim experience during 7-year period: tort claim data from Department of Veterans Affairs tort claim information system	Liability payments at intervention facility were moderate and comparable with those of similar facilities

CI, confidence interval; IQR, interquartile range; RR, rate ratio.

Kachalia 2010

Kachalia *et al.*[208] compared civil claims and costs at UMHS before and after implementation of a disclosure-with-offer (of compensation) programme (July 1995 to September 2007). Once fully implemented, the disclosure-with-offer programme was fully integrated with other efforts to improve patient safety. Experienced risk managers with clinical backgrounds led the investigations and mediated patient concerns through a process of collation of facts, evaluation of care quality and disclosure of the conclusions. The authors report that UMHS emphasises honesty and transparency with patients and staff, regardless of whether or not events resulted from error. After full implementation of the programme, the average monthly rate of new claims and lawsuits both decreased. Time to resolution decreased and average monthly cost rates also decreased for total liability, patient compensation and non-compensation-related legal costs. The authors acknowledge that the study design cannot establish causality.

Kraman 1999

This was a retrospective cohort study[52] of the effects of a new risk management policy intervention which was implemented at one Department of Veterans Affairs facility in Lexington, KY. The policy had two components: disclosure of the incident to the affected patient (or family) and assistance with filing a claim for compensation. The comparator group comprised 38 facilities where there was no organised effort to standardise or track the notification of affected patients. The main outcome was tort claim experience during the 7-year period, measured using data from the Department of Veterans Affairs tort claim information system. It was reported by the authors that liability payments at the intervention facility were moderate and comparable with those of similar facilities (analysis based on 35 facilities in the comparator group). No data were provided; however, a bar chart depicting liability payments ranked the intervention facility eighth out of 36 (first = lowest liability payments, 36th = highest liability payments). The authors draw attention to issues with the comparator facilities and the analysis which should be taken into account in interpreting the findings.

Included studies where the intervention was intended to support or promote disclosure

Eight studies (nine publications) were included in which the interventions aimed to promote disclosure.[205–207,209–214] One included a comparator group[212] and seven were uncontrolled before-and-after design.[205,207,209–211,213,214] Study characteristics are provided in *Table 2*.

Setting

All studies took place in North America, seven in the USA and one in Canada.[213] The majority of studies took place in educational establishments, six in training schools/colleges or universities[205,207,209–212] and one in a specialised simulation-based training centre.[214] In one study it was unclear from the published report where the intervention took place.[213]

Participants

The majority of participants were students from a variety of health-related disciplines including medicine, nursing, pharmacy and dentistry.[205,207,209–212] Two studies recruited qualified health-care professionals (paediatric oncology nurses, and postgraduate obstetrics and gynaecological residents).[213,214]

Interventions

In all eight studies the interventions were delivered as educational or curricular modules and workshops (either solely about disclosure or incorporated into a broader theme of patient safety). They included features such as didactic lecture sessions, pre reading materials, DVD materials, observation, small-group work, and discussions and role play or simulated training to practise open disclosure, often including feedback sessions. Further details of content are described in *Table 2*.

TABLE 2 Included studies where the intervention aimed to support or promote disclosure

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Gunderson 2009[205] (plus Gunderson 2008[206]) USA	Uncontrolled before-and-after	Students ($n = 18$) from the six health sciences colleges (medicine, nursing, pharmacy, applied health, public health and dentistry) at the University of Illinois at Chicago	Educational module on full disclosure Conducted as part of a 30-hour 2-week patient safety elective in spring of 2006. The 3-hour module consisted of: 1. pre reading 2. large group interactive lecture with facilitated discussion and training DVD 3. small groups for practise of the components of full disclosure using case scenarios 4. reconvened as a large group for discussion and debriefing 5. learning acquired reinforced throughout remainder of the elective	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)	1. Total summary score ($n = 14$): pre 11.5 (SD 2.9), post 15.4 (SD 1.3), change 3.9 (2.7–5.0), p change < 0.0001 i. Four domains of full disclosure confidence ($n = 14$): – understand full disclosure: pre 2.2 (SD 0.8), post 3.8 (SD 0.4), change 1.6 (1.3 to 1.9), p change < 0.0001 – do a full disclosure: pre 2.8 (SD 0.8), post 3.8 (SD 0.4), change 1.0 (0.7 to 1.3), p change < 0.0001 – admit an error to a supervisor: pre 3.3 (SD 0.7), post 3.9 (SD 0.4), change 0.57 (0.3–0.9), p change = 0.001 – admit an error to a patient: pre 3.2 (SD 0.8), post 3.9 (SD 0.3), change 0.71 (0.4–1.1), p change = 0.001
				2. Standardised patient case: standardised patient encounters were observed and subjectively evaluated by the course directors	2. Pre-course patient case: all 14 students failed to include the four essential elements of full disclosure and 13 (93%) failed to deliver a personal apology for the error. Postcourse patient case: two (14.3%) students failed to include the essential elements of disclosure and one (7.1%) student failed to deliver a personal apology to the standardised patient

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Halbach 2005[207] USA	Uncontrolled before-and-after	Third-year medical students ($n = 572$) attending 4-week family medicine clerkship in years 2000–1, 2001–2 and 2002–3	4-hour curriculum to raise awareness about medical errors and patient safety: 1. brief required reading 2. introductory 1-hour lecture/discussion 3. videotaped simulation with a standardised patient. Three-hour exercise including orientation to case material, review of skills required, 10- to 15-minute (per student) videotaped encounter with standardised patient and small-group feedback session	1. Self-awareness about patient communication and safety: seven-item questionnaire. Five-point scale: 1 = extremely aware, 5 = not at all aware. Two items relate to communicating medical error; awareness of own strengths and awareness of own weaknesses in communicating a medical error to a patient	1. Awareness of own strengths and weaknesses in communicating a medical error to a patient i. Awareness of strengths (mean, range): – 2000–1: before 3.4 (1–5), after 2.41 (1–5), change 0.99 (1–4), $p < 0.01$ – 2001–2: before 3.32 (1–5), after 2.24 (1–5), change 1.08 (1–4), $p < 0.01$ – 2002–3: before 3.28 (1–5), after 2.33 (1–4), change 0.94 (1–4), $p < 0.01$ ii. Awareness of weaknesses (mean, range): – 2000–1: before 3.35 (1–5), after 2.33 (1–5), change 1.02 (1–3), $p < 0.01$ – 2001–2: before 3.28 (1–5), after 2.14 (1–5), change 1.14 (1–4), $p < 0.01$ – 2002–3: before 3.28 (1–5), after 2.31 (1–5), change 0.97 (1–4), $p < 0.01$
				2. Evaluation of the curriculum: 13-item evaluation	2. 89% agreed or strongly agreed that 'the opportunity to present an error to a patient increases my confidence about discussing this issue with patients'; 82% felt that the lecture 'provided a good introduction to the issue'; 58% agreed or strongly agreed that 'the readings provided on this issue were helpful'; 94% reported the standardised patient exercise to be 'a valuable learning experience'

continued

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
				3. Students' experience with medical errors since their clerkship: 12-item anonymous follow-up questionnaire	3. 84% of respondents (259/307) reported that they strongly agreed or agreed that they had an increased awareness of errors in medicine; 67% strongly agreed or agreed that they were more aware of patient safety issues; 28% had witnessed a colleague make a medical error often or very often; 17% had themselves made a medical error often or very often in the course of other clerkships; 7% reported having discussed an error with a patient or a patient's family; 97% agreed or strongly agreed that it is important to teach students about medical errors; 87% agreed that the third year is the more appropriate time to discuss medical errors
				4. Confidence regarding error in medicine: Graduation Questionnaire of the Association of American Medical Colleges given to fourth-year students. One question relates to prescription error. Asked to respond to the statement 'I am confident that I have the appropriate knowledge and skills to discuss a prescription error I made with a patient' using a 5-point Likert scale: 1 = strongly agree, 5 = strongly disagree	4. National average 1.9 in 2001–4; average in students was 2001 = 2.1, 2002 = 1.7, 2003 = 1.8 and 2004 = 1.7

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Kiersma 2009[209] USA	Uncontrolled before-and-after	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 scenario – role play scenario on how to manage and communicate errors; (iii) feedback session on pharmacy observation assignment	1. Students' knowledge of medication safety: 16 open-ended items and true/false questions	1. Pre-test mean 12.1 (SD 3.2), post-test mean 13.3 (SD 2.4), average score improvement 1.2, $p < 0.0001$; 66.9% demonstrated post-test improvement. Individual item scores were also looked at. The percentage of students answering correctly increased on 12 of the 16 items. Of these, four were significantly different. These were 'non-preventable drug reactions are error' (91.3% to 99.4%), 'non-preventable injury is an error' (91.3% to 99.4%), 'in hospitals what percentage of doses given are incorrect' (25.0% to 95.6%), and 'in the community management experts believe errors occur how often?' (78.1% to 91.3%)
				2. Students' confidence in medication safety: 10 questions based on laboratory objectives	2. Significant differences between pre-test and post-test, $p < 0.0001$ on all items. 'I can appropriately communicate to patients about a medication error' pre-test mean 2.5 (SD 0.7), post-test mean 3.5 (SD 0.9). 'I can appropriately communicate to caregivers about a medication error' pre-test mean 2.4 (SD 0.7), post-test mean 3.4 (SD 0.9)
				3. Laboratory evaluation: seven statements with scale 1 = strongly disagree to 5 = strongly agree	3. Students indicated the information and skills learned in the lab can be applied to real world situations (mean 4.8, SD 0.4) and were relevant to their education (mean 4.8, SD 0.4). Students rated the overall laboratory positively (mean 4.8, SD 0.4). Students indicated that integration of the pharmacy observation assignment helped them understand concepts (mean 4.4, SD 0.4)

continued

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Madigosky 2006[210] USA	Uncontrolled before-and-after	Second-year medical students ($n = 92$)	Patient safety and medical fallibility curriculum (10.5 contact hours). Addressed five main themes: patient safety overview, error reporting systems, vs. human approach, safety tools and ethics/disclosure. Involved mixture of lectures, panel discussion, demonstration and interactive forums. 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	1. Knowledge, skills and attitudes: 28-item questionnaire. Five multiple choice questions to assess knowledge, five to measure comfort with skills (1 = very uncomfortable, 5 = very comfortable) and 18 to measure attitudes (1 = strongly disagree, 5 = strongly agree)	1. One skills item evaluated comfort with skills disclosing an error to a patient ($n = 53$): i. pre-test mean 2.08 ii. pre-test to post-test mean change 0.79 (95% CI 0.48 to 1.10) iii. Pre-test to 1-year post-test mean change 0.45 (95% CI 0.14 to 0.77)
				2. Assessment of self-reported behaviours: % of yes or no responses to questions about whether or not they used what they learned (at 1-year follow-up)	2. 56% (40/72) reported having used what they learned. 76% (55/72) reported observing a medical error. Of these, 71% had disclosed an error to a fellow student, 56% to a resident and 46% to a faculty member, and 7% had made a report to the system
				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	3. ($n = 88$) 72% agreed that the course improved their ability to meet the learning objectives either well or very well; 73% agreed or strongly agreed that it was useful in their medical education; 82% agreed or strongly agreed that it would benefit their future career; 72% recommended it be continued. Most important things gained were understanding that everyone makes mistakes and that error reporting and disclosure are important. Suggested improvements included changes in the timing, shorter sessions, less lecture and more small group, more on communication issues and more time for using reporting system

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Moskowitz 2007[211] USA	Uncontrolled before-and-after	Third-year medical students ($n = 229$)	1-day programme on patient safety. Included two plenary sessions, lunch discussion with dean of medical college and two 1-hour workshops selected from a list of nine topics (one topic was discussing medical errors with patients)	1. Attitudes and beliefs: survey containing 21 Likert-type scale items and two open-ended items related to a specific medical error observed by the student	1. Item for disclosing 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[212] USA	Controlled before-and-after	Intervention ($n = 51$): third- and fourth-year medical students and physician assistant students rotating on the general surgery service from January 2007 to June 2008 Control ($n = 24$): third-year medical students	Intervention: Medical Errors Educational Intervention 2-hour session comprising small-group discussion with slide presentation. Slides covered six major medical errors subjects including error disclosure. Frequent breaks throughout session allowed students opportunity to describe their own experiences with medical errors Control: no medical error education tool	1. No clear statement. Knowledge about medical errors? 12 multiple choice questions	1. Intervention and control groups i. intervention group: – Pre-test mean 29.4% correct (3.5 correct of 12 possible, SD 1.6) – short-term post-test mean 73.7% correct (8.8 correct, SD 1.9), $p < 0.001$ – long-term post-test ($n = 35$) mean 49.1% (5.9 correct, SD 1.9), $p < 0.001$ ii. control group: – pre-test mean 28.1% correct, 6-month post-test mean 26.4% correct, $p = 0.6446$

continued

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
Posner 2011[213] Canada	Uncontrolled before-and-after	Obstetrics and gynaecology residents (postgraduate years 2 to 5): year 2 ($n = 4$); year 3 ($n = 2$); year 4 ($n = 2$); year 5 ($n = 6$) Female ($n = 8$); male ($n = 6$)	2-hour workshop on disclosure Facilitated by a physician risk manager. Objectives of the workshop were to review the circumstances when a 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	1. Were residents able to follow the suggested CMPA guidelines and incorporate the necessary steps that are considered to be integral parts of 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. Twenty-one-point dichotomous checklist of performed tasks. Disclosure meeting videotaped and reviewed by two investigators who jointly agreed on the score for each resident	1. Pre-test disclosure mean 12.4/21 (59.1%) (range 8–17; SD 2.7); post-test disclosure mean 16.9/21 (80.1%) (range 13–20; SD 2.1); $p < 0.01$
Wayman 2007[214] USA	Uncontrolled before-and-after	Registered nurses on paediatric oncology ward at children's hospital ($n = 16$). All female. Fourteen (88%) had fewer than 5 years of experience, two had more than 20 years of experience. Representative of 36% of the nurses working on the ward at the time	Simulation-based medical error disclosure training 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 incorporated as actors in the simulation scenarios	1. Perceived self-efficacy in communication: 14-question self-assessment survey that was developed for the study. 0 to 100 points per question	1. A statistically significant improvement was seen in the total mean score from before the intervention to after the assessment ($p < 0.001$)

TABLE 2 Included studies where the intervention aimed to support or promote disclosure (*continued*)

Author/year/country	Study type	Participants	Interventions	Outcome: outcome measure	Reported findings
				2. Extent to which participants reported that the training evoked their 'true' verbal and non-verbal skills: three questions on a 5-point scale	2. Composite index score 13.1 (SD 1.8) out of a possible 15
				3. Intervention validity – the extent to which participants consider the physical environment, scenarios, parent actors and content of the training to resemble what they encounter in their day-to-day work: perceived fidelity index (five questions). Answered on a 0-to-5, disagree–agree scale	3. Composite mean score 21.0 (SD 2.2) of a possible 25
				4. Internal validity. Measure consisted of two parts: i. an assessment of training component effectiveness (seven questions on the scenarios, parent actors and debriefings) ii. overall effectiveness of the training (including relevance, engagement, communications skills and ability to transfer skills)	4. Composite mean scores: i. 32.8 (SD 3.0) out of a possible 35 ii. 18.7 (SD 1.7) out of a possible score of 20 94% rated actors as realistic, 56% rated scenarios as realistic. All components of the training were rated highly

CI, confidence interval; CMPA, Canadian Medical Protective Association; SD, standard deviation.

Outcomes/outcome measures

A variety of outcomes were evaluated related to knowledge about safety and disclosure, perceived self-efficacy to perform disclosure and confidence in dealing with error and disclosure. These included perceived self-efficacy to understand full disclosure, conduct a full disclosure, admit an error to a supervisor and admit an error to a patient,[205] self-awareness about patient communication and safety,[207] students' knowledge of medication safety,[209] students' confidence in medication safety,[209] comfort with the skills of disclosure,[210] attitudes and beliefs about patient safety,[211] knowledge about medical error[212] and perceived self-efficacy in communication.[214] Four studies also carried out descriptive evaluations of the curriculum.[207,209,210,214]

Outcome measures were nearly always designed for the study itself with no validation reported. These included a true/false questionnaire,[209] multiple choice questionnaire[212] and a number of rating scales.[207,209,214] Role play in which participants enacted disclosure with patient actors was measured by subjective evaluation,[205] a checklist of performed tasks extracted from the guidelines for disclosure of adverse events developed by the Canadian Patient Safety Institute[213] and a Likert-type scale self-assessment of comfort with skills of disclosure.[210]

Reported findings

All studies evaluating outcomes such as knowledge and confidence reported positive results, comparing pre- with post-test scores. Although one study included a comparator group, results were presented for within-group analyses only and did not compare the outcomes for intervention versus comparator groups.[212]

Summary

This review examined evidence for the effectiveness of open disclosure and interventions to support open disclosure. To our knowledge, this is the first time a systematic review of this topic has been undertaken. Findings from this review indicate that there is almost no evidence for the effectiveness of open disclosure, nor of interventions intended to support or enhance open disclosure. This finding is in line with a previous, wide-ranging review of the open disclosure literature.[35]

Phase 2: qualitative interviews

We generated an extremely rich data set. From our initial analysis of the sampled interviews we identified six primary themes and produced descriptive summaries of our data relating to these, using subheadings to help organise the material.

The primary themes are briefly described below.

Primary theme: broad understandings of open disclosure

When asked what they understood by the term 'open disclosure', stakeholders were all able to give an answer, and most talked about honesty and transparency. Despite some variations in its conceptualisation, from a very broad principle to a discrete set of behaviours, there was agreement across the sample that open disclosure in principle was the right thing to do. Most respondents defined the term open disclosure in terms of being 'honest' and 'transparent'. Typically, open disclosure was reduced to quite a simple set of values to be applied to practice.

Although widely understood, the conceptualisation varied. Some respondents suggested that it is a patient's right to know what has happened in the course of their care, whatever the outcome. Others articulated a position of openness as a way of providing an opportunity for patients to be involved in their care, recognising that patients may have a unique perspective and know or capture different information to that available to and from health professionals.

Other respondents conceptualised open disclosure in the context of, and with reference to, the Being Open policy framework. These respondents conceptualised open disclosure in terms of specific behaviour and processes. They tended to focus on how and when the process of open disclosure should be initiated and how it should proceed. A number of participants indicated the importance of face-to-face discussion and that a dialogue should follow between patients and/or families and those providing or overseeing care provision. Dialogue was described as critical in enabling patients and their families or carers to engage with health professionals, to ask questions, to be listened to and to promote the understanding of all parties.

The idea that there is 'no one size fits all' and that the disclosure process must be flexible and responsive to individuals' needs was identified.

Respondents identified the importance of health professionals choosing language carefully when communicating with patients and families, specifying the need to avoid using jargon or technical terms which can hinder understanding and be misinterpreted.

Primary theme: motivators

A dominant theme throughout the interviews was the role and conduct of the person or team who was responsible for disclosing information to a patient. Respondents discussed the motivators for health professionals to disclose, placing emphasis on the proposed relationship between open disclosure and the likelihood of litigation. Explicit links were made between openness and health professionals' self-preservation. Respondents commonly expressed beliefs that being open and honest might minimise complaints and the likelihood of litigation, and that this was a main driver for health professionals and managers. Openness with patients was also described as the essence of behaving professionally and providing a good standard of care.

Primary theme: the Being Open guidance and framework

Although nearly all of those interviewed seemed to have a good understanding of the term 'open disclosure', very few were familiar with the Being Open guidance – the exceptions being those patients and families interviewed who had first-hand experience of error and identified a lack of its application, and those involved in developing the guidance or associated policies. Only a minority of health-care managers indicated any degree of familiarity with its 10 guiding principles. Health professionals rarely had any knowledge of these nor of the existence of any national guidance; however, some respondents were aware of a local Being Open policy at their trust, and despite a lack of awareness of the NPSA Framework, most participants talked about open disclosure in terms that reflect the concept as delivered through the 10 principles.

Primary theme: 'good' disclosures

Although respondents lacked clarity around the Being Open guidance, it was clear from the numerous accounts of direct and indirect involvement in disclosures that there some common features which marked a better or worse disclosure. From these accounts, it was evident that open disclosure can take many forms and that the several different approaches described by interviewees were perceived to yield positive outcomes. The common features described as important for delivering effective and appropriate disclosures included the degree to which (a) responsibility was accepted on behalf of an individual, team or organisation, (b) language was used that patients understood, (c) an apology was given, (d) the reasons for the event were explained, and (e) the patient perceived the health provider to be genuine, transparent and compassionate.

The opportunity to prepare for a disclosure was described as important by some respondents, including taking time to consider what to say and who should deliver the information, speaking to other members of staff and having opportunities to pre-empt how the information might be received before approaching the patient or carers. Any recommendation of this approach may, however, present a dilemma. The desire to prepare for disclosure, while potentially enhancing the discussion, may also lead to negative feelings and uncertainty for the patient if dialogue with them is delayed as a consequence.

Although some common features of more effective disclosures were evident, scrutiny of accounts of disclosure suggest that the parameters of a 'good' disclosure are extremely difficult to delineate. Even in those disclosures perceived as effective, the tendency to attribute blame to team members and to deliver patients a monologue rather than engage them in dialogue was apparent. Moreover, qualities such as the degree to which patients perceive the provider as genuine and compassionate are subjective and complex to evaluate.

Primary theme: uncertainty

Although respondents expressed clarity around some common features of good or poor open disclosure, uncertainty and confusion about how to manage specific situations was apparent. Uncertainty was expressed specifically in relation to identifying an adverse event, handling complex circumstances, defining the circumstances in which disclosure is needed and deciding who should speak with patients and carers. Issues around the timing and nature of an apology were identified as a further source of confusion.

Definitional uncertainties

Considerable uncertainty was expressed by many stakeholders around defining when to be open and what constitutes an incident of the kind that needs to be disclosed. The primary concern appeared to be how to define an incident when little or no harm has been caused.

Circumstances of the event

Respondents recognised the complexity of the system in which disclosure is to be enacted. There was widespread acknowledgement from most respondents that health care is a complex system and unpicking events in any health-care incident is made more arduous by its complexity. The diversity of events that occur within this system creates a lack of clarity around how to proceed with disclosure in any given situation, as each circumstance is unique.

In spite of the complexity that characterises health care, some respondents suggested that the standardisation of process would aid the disclosure practice.

Although each situation is unique, common situations that presented dilemmas were reported, particularly missing information and the delayed discovery of an event. Missing information about what has happened was often mentioned by respondents in the context of decisions around whether or not to disclose and when to begin the disclosure process. Our findings revealed uncertainty and mixed messages around the level of information needed to begin the disclosure process.

Patients and families reinforced the notion that disclosure should begin as soon as it becomes apparent that something has gone wrong, even if not all the facts are clear. They were unequivocal about the need to be included from the outset in the process, the dialogue and the incident investigation.

The late discovery of an event was also a source of uncertainty. A number of respondents discussed the difficulties associated with making a disclosure when the event only became apparent after some time. The challenges associated with a late discovery included patients not being on site, uncertainty about how to make contact and uncertainty about whether or not to tell them at all.

Primary theme: professional and organisational context

Features of the professional and organisational context appeared to be significant drivers of decisions made around whether or not to be open with patients and the circumstances in which to do this.

Patient–professional relationships

The patient–professional dynamic was frequently discussed. Despite espousing openness, stories told by health professionals and managers directly involved in the practice of disclosure (or decision-making about disclosure) suggested that decisions about whether or not to share information with a patient, what information to share and when to do this were made by health-care providers. Dilemmas were generally

presented when the patient had come to no harm and would not otherwise find out that something had gone wrong. The perspective presented in such circumstances reinforced the position that information about the patient was perceived as the property of the health-care provider rather than of the patient.

The health-care team's judgement of the degree of resulting patient harm appeared to be a central driver of practice. Current guidance from the GMC,[95] local policy and national Being Open guidance[10] suggest that health providers must inform patients of events which caused them harm. Some respondents in management roles referred to these sources of guidance as a reason for not talking to patients about non-harmful events and for health professionals to use their own judgement regarding what information to disclose.

The changing dynamic of power relations between doctor and patient also created a sense of confusion for some professionals about the type of information to provide to patients. With more access to information, particularly from online sources, patients were described as more questioning and active in decisions about their care and as having higher expectations of the care they received. Both health professionals and managers described not always knowing how to respond appropriately, particularly when issuing information about things that have gone wrong.

Overview of main findings

There was inevitable overlap in terms of the issues that featured under the primary theme headings. Further consideration supported the development of a more theorised analysis that may help to explain why implementation of the Being Open framework, and indeed the principles of open disclosure more generally, are not consistently evident in practice. The analysis highlights the complexities of interpreting and acting on widely endorsed moral principles that underpin calls for open disclosure, and the inevitable limitations of attempts to promote good practice by prescribing quite standardised communication procedures.

Support for the values that underpin calls for open disclosure

Our interviews revealed broad-based and strong support for the idea of open disclosure. Strong associations were made with moral concepts of honesty, openness and transparency.

> *Being honest and open . . . the basics of being a good human being. You should be honest and open whether you're a builder, or an engineer or a pilot, it doesn't really matter, that's just being a good person.*
>
> *Manager 1*

> *The principles behind it are laudable, understandable; I don't think there's anything that you can argue against on sort of moral grounds, on ethical grounds, transferring that into practice is much more difficult than you would expect.*
>
> *Health professional 6*

These broad value statements were associated, by some, with the rights of individuals to know about all aspects of their care and the obligations of health professionals to tell them about all matters that affect them or influence their care. Both health professionals and patients suggested that it is a patient's right to know what has happened in the course of their care, whatever the outcome; that they have ownership of any information in relation to their health and their body.

> *Deference to professionals is definitely moving away. There's a sense in which people have a sense of having rights . . . and patients regard themselves as having rights to this information as I think we would probably say that they do, both legal rights to information that's relevant and also moral rights to information.*
>
> *Professional organisation 2*

If we don't adopt sort of an open approach to mistakes and errors we are never going to treat them as human beings because they have a right to know, it's their bodies, not ours, we only look after it but it belongs to them. And it should be treated with respect and so should their wishes and feelings.

Health professional 2

Anything that happens in the course of health care, including errors and omissions in health care, it should be the absolute, unequivocal right of the patient, or in the case of them being dead or lacking capacity, then their next of kin know about.

Patient organisation 1

The links between learning from safety incidents and improving care for the future were also apparent, and were linked to patient involvement in promoting safer care. Some stakeholders in senior positions (often slightly removed from the clinical front line) identified coming from a general stance of openness as an identified way of engaging with related concepts of patient ownership of health-care decisions and entitlement to a fully informed perspective. This included the view that patients may have a unique perspective and know or capture different information.

If the patient is still on the ward and you know the patients and the relatives become involved in it . . . and they can often help us as well.

Health professional 3

The patient or the family say . . . had you asked me, I could have told you that when I came into A&E [accident and emergency], I did report the symptoms . . . sometimes it's one person's word against another, you know. It may be recorded in the notes, patient attended A&E; didn't report this symptom, that symptom; full record taken. But the patient will say, oh no! I did say exactly I was having a bad headache or, you know, I was reporting these symptoms. So even from a practical reason, it's bad practice not to involve people from an early stage.

Patient organisation 2

The other thing we need to do is be much better at involving patients in their own safety so giving them permission to challenge us when they think something's going to go wrong . . . patients might just get a better sense of where the risk areas are but most of the evidence suggests that it improves their safety.

Professional organisation 3

Multiple meanings of open disclosure

Individuals held various ideas about what open disclosure entails in practice. When people talked about open disclosure in terms of communicative actions or processes, there was no consistent, clear, comprehensive definition in evidence. References to a number of features of communication were present in many of the accounts of examples of open disclosure, and were lamentable in their absence from accounts of examples where disclosure was deemed not to have occurred.

The common features described as important for delivering effective and appropriate disclosures included the degree to which (a) responsibility was accepted on behalf of an individual, team or organisation, (b) language was used that patients understood, (c) an apology was given, (d) the reasons for the event were explained, and (e) the patient perceived the health provider to be genuine, transparent and compassionate. The quote below provides a typical description of a 'good' disclosure that is representative of many of the examples given; the features commonly emphasised by respondents across the sample are shown in **bold** text.

*If we take where I had to go and do it because I had made a mistake or played a part in the mistake, it was a young lad with his mum and I just said, you know . . . it was about analgesia and because it clearly hadn't worked so I had then subsequently given him the right intravenous formulation and I said '**I'm really sorry**, as you know I came to review you because your pain relief didn't seem to be working and I know now why it wasn't working and **I'm sorry to have to tell you that we gave a drug that's normally taken orally, I gave it into your vein**'. That didn't really mean anything to them so **I tried to explain why that was important and why that shouldn't happen**, told them what I'd done about it and really in that particular instance it was about the main reason there's a problem in this particular drug is that it wasn't made . . . usually the problem is around sterility, is it made in a sterile environment, if it's going intravenously. So I had to wait for someone from pharmacy to ring and talk to the manufacturer and in fact this was made in a sterile fashion. **So I explained it to him I said 'You don't seem to have come to any harm from what has happened but clearly it is something that wouldn't normally . . . this should not normally happen'** and I told them why it had happened, **the nurses giving the drugs for some reason despite it saying 'IV [intravenous] morphine' had thought I must have meant Oramorph and given it to him**. **My part was that I didn't ask to see the little vial of morphine** which you would normally get with an intravenous morphine so I had played a part and I think I just told them what had happened and told them what would happen as a result so **that it would be reported formally** and **we would have a look at it to see if there were any things we could put in place to stop it from happening again** and I just apologised and they were fine and I never heard anything else about it.*

Manager 10

Instances in which poor disclosures were described reinforced the importance of accepting responsibility, explaining things clearly, and instigating and maintaining contact with the patient and family as early as possible.

*He came in for surgery . . . and it didn't go quite right. It was part of the risks, one of the things that went wrong is part of the risks that they do, they sign the consent and are given the information and I think that **was the start of it because I don't know how much this gentleman actually realised could go wrong with what he sees as quite routine surgery** . . . So it started off quite badly in that sense **because his family have said well we didn't realise that was one of the side effects**, that was one of the risks. So he was then **passed from the orthopaedic department to the vascular department and again the vascular people were saying well actually it is the orthopaedic department**, they have made a bit of a blunder and then of course the orthopaedic department are then saying no **you can't say that because it was a risk** . . . actually the patient has got quite a **bad history**, a lot of comorbidities and so it was a **disaster waiting to happen**. And it's been going on . . . he's had recent meetings where **nobody has actually been clear**. Now in the patient['s] and the patient's relative['s minds] it's that, **we are not being clear to him** because we've got something to hide. And actually when you come down to it we haven't got anything to hide at all. But that is **how they perceive it, that we are hiding** and we are actually not . . . you know you can bring people in but **they have this preconceived idea that hospitals don't make mistakes or if they do we hide it**.*

Health professional 3

A number of respondents (mainly policy-makers and managers) were keen to 'pin down' exactly what should be done to ensure open disclosure and saw the prescription of a standardised process as the key to this.

> *What I am clear on is that when you are in distress, process is really important. And if it's one thing that happens in one trust and it's different to another trust or whatever, I think the public are bemused and upset . . . so I do think we should certainly have some sort of standardisation of process . . . if you walk through the door of Primark, it says Primark, you know what you're going to get. If you walk through the door of Hugo Boss, you know what you're going to get, you know, it varies in cost and quality. If you go through the door that says NHS, you don't think it's going to vary in terms of cost and quality from another door that says NHS . . . So we should have standardised processes around handling something like this.*
>
> *Policy stakeholder 5*

However, others, specifically clinicians, emphasised the complexities of practice and insisted there could be no 'one size fits all' approach for disclosure, with each encounter requiring careful situational interpretation and value judgements which would always be needed to communicate appropriately about safety problems.

> *I think we should work towards that being a kind of professional value and responsibility rather than something that is enshrined in some sort of legislative framework because I think it is too difficult to put in there. And I think every circumstance needs individual interpretation on what the best thing to do . . . my concern is that kind of legal, making it a legal duty would lead to inappropriate responses sometimes for patients.*
>
> *Health professional 10*

We suggest that the distinction between agreement about the importance of several moral concepts that supported the case for open disclosure and diversity of opinion about how these concepts should be interpreted and reflected in practice is one important key to understanding why the NPSA's Being Open guidance, or even the concept of openness more generally, is not consistently implemented. When individuals want to act well they appear to be attempting to integrate a number of values into their decision-making and action. Judgements about the particular situation are context dependent and interpretive, and consider how a particular action may be related to other matters, morally or otherwise. As people do not always agree about what is required to reflect moral values, these can be variously interpreted and multiply realised in practice, although some actions are quite closely tied to particular moral concepts.

We draw on this distinction again below when we consider uncertainties and tensions in judgement; however, before doing so we consider the policy itself and its use.

The Being Open Framework and its use

Very few of the stakeholders we interviewed were familiar with the Being Open document. A number suggested this was because they did not have time to read all the policy documents that were issued and relevant to them. Some of the principles of Being Open were reflected in local trust policies on open disclosure, and we stress again that both types of guidance reflect the underlying moral concepts that were widely endorsed by stakeholders.

> *Being completely open about what's happened, why it's happened and informing those involved and affected.*
>
> *Manager 2*

> *It is common sense . . . it is basically just about not lying to people, being honest, being open, being explicit and sorting out problems when they occur.*
>
> *Health professional 1*

One reason offered for the limited use of Being Open was the fact that it was not designed for timely, practical application at the time of the safety incident.

> *In common with other policies we have in this organisation . . . it's just not easy to draw out the information you actually want on the spot. So when an incident happens, you don't have time to go and spend an hour wading through the policy and picking out the key points and making a plan, what you need is just do this, do that, do that first.*
>
> *Manager 8*

> *If you start getting into fifty pages for a policy, nobody's going to read that, they won't have time to read that and I think it's about taking what's in the national stuff but also then translating that to what's workable locally . . . thinking about anything that can make it more manageable for the staff on the ward, sometimes it might be a checklist, sometimes it might be a flowchart, as I say, something that people can see at a glance and think, 'that's what I need to do' or 'this is the person that I need to ask'.*
>
> *Manager 9*

Some of the stakeholders who were familiar with the Being Open document raised concerns about the scope of application and particularly the way it made different recommendations for incidents of different severity. Incident severity was consistently identified as a key determinant in deciding whether or not to follow the guidance. Notably, most health professionals and managers reported enacting the principles espoused through the Being Open guidance in circumstances of moderate or severe patient harm. Respondents repeatedly indicated that the Being Open process was not followed for near misses or minor incidents. Furthermore, it was often argued that disclosing events that were minor or did not result in harm may not be in the patient's or the organisation's interests.

> *The Being Open policy does say that there is no obligation to report, to let people know about near misses . . . or I think the low harm ones, again, it's whether it does more harm than good.*
>
> *Manager 8*

> *As things stand at the moment, we would expect to disclose to a patient any harm, moderate or severe harm, that has been caused by the treatment that they have received from us . . . I would imagine that (the Being Open process) happens more where there's a serious incident . . . If there was very limited or no harm we would expect clinicians to use their discretion as to whether it is in the patient's best interest at that moment, and I think that is based on the national policy.*
>
> *Manager 6*

> *I do not think that if things are minor or near misses you necessarily want to think about that in terms of patient involvement, but for serious incidents the family is told by the investigating team at CSU [commissioning support unit] level that an investigation is being undertaken and that the results of that investigation will be shared with them.*
>
> *Manager 4*

Uncertainties and tensions in judgements about whether and how to discuss safety issues

Between them, the stakeholders we interviewed identified a range of issues that they deemed salient to considerations of whether or not and how safety issues should be discussed with patients and family members. These included, but were not restricted to, ideas about why health professionals or managers did not behave well. There was widespread recognition of uncertainty and complexity, especially in relation

to the multiple values at stake in the complex situations referred to earlier in which decisions about the 'right thing to do' are being made. The diversity of events that occur within health care creates a lack of clarity around how to proceed with disclosure in any given situation as each circumstance is unique.

> *Health care is just not that cut and dried, so when something goes wrong it's usually a bit of a jigsaw.*
>
> *Policy stakeholder 2*

Respondents also recognised the complexity of the system in which disclosure is to be enacted. There was widespread acknowledgment from most respondents that health care is an intricate system and unpicking adverse events that occur within it is made more arduous by its complexity.

The main issues appear to be interlinked but we have separated them here to allow for examination of each in turn.

The first main consideration seems to involve *whether or not* the event or issue should be disclosed or discussed. Considerations include the type of incidents which need to be discussed and why, the implications for the patient and his or her family, which health professionals and health services are involved and whether or not there are opportunities to learn from the incident.

Simply identifying what it was necessary to disclose presented a source of confusion for a number of those interviewed across all stakeholder groups, with the exception of patients and families. Although the guidance appears to offer clarity on this in principle and suggests 'providing a full and frank explanation of the circumstances without regard to any other factor which might have influence in the situation',[10] many of those interviewed identified exceptions to this and circumstances in which it was not always considered necessary to disclose.

> *I am not saying that we would absolutely always at all costs think well we've found this we'd better let the family know, I think you've always got to weigh up what the risks and benefits are of talking to the family as well.*
>
> *Manager 11*

> *Somebody reports an incident because there was a delay in taking somebody to theatre because the theatres were full and then that person deteriorated and died, and you know they might be aged ninety-five and came in seriously ill in the first place with an acute abdomen, and yes it's a report of an incident because there's no barrier, people can report anything they like and they report it as an incident involving inappropriate delay . . . what do you go to the relatives and say, do you say well I'm terribly sorry she died, she was very seriously ill and elderly but there was a three-hour delay before theatre which isn't desirable. Well I suppose that is what you would say being open but then where does that leave the relatives thinking for the rest of their life that their mother or father would have you know lived another two years if it hadn't been for a three-hour delay in the hospital?*
>
> *Policy stakeholder 4*

> *I think truth will out and so I support the concept of openness and as an institution we will support it very, very strongly. But you will always get examples where you know it may not be in the interests of the patient to reveal all.*
>
> *Professional organisation 4*

Uncertainties around what types of incidents should be disclosed were often related to particular areas; for example, where there was a near miss or the patient appeared to have suffered no harm.

> *As things stand at the moment, we would expect to disclose to a patient any harm, moderate or severe harm, that has been caused by the treatment that they have received from us . . . I would imagine that [the Being Open process] happens more where there's a serious incident . . . If there was very limited or no harm we would expect clinicians to use their discretion as to whether it is in the patient's best interest at that moment, and I think that is based on the national policy.*
>
> *Manager 6*

> *I didn't disclose it actually but we had a patient who . . . was receiving chemotherapy for leukaemia and she was on the ward and . . . the chemotherapy came up for her and one of the nurses had to make it up as pharmacy had sent it up to be reconstituted on the ward, and the nurse did that . . . and she came to me a little bit later and said 'I've just thought about it and actually I've given the wrong dose'. And we sat down and worked it out and she'd given too much but not enough that it would make any difference. It wouldn't put the patient at risk but it was a bit more than she should have had and she was a very anxious girl . . . she'd had a rough time . . . I know she'd been through a lot and . . . she was quite emotionally fragile and we discussed what we should do about it and whether we should tell her or not. And we . . . decided between us really that . . . it would probably be detrimental to tell her that it had happened because she was so emotionally fragile we felt she might lose a bit of confidence, she'd be upset, she'd be worried . . . and we thought it would probably just do more harm than good by telling her about it really.*
>
> *Health professional 9*

> *Sometimes . . . the risk is that . . . you might undermine the confidence in the system that's one thing, perhaps you undermine . . . the patient's confidence in you as a practitioner . . . you make the patient feel anxious and insecure without any real benefit . . . if you undermine that trust what's the benefit.*
>
> *Health professional 10*

> *They [health-care team] had a patient who fell off the operating table. Now potentially that is very serious, you can do huge damage if you are unconscious and you fall like a sack of potatoes from a height like that onto a stone floor in an operating theatre. But there wasn't any damage and it was then questioned whether the patient needed to be told that they had fallen off the operating table because there was . . . no actual consequential damage to the patient . . . and that is a grey area which I think is quite difficult to work out.*
>
> *Professional organisation 5*

Situations where events might be seen as routine or unavoidable imperfections in care were also highlighted.

> *You know one surgeon said to me when this was first being discussed, he said: 'well if I was taking out somebody's gall bladder and I made a tiny nick on the liver which bled for two seconds and then I cauterised it and it stopped would I have to go to the patient afterwards and tell them this is what had happened?' He said, 'because that would happen kind of twenty times in an average operation.' I said well of course not you know that's just normal dissection in surgery that's not an error or an avoidable incident. He said: 'well what if the scrub nurse reported me to the GMC and then I was accused not just of doing it but not disclosing it, what would happen then?'.*
>
> *Policy stakeholder 4*

The arguments that there are more or less severe harms, and that disclosure may cause a particular patient more harm were individual and complex. If the situations were considered as a spectrum, it would be possible to ask questions of a similar situation, replacing variables to try to identify at what point a situation becomes an event that requires disclosure. However, if the relationship between patient and

health-care professional or organisation is viewed as one of transparency and is focused on facilitating involvement in care generally, then the 'step up' to disclosure of minor events may not be required. The discussions may take place within ongoing conversations rather than being viewed as 'incidents' per se.

There will be gains and losses for both patients and health professionals in decisions about whether or not to disclose. For example, we might ask what the patient could gain or lose from the discussion of the error described above by health professional 9 in relation to the chemotherapy dosing error. It is possible to argue that the right to know what has happened to you as a result of your care is a matter of treating patients with dignity, of an individual or organisation respecting the fact that it is the right of an individual to know about events, whether they harm or not. Although this may vary across situations and patients, needing to know that things have occurred in order to be able to move forward responsibly is highlighted by some and there is an increasing expectation that patients and families will be informed.

> *I see it as being entirely open and honest about things that have happened in health care. Which have caused harm or may have caused harm. It's as simple as that, that people's treatment and health care belongs to them. It doesn't belong to the institution or the health professional who has been treating them, and with that goes the information around what happens. Anything that happens in the course of health care, including errors and omissions in health care, it should be the absolute, unequivocal right of the patient, or in the case of them being dead or lacking capacity, then their next of kin know about.*
>
> *Professional organisation 1*

> *Deference to professionals is definitely moving away. There's a sense in which people have a sense of having rights . . . and patients regard themselves as having rights to this information as I think we would probably say that they do, both legal rights to information that's relevant and also moral rights to information.*
>
> *Professional organisation 2*

> *Some patients are real experts on their conditions, more than we could ever be. That dynamic has changed and therefore being open is way more relevant than it used to be.*
>
> *Policy stakeholder 2*

Health professionals may perceive a number of negative consequences from the disclosure of safety events. Professionals often identified impacts in terms of their professional identity, even in cases where they were not at fault or where no consequences arose for their employment, or no litigation or investigation ensued. However, professional self-integrity is also maintained by doing what a professional perceives to be the right thing.

There are a number of issues specific to the health-care organisation which principally concern reputation and litigation. There appears to be uncertainty in relation to the impact of disclosure on organisational issues. There are general ideas that being open and honest with patients will lead to less litigation but also a recognition that this cannot be guaranteed. Respondents explicitly discussed the value of openness for minimising the likelihood of becoming involved in complaints or legal proceedings.

> *The fact that he had discussed it [the error], had been open about it, hadn't tried to conceal it, meant that the patient wasn't moved to make a complaint.*
>
> *Professional organisation 3*

> *I think if we are not being open there are all kinds of consequences and one may be a complaint. But you know could be legal action, whatever. Which is one of the many reasons why being open makes sense.*
>
> *Manager 6*

We are taught that if you're open and honest and frank with your patient and apologise if appropriate then the subsequent difficulties in terms of litigation and what have you for the doctor will be reduced.

Professional organisation 6

I've learned that it's [being open] 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.

Health professional 4

If you are very honest and straightforward and treat the patients right then often they feel that, they take a generous view towards the mistake as opposed to getting very litigious about it, which I think they are more inclined to do if there's a big cover up and people aren't honest.

Health professional 1

I think the culture is, you say sorry, you explain what's happened and you do it promptly and openly and honestly . . . I think the understanding now is that it's much less likely to go to litigation if you are open and honest and say, 'I'm sorry'.

Manager 2

Health professionals described situations in which they perceived that an open and honest disclosure had enhanced patient satisfaction with the outcome, the ongoing patient–practitioner relationship and the way that the event was handled. Critically, even in such instances, health professionals described their initial fear that open disclosure might actually invite complaints or litigation.

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 . . . just let it be and hopefully things will quieten down. But you know every time I've done this has been a positive and rewarding experience, I've not regretted it.

Health professional 5

Through 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 kind of legal action and not taken grievance with the 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'.

Health professional 4

Despite concerns regarding the likelihood of openness inviting complaints or legal action, many health professionals recognised the patient's and carer's right to take legal action and distinguished this from their decision to be open and honest.

I think there are going to be times where I might meet with a family . . . who have got a threshold for complaining . . . who would you know take this opportunity with both arms and take it forward to a full litigation process and what have you but that is their right at the end of the day and it shouldn't in principle put me off being honest and upfront with my patients.

Health professional 5

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.

Health professional 2

> *If errors have been made, and those errors are to lead to long-term health problems, then it seems to me entirely appropriate, or where it's appropriate, for patients to make claims for compensation, in order that they can, quite directly, be compensated for errors that have been made.*
>
> *Professional organisation 2*

However, links between communication processes in relation to disclosure of error were not uniformly linked to outcomes at the organisational or the patient level. Patients will vary in their propensity to take legal action and what satisfies in one context cannot be guaranteed in another.

A number of respondents indicated a clash between the principles underpinning open disclosure and maintaining their professional identity, reputation and relationships with colleagues. Openness about incidents was perceived by some to have broader implications for breaching professional loyalties and to some degree siding with the patient. This concern may add an additional complexity and sense of confusion about the appropriate course of action to take following an adverse incident.

> *There is a sense in the medical profession I think, that they look after their own. They look after their own. They look after their own interests. I still think there's a kind of us and them between doctors and patients . . . at the moment I still think there is a kind of defensive mechanism, defensive instincts that you should cover up, look inside, protect the interests of the profession and the hospital and I still think it can be very difficult for patients to make inroads against that. My sense at the moment is that there's a lot of, there are big changes taking place, but they haven't bedded down in certain kinds of areas, and I don't think there's an instinctive culture of openness and candour.*
>
> *Professional organisation 2*

Therefore, in each context individuals will consider the attitudes of their colleagues, the stance that they perceive their employer will take or has taken and the likelihood of litigation, although this is not an exhaustive list of variables.

The opportunity to learn from error or improve care is also a factor in decisions about disclosure of patient safety events. Transparency around errors was identified as particularly important at the early stages of the process in facilitating learning.

> *I think as well, it's [openness] important because medicine has not always been great at learning from its mistakes. And partly that's been because there has been a culture of concealing them.*
>
> *Professional organisation 2*

> *[Not] being open with patients or families is, on the one hand, fairly terrible dereliction of duty to another human being, and a dereliction of ethical and moral duties. But it's also perpetuating a culture where people go into denial – where people refuse to accept that there's been error, or when there has been error, fail to investigate the root causes and any lessons that there might be to help prevent reoccurrence.*
>
> *Patient organisation 1*

There was notably less reference to disclosure as a proactive way of engaging with patients to enhance the quality and safety of their care, and that of service delivery more broadly, than to benefits associated with reduction of complaints or litigation.

The first issues may be moderated by how disclosure is or is not conducted. There were uncertainties and value tensions in relation to a number of areas. For example, deciding who should disclose error involved judgements balancing closeness to the patient, seniority, competence, well-being of the patient and available support for health-care professionals involved.

Many felt strongly that information should be delivered by the senior clinician closest to the patient if the incident was serious, and that junior staff should not lead formal disclosures. Others highlighted individual responsibility.

> *The obligation is on the person who made the mistake . . . I think there's a problem, documented to the point of absurdity, that dehumanising in medicine and dehumanising particularly in the hospitals, and if a doctor or another health professional makes a mistake, and three months later, someone, an administrator comes round to your house and knocks on the door and says, 'oh by the way, a mistake was . . .' it seems to me you further entrench those kinds of . . . if I make a mistake, and I harm somebody, then I've got a responsibility to discuss the mistake I've made with them.*
>
> *Professional organisation 2*

However, other respondents highlighted that junior staff may often be present or directly involved in an event and therefore make a critical contribution to its disclosure. Moreover, some respondents suggested that decisions around who should be involved in a disclosure should be undertaken on a case-by-case basis to ensure that the most appropriate person or team is involved.

> *If something's been designated as a serious incident and there's been an incident investigation and there's a formal 'being open' meeting set up with the relatives, that's where I think you can't leave junior staff unsupported to do it on their own. But, on an everyday basis, they're the actual first people who would probably see that something's gone wrong and so, of course, if they do, you can't, well, we shouldn't have a system which says they shouldn't apologise.*
>
> *Policy stakeholder 3*

> *There isn't clear guidance but we almost don't mind that so much because sometimes if you say it has to be the lead consultant that person may not be the best person, they may not have the best communication skills or they may be too emotionally involved to do it so sometimes it's better to have lots of flexibility in that and sometimes the family has been really close to a certain nurse who's actually quite gentle and they might, their communication skills might be amazing, they might be the perfect person.*
>
> *Policy stakeholder 2*

The different standpoints presented regarding responsibility for disclosure are likely to give rise to confusion among health-care team members when presented with an adverse event.

Apology appeared to be critical to a good disclosure. Patients expressed an understanding and acceptance that mistakes will be made but were unanimous in their expectation of an authentic and timely apology. In situations where individuals had fought for insights into health-care incidents, the lack of any genuine and sensitive apology was often highlighted as particularly distressing.

> *'All these meetings,' he said [Chief Executive], 'and you've never had an apology', but he said, 'if that's what you want I'll go over and write you a letter of apology now'. I thought just go you condescending, patronising man.*
>
> *Patient 2*

> *Never had a proper apology, a genuine apology . . . given a sort of a one-paragraph apology from the legal authorities . . . signed by the chief executive but it was clearly dictated by a solicitor, and it was the minimal possible grouping of words that would technically satisfy the NHS's requirement that apologies are given for accidents, but it was meaningless.*
>
> *Patient 3*

> *And the apology came after two and a half years . . . one two-sentenced paragraph and one one-sentence paragraph, and it started off with the chief executive two and a half years down the line said: 'it has come to my attention that', as if oh suddenly somebody's just dropped this on my desk, I didn't know anything about it and, 'the standard of care was not everything it should have been', and that's life-changing disabilities, and 'there have been some unfortunate side effects'. I mean that's how he actually phrased it!*
>
> *Patient 3*

Many other stakeholders suggested that an apology is a necessary and unquestionable aspect of disclosure.

> *We really need to question how we've got to a situation where we're even questioning whether we should apologise or not. Why are health-care staff having conversations about whether it's appropriate to offer an apology 'cause it should be a no brainer.*
>
> *Policy stakeholder 3*

> *The expectation on anyone and everyone in the NHS should be, you apologise and you apologise early on, irrespective of what your role is.*
>
> *Policy stakeholder 2*

> *If you've got someone who is man enough to say, 'look this is what's happened and we are very sorry, it shouldn't have done, we are taking steps to sort it out and so it doesn't happen to anyone else, we are willing to accept blame', you will then get people who will say, 'well all right, they made a mistake and it is not good, it shouldn't happen but it did. And we can move on, and we feel that our concerns have been addressed properly' . . . a simple 'I am sorry' works wonders . . . just tell them the truth, they are not idiots.*
>
> *Health professional 2*

Despite this recognition, uncertainty over whether or not to apologise, when to apologise, who should offer an apology and what this might include persists. A number of respondents discussed the variation in apology depending on level of harm.

> *So the way that the 'being open' policy is structured is . . . you have a formal 'being open' discussion with patients and carers when they suffer from moderate harm, severe harm or when a patient's died . . . if there's minor harm, then you just leave it up to the health-care team and if there's no harm, then they can just make a decision about whether an apology is appropriate on a case-by-case basis. So, in some ways, one of the weaknesses with the policy as it's written, is that we've linked the level of apology to the level of patient harm.*
>
> *Policy stakeholder 3*

We also identified the reluctance of staff to reveal that something has gone wrong in the process of care as inhibiting apology.

> *I don't think often that members of staff do apologise, I think things are still covered up to a degree.*
>
> *Health professional 2*

Organisational incident reporting systems were described as a barrier to giving a timely apology, as the reporting process and subsequent investigation (where relevant) was perceived to inhibit open discussion of events with patients and carers. Having to wait until information was gathered and documentation completed before issuing an apology was seen by some respondents as creating unnecessary delay. Incorporating apology into the uncertainty of the situation following an error is supported by some, and the need to apologise on different levels at different times in a process was stressed.

> *The internal bureaucracy that we've created around incidents and incident reporting, and claims and complaints, and time frames to respond to these things, acts as a barrier . . . it just creates a level of bureaucracy that can sometimes get in the way of a prompt apology.*
>
> *Policy stakeholder 2*

> *What I think needs to be clear is what you're saying sorry for is the outcome and I don't think that's clear, so you're saying, I'm sorry this has happened, this is awful, I'm really sorry this person's died, we don't know what happened but we're going to find out.*
>
> *Manager 3*

Linked to the earlier issue of more general transparency in health-care consultations, guidance on apologies was seen to miss the point if saved only for moderate and serious harm.

> *I think what is wrong with the 'being open' policy . . . the expectations should be on health-care staff to apologise even for minor things and the policy as it currently is written is that there's no requirement to offer an apology or it's left down to fight the local jurisdiction as a team . . . if there was no harm. But, if you can actually instil a culture where, even if someone's delayed in outpatients, someone offers them an apology and that's not an incident, that's just an efficiency issue. And, if people get into that habit of good customer service, then maybe it'll be more ingrained in NHS staff to apologise irrespective of the severity of outcome. And it'll make apology exercising more pervasive per say.*
>
> *Policy stakeholder 3*

Organisational, professional and policy support (what can be done to promote open disclosure?)

Policy is able to provide guidance to support the disclosure of adverse events to patients. However, rigid recipes for what to say and do will inevitably be limited and can lead to problems if they are not used in combination with discretion and judgement. Employing guidance for the disclosure of adverse events requires a number of sophisticated moral and value judgements which are contextual, usually unique and may or may not lead to a desired behaviour. Individuals are required to recognise a problem and also the individual components that make a particular issue a problem in that situation. As well as making their own judgements, they may be required to support junior colleagues to make judgements, individuals who may not have the experience or confidence to do so. Guidance conflates moral concepts with behaviours, and thus inevitably runs the risk of not being consistent in its outcomes. Therefore, the problem is not that individuals behave badly, but that the guidance fails to address the conflicting but multiple defensible values at play.

Organisational culture and managerial leadership can act as a facilitator of or a barrier to open disclosure and good disclosure practice. A reluctance to be open and honest about mistakes made in care can be due to fears of the repercussions for the health professional(s) involved. This may even extend to deliberately concealing mistakes in an attempt to protect their job or reputation.

> *[We] had to dismiss a number of staff who have made medicine errors . . . not . . . as a result of the medicine error, it's been as a result of them trying to cover up and hide the fact and the potential harm that could have come to the patient because they've either hidden it or falsified documentation to try and hide it.*
>
> *Manager 5*

> *Sometimes there's a culture of well if 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 . . . if you are there in a situation where you know that something is not right and you daren't say anything because you are frightened of what might happen to you, you won't say it, it's your job. And I think that goes with colleagues as well, you may have a colleague who is not performing well but you don't always say something because you don't want to upset them.*
>
> *Health professional 2*

There may be numerous reasons for a health professional's decision to conceal either their error or that of a colleague, but the most feared repercussions were of damaging professional standing or of disciplinary action. Current organisational support systems to support health professionals dealing with the experience of making an error may be inadequate.

> *There's a sort of culture of disclosing mistakes in most trusts but where I think things probably fall down if you look at the most extreme cases is in terms of support for doctors and other health-care professionals.*
>
> *Professional organisation 4*

> *I don't think we do talk very openly about these things at the moment and the levels of support are poor . . . I think at the moment the feeling is just go to an occupational health service but doctors don't do that, just don't do it . . . I think you need better support services for doctors because a lot hangs in our decisions, both in terms of consequences for patients and use of resources . . . I think there's certainly benefits for the health service in providing better support and certainly a duty of candour without appropriate support would be, I don't think would be useful or productive.*
>
> *Professional organisation 6*

> *The big gap is how we support staff. I think we're really not good at that and I think we think they're more robust than they are over these things because they don't show it outwardly, they go away and feel it deeply. I think we don't know the toll it takes on staff until it is too late.*
>
> *Policy stakeholder 2*

Health professionals commonly described the feeling that they experienced when realising they had made an error and the concerns this raised for them as an individual. Failure to manage these concerns may present a greater likelihood of either non-disclosure or a poor disclosure of the incident to the patient and/or carer. An individual who is struggling to manage his or her own anxiety is unlikely to provide the support required by patients and families in the event of a health-care incident.

> *Where I think doctors get very worried . . . is about the prospect that is then going to lead to litigation, a referral to the GMC . . . if you then say to a patient I am sorry, I blew it, I should have seen that sign, I should have picked this up earlier. If by apologising and saying . . . that's a lesson I must learn and if you think then those words are going to be quoted in a GMC hearing . . . then you are much less likely to say I am sorry I blew it, you are much more likely to say I am really sorry about what happened to your husband, it is really tragic what happened but actually I did everything I could and you . . . take a defensive pose.*
>
> *Professional organisation 7*

> *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 . . . there's still a concern I guess for everyone that there will be a whole weight off something coming on them.*
>
> *Health professional 11*

Furthermore, respondents identified links between reluctance to discuss mistakes and the inhibition of an open culture leading to reduced likelihood of learning from events.

> *I think as well, it's [openness] important because medicine has not always been great at learning from its mistakes. And partly that's been because there has been a culture of concealing them.*
>
> *Professional organisation 2*

> *[Not] being open with patients or families is, on the one hand, fairly terrible dereliction of duty to another human being, and a dereliction of ethical and moral duties. But it's also perpetuating a culture where people go into denial – where people refuse to accept that there's been error, or when there has been error, fail to investigate the root causes and any lessons that there might be to help prevent reoccurrence.*
>
> *Patient organisation 1*

> *I imagine if you're a unit that works on total honesty, total disclosure you'll probably find the quality of care in that unit is far better because it is just symptomatic of openness which can only be good.*
>
> *Professional organisation 4*

> *Staff often seem to be very doubtful about whether they should actually tell people about what has happened. So I would say the more scared staff are about what the consequences might be for them, the more chances are that they're unlikely to tell the person something has happened.*
>
> *Patient organisation 2*

The need to develop a culture of improvement and transparency with relation to error and unintended harm was clearly articulated by the majority of respondents. The importance of incentivising the desired behaviours is crucial to success. When staff or patients are concerned or suspect error the organisation needs to be receptive and welcome reports. This would be echoed in current patient safety thinking which emphasises feedback and learning, but existing systems, particularly those used to capture patient feedback, need to be improved.

> *There first of all on the whole needs to be a no-blame culture which is often misunderstood, it doesn't mean nobody's ever held to account because there are negligent acts but when there's a genuine error, that well you know was in good faith as it were, then I think first of all not to take appropriate disciplinary action and then to provide the sort of counselling and support.*
>
> *Policy stakeholder 4*

> *And it's about placing responsibility on organisations to ensure that staff aren't unfairly dealt with if they have unintentionally been involved in mistakes which have led to harm. Or unfairly dealt with if they've been open about incidents with patients and families where the organisation is worried about the consequence for itself. A lot of this is about raising awareness, about facilitating a change in culture, about showing understanding and support for people.*
>
> *Professional organisation 5*

It was also noted by some that patients should be given access to information regarding the incident report, and be included in its dissemination and learning.

> *I think we could be much more transparent not just about reporting the incident but also reporting what subsequently happened and how people have been allowed to learn really.*
>
> *Policy stakeholder 5*

Creating an open environment which facilitates staff to feel confident about being honest with patients and colleagues after making a mistake, and able to handle uncertainties associated with adverse events, was recognised as a key prerequisite to facilitating open disclosure.

There was little evidence of any training for staff in disclosing events, with many admitting that they did not know such training was even available.

> *I've never, me personally, I've never received training along those lines.*
>
> *Health professional 6*

> *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.*
>
> *Health professional 12*

> *No there isn't any training, the only training is life experience, nursing experience and, as you go along.*
>
> *Health professional 3*

However, training was highlighted, described as being necessary to improve both the culture and the practice of open disclosure. There was demand for training to be administered locally and internally by trusts, and to be inclusive, involving clinical and managerial staff at all levels.

> *They've got to have training and to understand what the policy means to them at their level, and what they should be dealing with at their level, and what they should be escalating to more senior people to come in and support them . . . handling a patient's negative impression of something at an early point is so important.*
>
> *Professional organisation 8*

Different people expressed different opinions as to the best way to implement training to support open disclosure. A bottom-up approach, where training takes place on the 'shop floor' and juniors learn by example from their seniors, led by clinicians, was contrasted with a more top-down approach. Few made a case for continuous training integrated into basic training and reiterated as part of ongoing development, including individuals from across the organisation to ensure a uniform and coherent message in terms of practice.

> *To be honest, it's people who've led by example. So, consultants who've shown that actually they're open and honest and they're still practising, they haven't been struck off . . . it's partly leadership by example and I mean I was, I did have particularly good bosses for a lot of the time I was training, so I did pick up some particularly good habits and I try to pass them on to my juniors. And juniors pass through lots of consultants, so if they pick up good things off each consultant, they should pick up a lot of good things and that should help disseminate good practice.*
>
> *Health professional 7*

> *It all boils down to see one, do one, teach one, which the educationalists say that but actually I think that worked quite well for doctors for a few hundred years. You watch people who are good at things and you think, 'that went well, I might do that myself'.*
>
> *Health professional 4*

> *I think the policy needs to be clear, I think it needs to be. I think it's up to senior people in an organisation to train people within that organisation so that they understand at their level what is expected to comply with that policy of openness.*
>
> *Health professional 12*

What might be useful is in formulating effective training programmes for junior medics, junior nurses, medical students, that sort of thing. I should think a lot of that sort of stuff's been hijacked by non-clinicians and doesn't reflect the reality of the situation often and there are some people that are very good at it.

Health professional 4

I think if we are going to talk about training you'd need to talk about it at undergraduate level so it would need, in my personal opinion it needs to be written in at the bottom end of medicine not at the top end.

Professional organisation 5

Doctors should ideally get it just through their training . . . inductions and so on are the ideal place to introduce how to report a problem and just encourage doctors that that's something that they can do without fear and all the rest of it.

Health professional 7

If you are really going to get into the culture you've got to do it at undergraduate level, you've got to do it to medical students who then grow up with those ideas and it's the same as any other education in life, if you take small children you can educate them much more freely than everyday teenagers because they will mop the knowledge up more easily. And I think that is true of undergraduate and postgraduate medicine as well, I think undergraduates will take it on board and accept it as part of the culture . . . so I think that is where it needs to be pitched at.

Professional organisation 5

Conception of formal training appeared isolated, specific to professional groups and stand-alone. We suggest that this is likely to perpetuate the professional tensions between groups already evident in the literature. Methods involving video filming practice in real-time and inviting clinicians to feedback on their own performance, discussion of complex events in multiprofessional groups, and reflection on the knowledge and questions that patients and families have about their care and about unexpected outcomes and clinical incidents, address the considered exploration of the evident tensions in patient safety events. Such methods could be used to underpin specific training in relation to disclosure conversations and encourage reflexive practice.

The wider concept of a statutory duty of candour was multiply described and has been a point of debate throughout the life of the project. This was raised as a broader contextual factor that might influence decisions around disclosure. Most policy-makers, patients and families expressed unremitting support for a statutory duty. In contrast, most health professionals and managers expressed reservations, although there were some exceptions to this. Those in favour of a legal duty of candour argued that it would be the most effective way of initiating culture change around open disclosure.

Passing a law doesn't change the culture, but the creation of that law has helped create a change in culture, a change in attitudes. It's a demonstration that society is no longer prepared to accept that behaviour. Similarly, with using seat belts or drink-driving, it wasn't the passing of the actual legislation that led to people changing their behaviour. It was cultural change underpinned by society making that strong, unequivocal statement this is no longer acceptable in this society.

Professional organisation 1

I would like to see a legal underpinning, I think it's very, very difficult to have it as a voluntary thing . . . it would be hard to police but all professional practice is hard to police and I just think a lot of it would be dealt with at the procedural level so if you're receiving an incident report to a risk management system in the hospital which is what happens at the moment then part of the procedure would be, you know, has the conversation taken place with the relatives or the patient if they've survived.

Policy stakeholder 4

We see it [substandard care] all the time and I hate it. And you just think, oh, if that'd been my mother, I'd be distraught, so I don't think you should, it should be legal.

Manager 7

You're relying on people's personal integrity, I don't think that's enough, I just don't think it's enough.

Patient 3

It's just saying look if you screw up you've got to be honest and is it really that harmful to put that into law?

Manager 3

I believe and my organisation believes that all of this also needs to be underpinned with a completely unequivocal understanding that these things are requirements. That at the end of the day they're not optional . . . I believe there's a lot of confusion around on the part of health professionals, managers and institutions about whether it's really absolutely required upon them to be fully open and honest.

Professional organisation 1

The NHS is a public service and we have a duty to be honest. So I think if there are people out there that aren't honest, it should be made a statutory requirement.

Manager 12

There were acknowledged tensions and limitations highlighted in relation to the ongoing lack of clarity that would remain in terms of defining an incident.

[It] would help to move everything towards disclosure when it should be disclosed, but it isn't obviously going to be able to deal with some of those areas of uncertainty.

Policy stakeholder 4

The alignment of professional and regulatory drivers requires professional directives and engagement of high-profile physician leaders; professional incentives in the form of revalidation, indemnity and professional development will need to be linked to patient-centred outcomes to align values in the direction of openness.

If I do something when I'm on my own and nobody else is aware of it, how is that going to be legally enforceable? I think that's the difficulty of it and you know when these things are legally enforceable, if you don't do it are you going to get a policeman knocking on your office door and saying, 'you're under arrest for not telling this person about X, Y and Z'? I think it makes the whole process more likely to go underground, rather than less. I think people would be less inclined to engage with it, if there was a legal status to it, than not.

Health professional 6

It'd be almost impossible to enforce and really challenging because how you do it is as important as doing it. And I think forcing people to be open and everyone doing it really, really badly will actually cause more harm than good.

Manager 2

> *I think we should work towards that being a kind of professional value and responsibility rather than something that is enshrined in some sort of legislative framework because I think it is too difficult to put in there. And I think every circumstance needs individual interpretation on what the best thing to do . . . my concern is that kind of legal, making it a legal duty would lead to inappropriate responses sometimes for patients.*
>
> *Health professional 10*

The identified need for opportunities for the careful exploration of held and multiple values which may conflict were apparent in our data. For any identified situation there is a need for a forum where individuals can discuss interpretations and reason through situations in a supported way, rather than over-reliance on a prescribed recipe outlined in guidance. This may promote a more reflexive approach which is likely to be critical to underpinning attempts to enhance safety and suggested methods for achieving both a more open culture but also more skilful disclosure.

Chapter 4 Discussion

This project set out to critically evaluate and extend both the evidence base and practice in relation to the implementation of a policy of open disclosure of adverse events to patients within the UK. The findings have been presented and the implications of both reviews and the primary research will be summarised here in relation to our original purpose highlighted below. The project set out to:

- identify current areas where evidence and knowledge remain sparse
- supplement the current guidance on implementing open disclosure
- inform training and support for organisations and individuals in this area
- identify continuing barriers to the implementation of open disclosure
- identify well-developed models for open disclosure

and:

- develop a series of short and pragmatic guidelines for NHS trust managers to facilitate the implementation and evaluation of open disclosure initiatives.

The following discussion will situate the findings from the reviews and the qualitative work within our research aim. We have been able to identify current areas where evidence and knowledge remain sparse and within identified limits we are able to supplement the current guidance on implementing open disclosure. The supplementation of the guidance is reviewed in the context of findings from the work conducted within the context of this report. Similarly, we have been able to identify issues and evidence which can inform training and support for organisations and individuals in open disclosure practice.

The gaps observed in the literature in relation to open disclosure of adverse events to some extent mirror observations which have been made in relation to patient safety research in a broader sense. Although patient safety research has made progress since *To Err is Human*[16] and evidence of success is apparent, this largely falls in quite specific clinical areas such as decreasing catheter-related infections[227] or surgical checklists.[228] Shekelle *et al.*,[229] in their appraisal of patient safety science, have suggested that a view that patient safety interventions have improved outcomes for patients is not entirely convincing based on a number of other reports (e.g. Landrigan *et al.*[230]). Their view that the science behind patient safety improvement is still developing and maturing holds true for the related area of disclosure of adverse events. Shekelle *et al.* have made four key recommendations for improving evaluation of safety initiatives: describing the theory, describing the practice in detail, detailing the implementation process and assessing the outcomes including unintended effects. They also stress the importance of attention to context when making conclusions about successful implementation.[229] The literature reviews that we have produced have emphasised the gaps that still exist in relation to these recommendations when considering open disclosure. Although the reviews have highlighted the lack of conventional empirical studies as a means of evaluation, they have located a body of useful opinion which raises a number of issues and provides useful illustrations. However, the area is undertheorised.

The development of theory is perhaps particularly important in relation to the design and evaluation of efforts to improve communication with patients and families about safety incidents that have (or may have) affected their care. The significance of the multiplicity of value considerations at play in these situations needs to be taken seriously, and considerations of context will be both particularly difficult and particularly important for good judgement both in and of practice. In relation to the conceptualisation of open disclosure, both the literature reviews and the interviews have highlighted the challenges in conceptualising acts of disclosure as processes, because these cannot be prescribed in any simple or linearly direct way from a broader principle of openness in health care or the moral concepts that lie behind this.

The act of disclosing (Being Open) and the broader issue of openness or transparency in health-care systems more generally are often discussed interchangeably but conceptually are quite different. There is a definitional problem around the area of Being Open which is highlighted in both the literature reviews and the qualitative data. Open disclosure in relation to so-called 'never events' presents a picture of greater agreement in that health services are morally obliged to communicate with patients and families in a way that is somehow 'open'. However, what exactly is required and why still seems to be open to interpretation. Events that are catastrophic, life-changing for all concerned and considered avoidable are the main focus of the Being Open guidance. However, the language of the Being Open guidance strays into a much wider domain which speaks to a broader perspective on openness. The broader principle of transparency within health care is highlighted in the content of the second Francis report[6] and in the very recent report by Berwick *et al.*,[200] which address a broader concept of openness and duty of candour. However, the lack of distinction between moral constructs and behaviour may cause confusion for those attempting to implement the guidance in that the definitions provided within it allow for interpretation, and it is this that appears to cause tensions within our data.

An alternative approach in addressing the disclosure of adverse events is to focus on the wider problem of candour on a bigger scale and to change the emphasis from candour associated with discrete events to candour associated with health care per se. This emerged as a theme in both the literature and in our primary data. If health-care providers were generally more open with patients then openness in the aftermath of error may be easier to achieve. However, there is a lack of exploration of the impact of such a blanket promotion of general candour, and even if such a culture were promoted and existed, the reliance on interpretation would still require good judgement in the promotion of moral behaviour. Organisations need to be clear about the focus of attempts to change. It is relatively easy to capture whether or not events are disclosed but more challenging to capture a change in broader concepts of openness. This broader focus would increase patients' confidence that all aspects of their care are being shared with them, extending from everyday decision-making about their care to a more involved consent process. This is not to say that care should be one long disclosure process but more to emphasise a culture shift which sees candour incorporated into everyday conversations in relation to care, which may in itself help with the process when things do go wrong.

There was little literature from the UK which allowed us to determine understanding, views and interpretation of a policy of open disclosure of adverse events among UK stakeholders, but the qualitative data from the wide variety of stakeholders we were able to access has provided a valuable starting point on which to base future efforts to promote both disclosure of discrete events and a wider principle of openness in care provision.

Many of our stakeholders were willing and able, in the context of anonymised individual interviews, to articulate clear examples of situations where they had made errors or had been involved in situations where errors needed to be or were disclosed. However, the reluctance of those who we approached to engage in focus group discussions highlights the considerable challenge of embedding discussion of real error and disclosure events into quality and safety improvement efforts at national and organisational level. The persistent reluctance of individual clinicians and managers to engage in reflective and reflexive processes around particular errors hampers attempts to unpick ways in which this is embedded and linked to quality and safety reporting and management in practice. This is an important finding and reflects the continued lack of confidence of individuals employed in health care that the professional and organisational systems in which they work will be supportive in managing the context in which a particular event has occurred.

The previous sections have presented the findings from the literature reviews and the primary research. The following section will discuss how the synthesis of these findings might further inform an evidence base and practice in relation to the implementation of a policy of open disclosure of adverse events to patients within the UK. Although no formal mixed-methods synthesis was applied, we have summarised the findings from both phases and presented them as a matrix (see *Table 3*) to allow simple comparisons

of the evidence in relation to each of the 10 principles of Being Open. The matrix summarises areas of convergence or divergence between the reviewed papers and our primary data, and identifies where gaps in knowledge remain. This synthesis has been used to explore ways in which future research might further inform and extend current practice and implementation of open disclosure and produce a series of short and pragmatic guidelines for NHS trust managers to inform and facilitate the implementation and evaluation of open disclosure initiatives.

During the course of the work reported here there has been a fast-paced change in the landscape of the NHS. Significant challenges to the belief that the NHS presents a safe and high-quality service at point of care have been raised. The recent Francis report[6] has highlighted the urgent need to address transparency and openness within the NHS, and the decision to implement a contractual duty of candour within health care from April 2013 has been challenged by Francis, with a recommendation for a statutory duty of candour. Although the debate appears to have moved from a contractual duty of candour to a statutory duty, the implications of this for organisations and individuals remains unclear. The current attention to openness within the NHS means that our examination of the existing evidence and thinking around open disclosure of unanticipated outcomes in health is not only useful but timely.

A synthesis of the literature exploring open disclosure and primary data from stakeholder interviews reveal that although knowledge around some of the concepts presented in the 10 principles of Being Open is well established, little is known about the way in which other principles feature in practice or in the perceptions of stakeholders.

This discussion will examine areas where literature exists and which are aligned with the issues raised by respondents in our primary data collection, and raises novel concepts which are highlighted in the primary data but where little literature exists. We also propose to look at the areas where little evidence was identified from either phase and begin to situate our findings within a broader theoretical perspective of safety and organisational change.

A summary of the evidence and brief synopsis of the synthesised findings is presented in *Table 3*.

An abundance of literature was identified in relation to four of the principles of the Being Open guidance: acknowledgement, apology, professional support, and truthfulness, timeliness and clarity of communication. These issues were also some of the most pertinent arising in stakeholder interviews. It was apparent that these issues were perceived as critical to open disclosure by all stakeholders, but also as problematic when not implemented effectively.

The *acknowledgement* of an adverse event demonstrates one such example of where there was a large amount of literature and was widely discussed by respondents. There was an emphasis in the literature review on the importance of health professionals and organisations acknowledging events (e.g. Mazor *et al.*,[20] Gallagher *et al.*,[28] Wojcieszak *et al.*,[48] Berlinger,[50] Anon.,[231] Brahams[232]), and this belief was echoed by patients and many other stakeholders in interviews. Despite this, one of the most commonly reported features of poor or non-disclosure emerging throughout this project was the lack of consistent acknowledgement of adverse events (e.g. Pham *et al.*,[58] White *et al.*,[62] Kroll *et al.*,[63] Martinez and Lo,[66] Garbutt *et al.*,[68] Gallagher *et al.*,[71] López *et al.*[111]). The primary reason cited for this in our interview data seems to be the difficulty health professionals experience in defining an adverse event and the particular circumstances in which disclosure is required. Most interview respondents raised the difficulty of knowing which events should be disclosed; as the Being Open and GMC guidance both use patient harm as the determinant for whether or not disclosure is needed,[11,95] respondents who were familiar with either defined the need for disclosure in these terms. The dissonance between patient or family and health professional definitions of harm shown in the review[69,233] may mean that the use of patient harm to define what should be disclosed is problematic. Although one solution may be to define the types of events that warrant disclosure, it was apparent from the range of search terms required to capture all of the relevant literature (see *Appendix 2*) that numerous terms were used to describe adverse events in health care.

TABLE 3 Summary of findings in relation to the 10 principles of Being Open

Being Open principle	Reviews	Primary data/interviews	Synthesised findings/conclusions
Acknowledgement	Clear events for disclosure are serious errors which lead to harm that is obvious to the patient. Difficulties with definitions of what should be disclosed persist. Terms are inconsistent and patients, professionals, organisations and the legal profession do not view or define patient safety incidents uniformly. Harm is usually conceptualised within a biomedical model, discounting patient reports of incidents which are sometimes dismissed or treated with discourtesy	Concern around defining an incident particularly related to minor/little or no events. Borderline cases present definitional difficulties. Widely held understanding that only events of moderate to severe harm are disclosed. Opinion divided over whether or not to tell the patient as soon as event becomes apparent or wait until information is gained from an investigation. Patients stress disclosure should begin immediately, irrespective of missing information	Differences of opinion remain about which kinds of incidents should be mentioned to patients and families. Further work could investigate conceptual variations between clinicians and patients to establish what is relevant to patients. Beginning the process of disclosure as soon as an event is discovered may help patients to feel more confident and trusting in the process. Being honest about uncertainty and missing information seems preferable to withholding information which patients may perceive as covering up
Truthfulness, timeliness and clarity of communication	The disclosure gap persists. The number of errors disclosed to patients does not map to the number of errors that occur. Although the principle of disclosure is largely supported by most people, there are a number of identified barriers including fears around litigation, being unfairly punished, tarnished reputation and loss of trust. Additionally, clinicians report a need to gatekeep information to protect patients, despite evidence suggesting that patients wish for honest disclosure of all incidents	Wide support for ideas of truthfulness, timeliness and clarity of communication being important although evidence suggests challenges associated with translating principles into practice. Uncertainty over how to react when information is missing or discovery of event is delayed. Concern over how to deal with complex circumstances where causes are unclear. Dilemma over who should disclose, where and how. Fear of legal action and desire to self-preserve seemed to be more active drivers for clinicians' openness than concern for patient. Gatekeeping approach endures with clinicians deciding whether or not it is in patient's best interest to disclose	There appears to be a need for standardisation of the process associated with disclosure to ensure quality and consistency in how being open is practised. Perhaps patients should be asked who they would like to lead the disclosure process. Organisations and individuals may need to consider the use of language carefully, avoid jargon and technical terminology and check patients' understanding of the discussions. It would appear that disclosure should begin as soon as it becomes apparent that something has gone wrong and should be considered as a process, ongoing from its inception to final closure and not regarded as a single entity
Apology	Apology has a strong presence spanning ethical, legal and medical literature. It appears to be regarded as a fundamental feature of disclosure. Widely documented debates focus on whether or not apology can be used as evidence of fault, and what constitutes an apology. Less practical guidance is available	Evidence of conflicting opinion on apology. Some support waiting until investigations complete before apologising. Others see delay as missing the point that apology must be prompt even if all that can be said initially is 'sorry for the outcome'. Patients stated apologies must be sincere and timely to be authentic	Some feel that apologising for *any* untoward event, like being late for an appointment, should be actively encouraged. It is thought that by doing so, saying sorry and empathising with patients becomes commonplace and part of the culture. Clinicians need to be clear and confident about associations between apology and liability

TABLE 3 Summary of findings in relation to the 10 principles of Being Open (*continued*)

Being Open principle	Reviews	Primary data/interviews	Synthesised findings/conclusions
Recognising patient and carer expectations	There seemed to be a lack of focus on the need to think about patient expectations. Patients' actual expectations of disclosure were only studied in a small number of papers	Managers and professional organisations highlighted the need to consider patient and carer expectations within disclosure. Health professionals did not conceptualise disclosure as a dialogue, in direct contrast to expressed patient perspective	By considering disclosure as a dialogue in which the patient is an active participant, health professionals might acknowledge the need to adjust the interaction to respond to patients' expectations. Policy material could make explicit reference to the role of the patient within disclosure
Professional support	Clear and consistent messages from professional bodies, NHSLA and Being Open guidance. Openness should be the norm and expressions of regret and apologies are not the same as admissions of liability. The discussion of apologies in a wider international literature may be confusing for the UK context. Professionals receive little training in disclosure but this is identified as a key to any successful implementation. Patient reports identify unskilled and clumsy disclosures which often add insult to injury. The evidence for the effectiveness of current training is weak	Evidence that openness is considered part of duty of care, adhering to guidance from professional bodies. Support to implement professional guidance from local trusts often reported as lacking. Reluctance to be open attributed to fears of negative repercussions relating to professional identity, reputation and litigation. Sparse evidence of training despite most viewing it as critical to adopting a culture of openness. Suggested that training should be inclusive and delivered to both clinicians and non-clinical stakeholders and at all levels	Professional bodies could facilitate dissemination of guidance on being open to optimise clinician engagement. Most people believe that support is critical to both clinicians *and* patients/families if a change in culture is to succeed. This needs to take place throughout any disclosure process, inside and outside of office hours. Training may be best delivered locally and internally through trusts, although more evidence for effectiveness of different models is required. Training of all staff who may be involved in disclosure is required but awareness of transparency should exist throughout the organisation
Risk management and systems improvement	The majority of literature is focused towards a 'no-blame' culture although there is little evidence that this will create a climate of openness. The wider effort to involve patients in ensuring their own safety seems to offer few opportunities within the disclosure context. Little evidence to support statements in support of disclosure in relation to reducing litigation, improving well-being for patients and clinicians, patient satisfaction. Areas of policy development and communication cited as key for embedding a culture of openness	Openness is seen as presenting an opportunity for patients to be involved in their care and offer a unique perspective, capturing different information from health professionals. Discussed by many as minimising likelihood of becoming involved in complaints or legal proceedings. Openness often linked to risk management processes. Such links highlight reactive rather than proactive link between openness and quality and safety via these risk management processes	Expert opinion stresses links between openness about adverse events and reduced organisational risk. Openness may have practical benefits, enabling learning from mistakes, improving systems and finding solutions; however, the mechanisms by which this may occur are under-researched. There is a consistent emphasis on culture change from the negative associations with reporting incidents to a focus on positive outcomes of learning from mistakes, and improving practice and care

continued

TABLE 3 Summary of findings in relation to the 10 principles of Being Open (*continued*)

Being Open principle	Reviews	Primary data/interviews	Synthesised findings/conclusions
Multidisciplinary responsibility	The majority of literature focuses on the role of doctors but recognition that a number of key professions may have useful roles within disclosure process. No clear consensus as to who should disclose. Given the complexity of disclosure conversations there is a lack of research about how team members could or should participate. The role of risk managers is more widely discussed in the US literature and the role of risk managers in the UK is less well defined in relation to disclosure conversations. Nurses are identified as often feeling excluded and vulnerable in relation to disclosure	Evidence of constant dilemma over who should disclose. Often seen as responsibility of senior clinician closest to patient, particularly for serious incidents. Lack of consensus over role of junior staff and whether or not to 'burden' them with responsibility of disclosing. Question of how to gain experience if responsibility not shared. Nurses reported limited opportunities to be involved. Scarce evidence of multidisciplinary disclosure. The role of risk managers is clearer at some trusts displaying practice consistent with Being Open guidance. Patients ask for those directly involved to disclose events	There remains a lack of evidence to support what might be considered best practice with relation to individual vs. team disclosures and the role of risk management in the UK. Accounts suggest that junior staff are often 'protected' from being involved in disclosures rather than using such opportunities for learning and modelling best practice. Patients express a desire to interact with staff involved in error and reports often describe staff who meet patients as courageous and authentic. Lack of evidence to underpin the effect of this on patients or health professionals remains the case
Clinical governance	The implementation of learning and subsequent monitoring of change is challenging in relation to fostering a culture of openness with patients. Over-reliance on measurement and reporting open disclosure conversations may miss the point. The focus on moderate to severe harms may miss opportunities for organisational learning. The policy and patient perspectives seem to indicate disclosure within an ethical framework rather than focusing on governance and risk management. Lack of information about what a 'good' disclosure looks like, and the reports of unskilled and insincere disclosures, supports the need to ensure a focus on quality as well as quantity is maintained	Statutory duty is supported by policy-makers and patients/families to initiate cultural change. Contrasts with most clinicians/managers who oppose it as difficult to police and promoting a negative image of clinicians. There is a suggestion from practice that professionals may not give the best care when they feel policed rather than valued	The recent debate on duty of candour as a contractual rather than statutory duty was contentious; however, the recent Francis report and new announcements with relation to statutory duty of candour may have implications for the current Being Open guidance. However, the implications of what this statutory duty will mean for organisations and individual clinicians remains unclear. Championing a no-blame culture may be challenging but there is an enduring concern that genuine mistakes should not be punished to ensure that health professionals are confident to be open and feel supported by their organisation Over-reliance on measurement and reporting of open disclosure could reduce the principle of openness to numbers of disclosures, with a focus on documentation of disclosures which may lose information on aspects that represent a good-quality disclosure

TABLE 3 Summary of findings in relation to the 10 principles of Being Open (*continued*)

Being Open principle	Reviews	Primary data/interviews	Synthesised findings/conclusions
Confidentiality	There is little focus on issues of confidentiality within the literature. Discussions about confidentiality seem to centre more on internal rather than outward, patient-facing conversations. Some literature discusses the right of an organisation to protect an individual staff member from being exposed to patient or family contact	Confidentiality of any party involved in disclosure was not identified as a concern among most interviewees. Some patient respondents identified difficulty in accessing information in relation to their case. They were often told the information was confidential as a justification for not sharing this	The links between the principles underpinning confidentiality in relation to individuals or information are underexplored. It is unclear how confidentiality sits in relation to disclosure of events to patients. Sometimes patients perceive the principle of confidentiality as a barrier to accessing information in relation to an error or harm. It is not possible to legislate for confidentiality in patient accounts of error once these have been disclosed
Continuity of care	It is well established that patients and families express a desire to have early and complete information wherever and whenever possible. There is a small literature emphasising the ongoing nature of disclosure conversations in relation to individual events and the importance of having one individual as a common point for patients and families. Current expert consensus would appear to be that continuity of care seems to be the ability to convey a supportive dialogue for those affected, even when emotions run high. Continuity does not relate well to playing down the incident, obscuring the content of information or being perceived as protecting the medical system or clinicians involved	Ongoing support and dialogue described as critical to enable patients and families/carers to engage with health professionals, ask questions and be listened to, to promote understanding for all parties	It seems unlikely that one approach will provide perceived continuity of care for all affected individuals. It is likely that there will be a need to be flexible. Disclosure processes require judgements to be made responding to individuals' needs. Current consensus stresses the need to adopt an empathic and transparent process focused on the need of the patient or family rather than focusing on the risk to the organisation

The use of diverse terminology means that even when issuing guidance in relation to events that warrant disclosure, organisations, health professionals and patients may not always attribute the same type of event to each term.

The literature and the interviews relating to the topic of acknowledgement demonstrate the complexity of developing appropriate strategies to ensure that open disclosure occurs; at a basic level, simply recognising that an event has taken place and that disclosure is needed can be challenging. In the context of patient safety and protecting patients from harm, decisions regarding events that warrant disclosure become additionally complex as they appear to link the potential for patient harm and what may be the subjective judgements of providers. An additionally complicating aspect seems to be that the further from obvious error with apparent harm an event moves, the more opaque the decision seems to become. However, when conceptualised in the context of care quality, the complexity relating to terminology may be lessened. In providing high-quality care, health providers may need to consider whether or not a general principle of adopting an open and ongoing dialogue with patients may contribute to improvements in

patients' perceptions of quality and commitment to it; this includes discussions about everything that occurs in their care, including minor or more serious undesirable events.

Discussion of patient–provider communication featured prominently in the interview data and in the literature around the ethics of disclosure and disclosure training. This evidence relates closely to the principle of *truthfulness, timeliness and clarity of communication*. Data from both the reviews and interviews consistently demonstrated that most stakeholders strongly support the principle of being truthful with patients (e.g. Kohn *et al.*,[16] NHSLA,[22] Scheirton,[41] Shapiro[152]). This consensus about broad values sits alongside reports from practice in which interviewees describe staff withholding information from patients. The discrepancy might be variously explained by failures to reflect the key value of truthfulness appropriately in practice and/or by appropriate efforts to balance this value with other values that suggest different ways of acting in particular circumstances.

We found it striking that a number of health professionals considered it their prerogative or role to determine the type of information patients and carers needed to know, and that they used the aim of protecting patients from harm as the primary reason for withholding information. They seemed to have few reasons that might strengthen their imperative to act on considerations of truthfulness, but potential to develop these can be found in the reasoning of some of their peers who gave accounts of what seemed to be more open and truthful disclosures. The professionals who seemed to adopt more truthful practices were not neglectful of considerations of harm, but also mentioned considerations of who owned the information, and of patients' rights to know. The language of rights and concepts of information ownership that they used might not be ideal, but could be further explored and developed for use in efforts to encourage a greater emphasis on truthfulness in relation to the discussion of safety incidents.

Similarly, the literature and patient accounts suggest that timely and clear communication are central to good disclosure, and though this view was reflected in interview data, descriptions of the complexities that prevented this happening were also described. More complex (but possibly common) scenarios in which information was missing or the discovery of an event was delayed led to uncertainty regarding when communication with the patient should take place and what this might include. There is a tension between acknowledging promptly and presenting a delayed, but more complete, picture of the implications and cause of errors. Early disclosure conversations may leave patients with uncertainty in relation to their current condition and vulnerable to delayed and unclear communication from health providers. Communication could be further hampered by dilemmas regarding who should disclose, where and how.

One of the most widely discussed barriers to truthfulness was health professionals' fears regarding litigation. This was discussed in interviews and apparent in the literature. Concerns about litigation and studies of the impact of disclosure on litigation commonly featured in the reviews, particularly those originating from the USA (e.g. Gallagher *et al.*,[67,71] Studdert *et al.*,[79] Wu *et al.*[193]). In relation to these, numerous articles presented disclosure as a strategy for health professionals to protect against litigation, suggesting that openness with patients may prevent legal action (e.g. Boothman *et al.*,[32,182] Kraman and Hamm,[52] Kachalia *et al.*[208]). However, a marked lack of any evidence to support this widely held belief was apparent from the reviews. The stakeholder interviews suggested that though health professionals were aware of the potential for litigation in relation to adverse events, this did not appear to be such a pervasive fear in our UK sample. Health-care managers discussed the possibility of litigation more than front-line staff, suggesting that this may be a more salient barrier for managers attempting to manage organisational risk than for clinicians. However, where health professionals made reference to litigation, it was generally to suggest that their fears had not been realised in their own experience, and that patients had not pursued legal action as a result of disclosure. The literature review suggests that patients often litigate to obtain information that they feel they have failed to access through other discussions and this was reinforced by the patient respondents in our sample. However, litigation may be pursued as a legitimate claim for loss of earnings or care costs even though individual patients and families are happy with explanations of error and apologies.

Professional support is identified as a principle of Being Open which can be conceptualised as support for professionals in a number of ways. Support may be in the form of support from professional organisations, the organisation that employs the health professional and managerial support. Additionally, support may be from peers and may occur within and between professional groups. Support can be enacted in ways that promote learning and inform how to disclose effectively, and as emotional and instrumental interventions for health professionals to cope with the burden of clinical work and emotional responses to adverse outcomes that may impact on their ability to disclose effectively. With regard to the former, although training was developed to accompany the Being Open guidance and support its implementation, both the review and interviews revealed a lack of awareness of its availability. No evaluation of any training specifically associated with the UK Being Open guidance was identified in the reviews. Only interviewees involved in developing or delivering the training, and senior leaders in one trust in which it was used, were aware of its existence. Those who were aware of the training package cited cost as the main barrier to wider uptake. Beyond the training that was explicitly developed in relation to the UK guidance, there was a wider absence of any evaluation of training approaches to support disclosure, although in the accounts of successful implementation of a disclosure policy, training was always featured as key to success.[150–152,154] Interview participants consistently articulated the view that professional training is imperative to support and enhance the disclosure process. Such findings suggest that while professional support and training are widely recognised as valuable, little is known about the most acceptable and effective models on which to base such interventions. Further research may help to clarify the most effective training models, the most appropriate outcomes on which to judge effectiveness and ways to support implementation. Iedema[234] suggested that the promotion of reflexivity may be critical to underpinning attempts to enhance safety, and suggested methods for achieving this, such as video filming real-time clinical practice and inviting clinicians to feedback on their own film, and reflection on the knowledge and questions that patients and families have about their care and about unexpected outcomes and clinical incidents. Such methods could be used to underpin specific training in relation to disclosure conversations and encourage reflexive practice, enabling individuals and teams to reflect upon and appraise their actions in light of a range of salient values.

With reference to broader support for health professionals, interviewees recognised the lack of support available to staff to manage their experience of making an error or of being involved in an adverse event; this is reflected in a growing body of literature about the distress experienced by health professionals in these situations. This literature was not included in this review but has a growing evidence base.[235] A small number of papers referred to the belief that disclosure may help professionals involved in error to come to terms with their own associated distress; however, while this may convey empathy in some situations this may not always be the case, and we currently know little about how disclosure affects either health professional or patient well-being. Interview respondents (particularly those representing professional bodies) indicated that without the necessary support for health professionals, they may not be as willing to disclose events or may do so with low levels of commitment or skill. This belief is reflected in the broader literature (e.g. Levinson,[69] Stroud *et al.*[73]). There is a well-established literature and understanding (shown through our interview data) that broader professional support is important to enhance open disclosure, but the availability of support appears to be inconsistent and, as with training, based more on the motivation of well-intentioned institutions than evidence-based guidance. US-based accounts of providers who have implemented such support are enthusiastic[152] but no evaluation data seem to be available.

Apology was one of the most widely debated issues identified in the review, spanning the medical, ethical and legal literature. Literature reporting patients' beliefs indicated that a genuine and timely apology was one of the most important aspects of effective disclosure.[86] Policy material from the NHSLA also supported the notion that health professionals should be free to give an apology without fear of the possible impact it may have on a claim.[22] Although the value of apology was widely discussed, health professionals and managers described several dilemmas in deciding when to apologise, who should apologise and what this should include. Additionally, there is a sense that although the message seems to be that apologies are welcomed by patients, and often by professionals and their regulatory organisations, this may sometimes conflict with interpretations of that message from those involved in risk management. This can be

understood as reflecting different interpretations of the concept of apology and how it relates to a range of values and consequences. For instance, the legal system in the USA in particular means that the caveats placed on apology translate to nervousness around the timing and content of apology, which may appear to convey insincerity and a lack of empathy if not handled sensitively by the individual or team making the disclosure. The absence of pragmatic guidance around apology to support professionals to translate the principle into practice was evident; however, as we have emphasised throughout this discussion, the presence of guidance that may be interpreted as a recipe for what to say is unlikely to facilitate any progress towards helping individuals in appraising their moral reasoning about apologies. In the UK, an apology is clearly articulated as not being the same as an admission of fault. There seems to be a present need, articulated in patient accounts, to distinguish between an 'apology' whereby a health-care provider accepts responsibility for something that happened or did not happen and apologises for this, and the situation where a provider expresses sympathy or regret at an outcome but fails to take responsibility for harm. Confusing these two situations appears to have the potential to cause more harm than good when a patient feels that failing to accept responsibility for an error fails to address the impact it has had.

Continuity of care and multidisciplinary team responsibility were primarily highlighted by our interview respondents but had a less established literature. Continuity of care may relate to the implications of disclosure for the ongoing treatment of the patient but was also conceptualised in relation to the ongoing nature of a disclosure process. Often 'good disclosures' or training for disclosure models were represented in the literature in terms of a single conversation between patient and provider. Interview data and a small number of written accounts suggested that conceptualising disclosure as an ongoing dialogue between patient and health-care team was of great importance for ensuring real transparency.[31,85] Only a small number of professional respondents recognised disclosure as a dialogue, suggesting that mismatched expectations of the disclosure process between patient and provider may be an issue. Preparing health professionals for a disclosure conversation may exacerbate the belief that disclosure occurs at a single point in time; therefore, defining disclosure more explicitly as an ongoing process in any guidance, but also in training and education, may be helpful.

A failure to recognise disclosure as a process over time may be part of a broader lack of recognition of patient and carer expectations about disclosure. Patient and carer expectations of communication with health professionals are referenced in broader health-care literature, particularly in relation to patient involvement and shared decision-making. However, the literature that focused on open disclosure revealed that patient and carer expectations of disclosure, and the ability of health professionals to recognise these, received little attention. In contrast, interviewees who were health-care managers and representatives of professional organisations consistently raised the need to consider and respond to patient and carer expectations. More work may be needed to establish the most effective way to support health professionals in determining patient expectations and representing these in disclosure dialogue, in order to promote responses and reactions that meet the needs of patients or carers and allow them to contribute to the disclosure discussion.

Interview data revealed a lack of consistent agreement regarding who is responsible for leading disclosure communications with patients and carers, and this appeared to contribute to inconsistency and some confusion for both clinicians and patients. Although Being Open identified *multidisciplinary team responsibility* as one of the 10 principles, most respondents identified the most senior doctor in the team as responsible for disclosure. Perceptions of the roles of other team members varied widely, particularly in relation to nurses and junior team members. In keeping with the limited literature that we found,[99,100,168–170] nurses were not depicted as central to disclosure conversations by respondents, despite the common belief that nurses are often closer to the patient than other team members. There was divergence between interviewees regarding the degree of responsibility that should be held by junior team members. Some felt that junior staff should be protected from challenging discussions with patients, whereas others suggested that involvement in disclosure is critical to their learning and may also be helpful for the patient if the junior team member was directly involved in the incident. Interestingly, although the literature around disclosure training demonstrates that much of the training has been directed at junior

medical staff, studies exploring the role of the wider multidisciplinary team in disclosures beyond the lead doctor were limited.[175] Such findings suggest that although multidisciplinary responsibility is identified as a principle of Being Open, there is a lack of clarity about what role each team member should play and how teams can work together to deliver more effective disclosures.

Reference was made to the majority of the principles in the Being Open guidance to at least some extent in both the literature and interviews, but we noted an absence of evidence from existing literature or our interviews that related explicitly to three of the principles: confidentiality, risk management and systems improvement and clinical governance.

Confidentiality around disclosure was not raised by patients or other stakeholders as a primary concern and this was reflected in the absence of literature that discussed this. Moreover, it was apparent from interviews with patients and health professionals that concerns about breaking confidentiality may be used by health-care providers as a reason for delaying or not revealing certain information to patients. Being unable to discuss an error with those directly involved seemed to be a particular frustration for families for whom this was an important part of the process of coming to terms with what had happened. In the literature, limited work made reference to the level of confidentiality offered to the health professionals involved in an incident, but it was not clear how confidentiality would be conceptualised in the context of open disclosure beyond patient confidentiality that is part of day-to-day practice. Confidentiality regarding serious adverse events was highlighted as challenging, and many respondents identified that in the case of serious errors information was often widely discussed within the organisation beyond the immediate team and risk management. Teams may wish to explore the motives around maintaining confidentiality in relation to health-care staff in their reporting of error and harm to patients, and the value of this approach in relation to both patient expectation and learning. Issues around confidentiality may be particularly challenging in the area of mental health care where patients may not wish discussion about their care to take place with family members or representatives, and this requires further exploration.

Implications of disclosure for *risk management and systems improvement* were discussed in the context of *clinical governance* by some health-care managers, but these were not addressed as distinct issues. Literature from the USA reports the role of risk managers in relation to incident disclosure to some extent, but work originating from the UK does not explore the role of this group, which may be very different from the US context. The explicit links between disclosure, risk management and clinical governance remain underinvestigated. Establishing which outcomes might link these areas requires more examination. Interview data linking disclosure with risk management, clinical governance or systems improvement were limited to the reporting of risk incidents and action taken with staff as a result. The contribution of patient perspectives was described by some interviewees as a source of information that might guide systems improvement but is currently not exploited to its full potential. This strategy relates closely to a broader literature on patient involvement,[236] but respondents did not explicitly make this link. Risk management, clinical governance and systems improvement may each be critical to open disclosure and informed by open disclosure, but these principles are currently under-represented in the literature.

The recent debate on duty of candour as a contractual rather than statutory duty was contentious; however, the recent Francis report[6] may mean that this is reviewed and changed to a statutory requirement. Since 1 April 2013 the new standard NHS contract has been used by all organisations commissioning NHS services, with the exception of services commissioned under primary care contracts. The contract requires all NHS and non-NHS providers of services to NHS patients to comply with the duty of candour. Unlike professional ethical duty (e.g. Good Clinical Practice), the contractual duty of candour only applies to incidents that result in moderate to severe harm or death. This will present considerable challenges for both organisations and professional bodies in terms of clinical governance and monitoring. The impact of contractual or statutory duty of candour is unknown but there seems to be a concern from practitioners that an over-reliance on measurement and reporting of open disclosure could reduce the principle of openness to numbers of disclosures, with a focus on documentation. This may result in the loss of information regarding which criteria represent a good quality disclosure. The interviews suggest that the

messages from the various sources and organisations that clinicians look to for support are interpreted inconsistently and differently. In the UK, the requirement to be open about adverse events is currently disseminated as guidance, although a contractual duty of candour may mean that the pace of change is accelerated. Those in favour of statutory duty of candour feel that genuinely essential practice can only be achieved through this route.[201] NHSLA guidance emphasises openness, and the MDU and MPS have publicly advocated candour. However, the evidence in the literature and the interviews in this study demonstrates that despite this practice is often different, and more recently, *A Promise to Learn*[200] has called for a clearer supervisory and regulatory system, with clearer incentives which do not conflict, to ensure that individuals and organisations feel confident in being transparent.

The challenge of defining appropriate outcomes for individual trusts to allow them to demonstrate both quality and quantity of disclosure needs further clarification. The current emphasis is on championing a no-blame culture, despite a lack of evidence that this improves safety in health care. The concept of just blame is becoming increasingly discussed, but there is an enduring concern that genuine mistakes should not be punished to ensure that health professionals are confident to be open and feel supported by their organisation. This has been reinforced by Berwick *et al.*[200] in their recent report into the NHS, which has called for recognition that transparency is essential and that organisations, health professionals and patients should expect and insist on it. This recommendation was balanced with a clear message that blaming staff should end and that they should be trusted to do the right thing with adequate support throughout their careers.

Although this report concentrated on open disclosure, we are aware that there are a number of theoretical perspectives which might be brought to bear on any examination of the disclosure of adverse events. The area itself is undertheorised but there appear to be several useful perspectives from related fields which might be employed to progress thinking in this area and inform future research questions. Patient safety more generally draws upon a theoretical body of work around systems and behavioural change in health professionals and organisations. There is also a body of change management, transformational, entrepreneurial and ethical leadership, and organisational change literature equally relevant to this report. Although a detailed analysis of appropriate theoretical models is beyond the scope of this work, we are aware of some approaches which appear to sit well with our current analysis of the available literature but in particular with our interview findings.

In theory, the UK NHS is a collection of organisations that share, to a greater or lesser extent, a common mission and values. It is referred to as a 'national institution' and described by both staff and patients in a way that depicts a well-recognised brand. However, Checkland *et al.*[237] suggest it is more accurate to consider it as a heterogeneous and evolving organisation, which is becoming more diverse as it evolves in response to the considerable changes which have occurred in recent years. This makes it a complex adaptive system, and as such there are a number of theories through which we would be able to view the attempts to introduce greater transparency around adverse events. The purpose of the complex adaptive systems perspective is to draw attention to basic tenets or principles rather than provide hard and fast rules about what works. The recommendation of this approach is that policy should avoid elaborate checklists or specific instructions for change. The idea that health-care systems are complex adaptive systems has been established for a number of years, and several influential papers from a number of authors in mainstream medical journals are emphasising the usefulness of the complex adaptive systems lens in understanding improvement and transformation in health care.[238,239]

The majority of literature on transformation in health care describes change on a relatively small scale, often by one organisation or service.[240] Generally it lacks both definition and an evidence base.[241] Best and Holmes[240] define large-scale transformation in health-care interventions as change which is aimed at 'system wide change affecting multiple organizations and care providers with the significant goal of significant improvements in the efficiency of healthcare delivery, the quality of patient care, and population-level patient outcomes' (p. 422). Embedding a culture of openness in the NHS can, at least to some extent, be considered a large-scale transformation. Therefore, this work may be usefully employed

here. Lanham *et al.*[242] has stressed the need to move away from top-down efforts and focus instead on the natural creativity of health professionals to adapt and develop new ways of achieving quality – a suggestion which was recently endorsed by Berwick *et al.*[200] in their report on the NHS. However, this can only be achieved when positive conditions allow a supportive work environment. Those working in health care need to be able to make use of relationships and skills within the system, and it may be at this point that complex adaptive systems theory is able to link into the systems theory. The focus of systems theory on just blame may complement organisational theory in terms of supporting the development of a culture where candour is able to become a more ingrained cultural norm in health care.

Work from a realist review of large system transformation (LST) in health care has identified a number of findings which may be applied to the practice of disclosure but are, as yet, largely untested outside of individual accounts.[240] Our review highlights examples where the principles of LST, which makes use of the engagement of individuals at all levels in leading change, have been applied. There are examples in practice-based literature where this need has been recognised, and where there are identified individuals leading on efforts to mobilise delivery of change in terms of disclosure.[150–154] This would suggest that each trust should have an individual lead for openness. However, engagement at the levels of policy, regulation and indemnity bodies through to risk management and patients all need to be considered. The model of more distributed responsibility may be useful and possibly more sustainable, but in the few reported examples where organisations are perceived to have adopted more transparent ways of working, they appear to have significant figureheads usually accompanied by a stakeholder, often from among relatives who have been instrumental in helping to bring about change. Distributed leadership appears to focus on practice and relationships in leadership as well as developing leadership through mentoring. Pedagogical approaches which support and model good practice to promote leadership may be useful models with effective feedback loops to further bolster learning and development. A number of recommendations for LST change have been suggested by Best and Holmes[240] and are discussed below in relation to open disclosure.

Ensuring that it is valuable and safe for staff to engage in good disclosure practice is crucial to success. The need to promote the reflection of important values and principles in practice, and to provide cultural and interpretive support for those values, is likely to be important and has been highlighted in our data. When staff or patients are concerned, or suspect error, the organisation needs to be receptive and welcome reports. This would be echoed in current patient safety thinking which emphasises feedback and learning. *A Promise to Learn*[200] emphasises the need to engage both staff and patients in gathering information about risks and harm and the involvement of both in establishing the important information that needs to be collected. Additionally, it seems important to focus on how this might be achieved, as this will avoid measures that could potentially influence behaviours in negative and unintended ways, and employ metrics which capture things of importance to both clinicians and patients.

Clarification of concepts, and consistency and transparency of definition have also been highlighted as important. There is a pervasive problem around definitions of error and harm which are defined solely by one side (the provider) and are driven by definitions of events which are classed as moderate or severe. We would suggest that the naming of harm, beyond so-called 'never events' (or those that the organisation judges to have harmed the patient), appears to be open to interpretation and would benefit from such examination and consistency. This lack of clarity was conspicuous in the accounts of stakeholders in our data. Unless definitions are applied and seen to be used consistently, patients will be frustrated by such inconsistencies and report this in their accounts of instances where they seek an apology. Incentivising acting on feedback should include patient feedback but has to be sustained to avoid gaming.

Open disclosure could connect to the valued commitment to learn from previous safety problems to prevent future errors and harms. Careful analysis of events is an important step but will not predict how things might happen in the future. Analysis of events should be viewed as an opportunity for sensitive discussion and planning of how to avoid the situation or, more realistically, how to handle a situation if it happens again. Although the aspiration of the NHS may be zero harm, in the journey to this aspiration the

usefulness of the approach of handling how to disclose error must not be forgotten. Broader literature on quality and safety will need to address how the aspiration of zero harm can be made to sit more comfortably with values and behaviour in relation to open disclosure where the very aspiration of a service has been challenged by the occurrence of error. It is exactly this tension which was raised by our stakeholders, and failure to address this as part of ongoing support and development is unlikely to result in changes in action.

The importance of engaging physicians and their indemnity and professional bodies in LST change has been identified. The issue of who makes decisions about disclosure and how it is done seem largely to fall in the domain of doctors, although our data do support the active participation and in some cases leadership of nursing colleagues. Transformative initiatives are often championed by nurses or non-clinical mangers (who have less power) involved in the system and the literature identified the frustration expressed by nurses in relation to their involvement in disclosure. Although doctors in the UK tend not to operate as independent practitioners (though GPs and those in private practice may be an exception to this), their collegial regulatory framework is geared towards detecting extreme examples of poor practice or unethical behaviour to protect the profession rather than monitoring quality. That gives them a great deal of power in responding to transformative events. Our interviews supported this and it was clear that professional regulatory guidance had most influence on the moral perspective articulated in practice. The influence of professional regulation was apparent during the duty of candour debate, with the medical profession objecting to a legal duty of candour on the grounds that their professional regulatory framework already meant they had a duty to be open with patients. Nurses and patient organisations, on the other hand, were supportive of regulation around openness in care which went beyond a statutory duty. As doctors often have a power of veto when other groups adopt a normative aspirational target, the engagement of the medical profession in making this a normative aspiration seems essential and the current literature and our interview data would suggest that this is currently equivocal.

The role of situated judgement in both the literature review and the interviews with stakeholders has been discussed in all sections, and the importance of attention to context in both practice (for professionals) and in evaluating practice (for those who would judge them) is clear. Context has emerged in the theoretical literature as important and is discussed separately from effectiveness of interventions.[243,244] In a systematic review of interventions, context was highlighted as poorly described and reference to the general lack of understanding that still exists in relation to context in patient safety practice interventions was made.[243]

Implications for research suggested by some patient safety researchers are that there needs to be clarity about both theory and concepts in relation to any safety practice[244] and this could equally apply to the broader but related value of openness in health care. Defining the events to be disclosed without due care and attention to the multiple values inherent in decisions about disclosure behaviour fails to address contextual issues and thus the effectiveness of guidance such as Being Open.

Providing care for individual patients and organisation of care for populations are related but different endeavours and this may lead to tensions, which has been highlighted by Shale[245] in relation to the concept of ethical leadership. Health-care professionals and health-care organisations aspire to provide the best possible care for individuals but the reality of health care, especially in a system such as the NHS, is that this is achieved through providing shared resources at a population level. Thus, there is an inherent challenge in managing a shared resource in an ethical way which often differs from managing a resource for an individual. Therefore, managing the reputation of an organisation to maintain the trust of the larger population may conflict with disclosing information about an individual error.

Such dilemmas are apparent at all levels from the boardroom to the bedside and solutions present a constant challenge. These observations were reflected in every interview and by the differing perspectives represented in the review literature. Such work may also be useful in starting to unpick why moral values do not automatically translate into ethical action.

Shale[245] also points out the importance of doing the right thing in the right way and this point is particularly salient in disclosure conversations. Training, where it exists, focuses on raising awareness of the moral and legal imperative, but occasionally also on how to have a challenging conversation. In both the literature review and our interview findings, clinicians highlight their anxiety about having disclosure conversations and patients highlight the damage that can be done by the right thing being done in the wrong way. A doctor who wishes to tell a patient that an error in his or her care has occurred is ethically correct, but blurted out in the wrong circumstances and in the wrong way, it would not be considered an action which was necessarily morally strong. So the skill involved in doing the moral thing in the right way is important. Finding the right place, having all the information and rehearsing this all underpin efforts to train people to do this well, if the ethical course of action is to be carried out in a morally appropriate way. Preferences of the family or patient need to be taken into account; therefore, the person disclosing should have good knowledge of the individual being dealt with, and this has implications for who discloses. Moral communication requires skills and these skills need to be practised and experienced. There are the real skills of expressing the situation clearly, listening and tailoring information to suit the context. However, the degree of emotional intelligence required in such situations is important in relation to managing difficult conversations; being able to express empathy, and managing anger and distress are all important in making the communication with the patient or family sensitive. Equally important are the skills enabling the professional to self-manage his or her own emotional response, as feelings of defensiveness, distress, shame and anger are often cited by professionals in relation to errors. Forgiveness may not be forthcoming from the patient and family and dealing with this response when an individual and an organisation feel they have acted with integrity can be hard to accept.

Interventions to train people in disclosure may well find the work around ethical leadership and emotional intelligence useful as a starting point for their construction. Although emotional intelligence theory would not state that managing emotions either in oneself or in others is easy, or that every individual can become skilled in such conversations, it does support the notion that skills can be developed and that levels of improvement can be measured. The simple ethical question of ‘is it the right thing to do?’ to disclose error is easily answered. An ethical perspective and our data suggest that the answer is yes, but any exploration of its enactment highlights the numerous challenges associated with action. It is both emotionally and legally sensitive and takes considerable skill that is not captured well by current guidance, which is unlikely to be able to address the complexity of decision-making underpinning disclosure of an adverse event, whether serious or associated with less or no apparent harm.

There is an inherent sense of risk for organisations in relation to disclosure and the wider principle of candour. In order to achieve an open culture they must be prepared to give up some control. Patient safety initiatives are, for the most part, aimed at exerting as much control over processes as possible, limiting the points where initiative or opinion come into play in order to prevent error, and checking the process at as many identified points as possible to reduce the likelihood of mistakes. However, disclosure requires a degree of resilience and the ability to manage uncertainty if organisations and individuals are to deal with errors and disclosure effectively. The process linking the monitoring of quality and safety is unlikely to be able to measure or quantify a sea change in openness which may be imperceptible even to those using health-care services, and so cannot be conceptualised in the same way as the majority of safety interventions. Disclosure of adverse events should be focused around informing future practice and improving quality and safety but it has wider implications for the staff and patients involved. For these reasons, sitting disclosure entirely within the current patient safety theoretical models is unlikely to fully address its challenges, and theoretical models which are able to address the complexity of values within health care and emotional intelligence in practice are also likely to be useful.

Strengths and weaknesses of the work

The review was extensive. All identified potential sources published over a 22-year period were searched. This inevitably produced a large volume of literature but should ensure that most relevant literature has been appraised and included. Publications were not excluded on grounds of quality and peer-reviewed publications sit alongside journalistic literature and guidance from professional bodies. This was necessary to gain a wider sense of the movement in the attitudes as well as the evidence base within the field of open disclosure, much of which has involved disparate, common-sense responses adopted by individual organisations or in particular areas.

A large part of this literature originates in the USA and refers to US health systems, and for this reason applicability in other countries may be limited. However, the range of interventions described from different countries with different health-care systems illustrate that similar approaches are being adopted within many systems. The practitioner–patient relationship, which is at the heart of all health organisations and systems, appears to have key similarities worldwide; that is, a knowledge and status imbalance which means that the ability of a patient to access information in relation to their care, and to fully contribute to making an impact on safety-related behaviours within health care, depends upon a number of things. The behaviour of patients is likely to be profoundly affected by the information their health-care professional chooses to share with them and the extent to which the health-care system is prepared to engage in dialogue after an error or adverse event. The review conducted here has illustrated how few empirical findings exist in relation to open disclosure and how few models of good practice have been described or tested, and indeed, how unclear the possible outcome measures that are applicable to such work are. These factors make any recommendations challenging from the perspective of both generalisability and a lack of any firm evidence base on which to base them.

There may be examples which have not been captured by the searches where implementation of disclosure policy is being conducted consistently and linked to safety outcomes within organisations and is being evaluated. Such accounts may not have been written up for dissemination.

The searches were conducted in 2011 and rerun at the end of 2012. Although we have not systematically searched all reports published since this date, we have, through monitoring relevant publications, attending conferences and maintaining contact with experts in the field through the project steering group, closely observed the field for any new themes or ideas. We are not aware of any literature which would change our overall conclusions.

The qualitative component of this project makes an original contribution to the field of patient safety research by providing empirical data relating to stakeholders' awareness and understanding of open disclosure and their personal experiences and perceptions of both the principle of openness in relation to disclosure of adverse incidents and the Being Open guidance, in the context of their own position in relation to health care. A major strength of the study was the deliberate inclusion of a wide range of participants (drawn from different stakeholder groups) in order to capture a broad range of views and perspectives from people with varying disciplinary and professional characteristics as well as patients and families who had been affected by health-care error.

In-depth interviews proved to be a highly effective way of exploring people's knowledge, beliefs and experiences in relation to open disclosure of adverse events and policy implementation, allowing the interviewers to probe and clarify responses in order to produce a rich data set that was grounded in the experiences of interviewees themselves. Individual interviews yielded highly detailed information on aspects of process (e.g., on the nature of communication between patients and health-care professionals) which contributed to identification of the ways in which particular beliefs or experiences were likely to influence behaviour.

Although the original protocol had planned to conduct focus groups, a number of challenges meant that we were unable to achieve this. Research governance processes took longer than expected which, given the 18 months available to conduct this study, meant that the time available to achieve these was short. This, coupled with the reluctance of stakeholders to discuss this topic in groups, meant that the qualitative data are based on interview data rather than a combination of methods. However, the breadth of the interviews was extensive and it seems unlikely that focus groups would have resulted in a change in our conclusions.

There are well-recognised limitations to the qualitative approach used in the study. One of the obvious disadvantages is that it does not support the formulation of quantitative estimates of either the frequency or distribution of particular views or experiences within a population. The current study was designed in order to explore how knowledge, beliefs and experiences in relation to open disclosure of adverse events and policy implementation might vary according to job role, professional discipline and distance from direct patient care. It is feasible, therefore, that findings from the current study could be used to usefully inform future survey work to investigate the significance of such contextual variables in a quantitative fashion.

Owing to the large number of data collected, and the complexity of that data, analysis of the study data is currently primarily descriptive in nature, which imposes limitations on the generalisability of the study findings at this point in time. Although the analysis that has been undertaken enables us to meet the study objectives, and to comprehensively answer the research questions (as stated in the protocol), further analyses are possible. These will be carried out prior to the production of papers for publication in order to develop theoretical hypotheses and to refine an explanatory model. This should allow for inferential and theoretical generalisation from the study findings.

The evidence-based guidance for managers to facilitate the implementation of open disclosure had been planned as a consultation event. The lack of evidence currently available to support this activity meant that the work is only able to support a short pragmatic set of suggestions which have emerged from the work covered, and we remain somewhat tentative in suggesting these in light of our work as presented here. What is apparent from this project is the need for a focused programme of work to determine an evidence base for almost every aspect of open disclosure policy. Until this time, such guidance is advice based on expert opinion but little more. There appears to be a fundamental problem with attempts to simplify and standardise an area as complex as disclosure, which has been clearly articulated in work by several authors in the reviews and in our stakeholder interviews, and has been further supported by extended discussions in our synthesis and calls from both the Francis[6] and Berwick[200] reports which have been published as this research was ongoing.

The majority of work in the literature and in primary research has engaged with secondary care services. However, error occurs in all areas of both health and social care. Although we were able to interview some primary care practitioners, they made up a small number within our sample and we acknowledge that the generalisability of this work to other areas may be limited. This said, the principles of transparency in care may encounter some differences of context but the issues raised by our predominantly secondary care-focused sample of stakeholders have many themes which are likely to translate well to other settings.

Finally, we would highlight a limitation which has been articulated in other work reviewing LST.[240] The time frame in which to conduct this work was short (18 months). Although this was useful in providing focus and discipline and keeping us aligned with the fast-paced change in policy and structure within the NHS, it has posed a challenge in making less time for reflection on the complexity of disclosure values and practice and the wider literature which might apply. Thus, our work and discussion has been limited by what we have been able to achieve within this time frame. We intend to extend this work with further analysis of our findings in the future.

Chapter 5 Conclusion

Health-care reforms are often difficult to enact and the changes that policy-makers envisage and aspire to may not translate into practice, or change may take longer because working practices are institutionalised. This is apparent in a policy of open disclosure and is complicated by the levels at which the policy needs to be delivered. The US VA classifies the strength of patient safety interventions based on the probability that they will reduce risks; checklists are classed as weak interventions. Being Open is, in fact, a clear set of guidance rather than a checklist per se, but short pieces of advice run the risk of being used in such a way. It is intended to act as a simple reminder of what to do, but unless it is coupled with attitude change and efforts to remove barriers to actually disclosing, it will continue to have limited impact. This has been demonstrated by both the reviews of the literature and the interviews with stakeholders.

Both the literature reviews and participants' accounts identified a range of benefits of a more open culture as well as reasons for the reluctance within health-care institutions to fully implement policies of open disclosure in an international context and, more specifically, in the context of the Being Open guidance. Virtually all stakeholders discussed the need for cultural change when considering ways to make Being Open become more ingrained in health-care practice. Respondents explicitly referred to how a change was needed from persistent negative associations in relation to reporting incidents towards a focus on the positive outcomes of learning from mistakes, and improving practice and care. Although there was a lack of familiarity with the guidance itself beyond general principles, there was a widely held belief that poor implementation may be due to a lack of appreciation of hypothesised benefits. Despite the enthusiasm for a move to a culture of openness, issues around defining the events that should be disclosed persist, and there is a pressing need to establish a robust evidence base in relation to open disclosure practice. Health-care institutions and the individuals who work within them need to be receptive and responsive to patient concerns about unanticipated outcomes in relation to their care, whether these are mistakes, errors or simply a case of unmet expectations. This approach may allow patients to participate in the broader agenda of contributing to improving quality and safety of care. The nature of the patient–professional relationship would seem to be crucial in achieving a disclosure which supports information-giving to patients and families and mitigates risk for the organisation, but this is currently unsupported by established training or professional support.

A number of gaps in the evidence base persist and current practice is based mostly on expert consensus rather than an existing evidence base. This needs to be addressed if culture change is to occur and disclosure is to be performed consistently and with skill. At a fundamental level, there is a tension between the pragmatic guidance issued by a number of professional bodies and organisations and the more in-depth critiques of what being consistent and transparent in health care really means. The tension between a more reflexive sociological approach and a systems failure paradigm has not been fully resolved. There appears to be a protective agenda from the systems approach which focuses on learning and the non-attribution of blame. However, the literature and respondent accounts highlight that emotions are a very real part of disclosure for both patients and their families and the members of the health-care teams involved. Further work needs to focus on how these two paradigms can be used to inform disclosure of events to patients and support for patients and professionals, and to provide learning for health-care systems effectively.

It has been suggested that there are several common contextual factors which contribute to successful implementation of safety practices: commitment from the top, dedicated staff and financial resource, an open process to encourage buy-in and enthusiasm from end users, and sheer persistence.[246] In the small number of reports of institutions where authors report progress in open disclosure, these factors are all apparent, and it would seem that efforts to improve open disclosure practice in the UK will require the same. The impetus for change is currently strong, with influential reports and public opinion very much behind increased openness in health care and more transparency in relation to learning from error, and we would suggest that efforts towards change should ensure that this normative cultural change in the policy and public spheres is captured and facilitated in practice. This will require visible support from influential parties such as professional and indemnifying organisations and senior members of trust boards to facilitate clinicians in having the confidence to negotiate complex decision-making in relation to disclosure practice, and to promote skill-building throughout careers through formal support and insightful mentoring.

Chapter 6 Future research

This work has highlighted that there are a number of areas which require further investigation.

At the level of individual health-care trusts we have little information about how the Being Open guidance is being interpreted and implemented in local policy. Mapping this would allow the identification of any potentially well-developed implementation which could be tested in other settings. More work is required to better understand the facilitating and impeding factors that have the greatest influence on disclosure and how these might vary by context (at the level of profession, trust, patient and clinician characteristics). Exploration of the links between outcomes of interest for risk managers (and those concerned with clinical governance) and open disclosure is needed to determine whether or not outcomes relating to safety can be used as proxy measures for a successful disclosure process.

Very little is currently known about the influence of specific factors such as how the level of training undertaken, speciality or professional environment might affect attitudes towards disclosure, or the effect of particular training models in supporting or discouraging disclosure. Future research will need to determine whether or not educational and institutional interventions actually reduce the influence of impeding factors or enhance the influence of facilitating factors. This requires good-quality effectiveness studies with robust controlled studies and appropriate outcomes that reflect both patient-centred outcomes and clinician and organisational outcomes. Future studies should explore the mechanisms through which open disclosure might address and reduce some of the psychological and health-related consequences of error for patients, their families and the health-care providers involved.

Observational work in any context is challenging but in the context of disclosure conversations this may be even more so. Practitioners often find the observation of practice challenging, and using observational methods in relation to disclosure conversations would pose many difficulties for consent and methods. This said, there seems to be a need for a number of interesting but methodologically challenging studies. Being able to understand in more detail the impact of organisational culture and leadership styles on disclosure practice at the hospital and departmental level, and the ways in which individuals interact during specific disclosure conversations, seems essential for understanding and improving the status quo. These studies are likely to employ complex mixed-methods approaches to capture observational, experiential and quantitative outcomes in relation to disclosure practice. What is also clear is that any evidence base is unlikely to be able to make hard and fast statements about what works. More likely are broad statements about what tends to work, for whom and in what circumstances. Best and Holmes[240] also suggest realist evaluation as a tool to generate such statements to understand and explain different outcomes. The realist review is still an emergent field but may be a useful way to take forward a more detailed examination of contexts where openness is perceived to be established. Future research might examine which disclosure styles patients perceive as competent, and assess their causal impacts on objective and relational disclosure outcomes. The involvement of patients and the insights this perspective may bring to the prevention of adverse events and promotion of service improvement should also be considered. The need to observe and explore real-time disclosure as well as in anticipation of and after disclosure interactions is apparent.

Most of the work looking at disclosure takes place in secondary care and the majority of respondents we engaged with were based in secondary care. There is almost no literature addressing other contexts more specifically, either internationally or in the UK. We know little about some health-care contexts, such as private health care, social care providers, general practice, learning disability or mental health settings as five examples, but this is not an exhaustive list. These areas require focused exploration to determine the transferability of findings from other, more general contexts.

Chapter 7 Summary of evidence-based guidance for managers to facilitate the implementation of open disclosure in individual trusts

As part of the commissioning brief for this project we were asked to produce some short evidence-based pragmatic guidance which NHS managers may wish to consider in relation to developing and implementing local policy for open disclosure. The lack of a robust evidence base in relation to the majority of individual Being Open principles, and the arguments presented in this work for the problems associated with the use of such guidance to improve or guide practice, means that the following suggestions are based largely on expert opinion and consensus. In using them organisations should be mindful of their extensive and inherent limitations. As such, they are tentative observations. These would need to be revisited and revised as the evidence base in relation to specific principles develops.

Organisations may wish to consider assembling a multidisciplinary team to establish the working definitions to which the policy will apply. As part of this they may wish to consider the following factors in team composition. All levels of the organisation, from the board down, should be represented, including senior and junior doctors and nurses, and service managers including clinical governance and risk management. Consideration should be given to the inclusion of lay members to keep policy and practice focused on the needs of patients and families who have experienced harm. This is supported by the findings from both reviews and our interviews with stakeholders.

In considering the specific principles of the Being Open guidance, we suggest the following points for consideration by trusts.

Acknowledgement Try to ensure that everyone in the organisation is working to the same definition of an event that requires disclosure and that patients and families are also clear about the events that will be disclosed. Explore and acknowledge the difficulties associated with definitions. Consider a small group who can discuss any contentious events, perhaps with lay representation to enhance transparency.

Truthfulness, timeliness and clarity of communication Try to ensure that patients and families are given information relating to events as soon as possible. Although investigations may be ongoing, convey this uncertainty to families and keep them updated with facts as they emerge.

Apology Apologies are important to families. These should be sincere and issued as soon as any error or mistake is established. Trusts may wish to provide regular updates and support to ensure that clinicians and risk management are clear about both professional and legal obligations in relation to open disclosure.

Recognising patient and carer expectations If the expectations of the patients and carers are established before, during and after treatment, this may help in discussing perceptions of harm and error when outcomes are unexpected. This can be facilitated by ensuring that accurate information is given, that patients and families understand possible outcomes and risks and that information is updated if and when necessary to manage expectations.

Professional support Trusts may wish to consider the availability of professional support for those involved in disclosure. This may take the form of individuals who model good practice within the institution or specific training available in open disclosure. There is little evidence for any particular model of training over another, but given the observed complexity of decision-making in relation to disclosure and disclosure work, opportunities to practise conversations and apply reflexive thinking alongside reflection on real disclosure are likely to provide the most useful approaches. Consider multidisciplinary training and support. Working alongside patient groups and advocates to ensure that such training is also focused on the needs of patients is also likely to be important.

Risk management and systems improvement Patients may have useful insights into systems informed by a unique perspective and as experts in their own care. Viewing the disclosure process as a conversation will allow patients and families to add their views on factors which may have contributed to errors or harms.

Multidisciplinary responsibility Errors are usually systemic in nature, involving a number of team members. There is no evidence to support any particular discipline as being more effective in disclosure. Trusts may consider exploring the use of team disclosure and consulting with patients about the information they require to tailor the best approach and the best team to be involved in the disclosure process.

Clinical governance Try to ensure that the focus of disclosures remains in the realm of quality. Counting and recording disclosures is important but not at the expense of monitoring quality. A more reflective approach to capturing performance of the organisation in relation to disclosure processes is likely to yield more sophisticated insights into quality and help to inform future efforts to improve. Asking individuals how the process met their needs and what could be improved, in the case of both individuals enacting disclosures and families, may be useful.

Confidentiality Try to ensure that issues of confidentiality are not invoked to prevent patients from accessing information or discussions which they need to understand error or harm. Being unable to discuss an error with those directly involved can be a particular frustration for families, for whom this may be part of the process of coming to terms with what has happened to them. Try to support clinicians to be able to talk directly with patients and families.

Continuity of care The focus of open disclosure should be on the care of patients rather than on mitigating organisational risk. Preserving continuity of care by respecting patient choice and consulting with them about what their care preferences are moving forward after an adverse event are likely to contribute to maintaining the patient–provider relationship in the best interests of the patient.

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Appendix 1 Sampling strategy for qualitative interviews

Group	Recruitment strategy	Recruitment for individual interviews and/or focus groups	Sampling notes
Senior managers ($n = 10$)	Participants recruited from local trusts. Targeted written explanations with an invitation to be interviewed	Individual interviews only. A focus group of these senior figures likely to be impractical	Senior-level managers in secondary and primary care including chief executives, medical directors and directors of nursing and midwifery
NHS litigation ($n = 5$)		Individual interviews only. A focus group of these senior figures likely to be impractical	Authority and key senior figures in NHS litigation (as identified by DR from the team)
Professional bodies ($n = 10$ maximum)	Targeted written explanations with an invitation to be interviewed. Start with board members and key contacts identified by the team. Senior colleagues may suggest someone to take part	Participants will be invited for interview. The practicalities of a focus group will be explored and pursued as practical	BMA, GMC, the Royal Colleges, RCN, RCM, NMC, Royal College of Pharmacists
Patient groups (maximum three focus groups)	Disseminate invitations via the patient groups and key contacts within the groups. Individuals will be asked to take part in a focus group	A focus group will be explored and pursued as practical with AvMA, WHO and PA	Contacts via AvMA, National Patient Champions, WHO, AIMS, MRSA support groups and other patient support groups. Patients who have been part of a disclosure and those who have not Maximum of three focus groups
Health professionals ($n = 50$ maximum)	Individual participants invited via publicity within trusts across the UK and through key contacts within the trusts approached. Focus groups will take place in trusts across Yorkshire	Participants will be invited for individual interviews. Separate focus groups will be set up in more local trusts as this is a more feasible approach	Ensure representation from health professionals at all levels and in all professions including doctors, nurses, midwives, pharmacists and other allied health professionals Focus groups likely to consist of one group of health professionals. Once analysis starts the team may consider a more mixed group of it is considered appropriate Maximum of five focus groups
PALS (one focus group)	Individual participants invited via publicity within trusts across the UK and through key contacts within the trusts approached	Individual interviews only. A focus group of these people is likely to be impractical	As broad a representation of trusts as possible. Ensure a mental health trust if at all possible

Group	Recruitment strategy	Recruitment for individual interviews and/or focus groups	Sampling notes
Other ($n = 5$ maximum)	Individuals who emerge as significant players in the field of open disclosure in the UK who have not been previously considered will be invited by letter or, if appropriate, in an opportunistic strategy. These people may emerge in the course of visits to other participants or in the course of meetings to disseminate the project. They may also become apparent from ongoing monitoring of the project at team meetings	Participants will be invited for interview. If there is a significant group who would provide useful data in a focus group setting, this will be considered	Maximum of one focus group if appropriate

AIMS, Association for Improvements in the Maternity Services; AvMA, Action Against Medical Accidents; MRSA, methicillin-resistant *Staphylococcus aureus*; PA, Patients Association; PALS, Patient Advice and Liaison Service; RCM, Royal College of Midwives; RCN, Royal College of Nursing; WHO, World Health Organization.

Appendix 2 Search strategy

Health-related databases

MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations

OvidSP, http://ovidsp.ovid.com/

1948 to November week 2, 2011.

Searched on 18 November 2011; 3222 records were retrieved.

1. Disclosure/ (9552)
2. Truth Disclosure/ (10,655)
3. disclos$.ti,ab. (45,475)
4. (nondisclos$ or undisclos$).ti,ab. (641)
5. (candour or candor or candid).ti,ab. (413)
6. duty of care.ti,ab. (489)
7. duty to advise.ti,ab. (8)
8. apolog$.ti,ab. (768)
9. sorry.ti,ab. (321)
10. openness.ti,ab. (2522)
11. being open.ti,ab. (277)
12. ((express$ or show$ or communicat$ or convey$) adj2 regret$).ti,ab. (123)
13. ((express$ or show$ or communicat$ or convey$) adj2 remorse).ti,ab. (15)
14. ((express$ or show$ or communicat$ or convey$) adj2 sympathy).ti,ab. (45)
15. or/1-14 (66,283)
16. Medical Errors/ (10,486)
17. Diagnostic Errors/ (27,982)
18. exp Medication Errors/ (9010)
19. Iatrogenic Disease/ (11,989)
20. Malpractice/ (24,338)
21. (adverse adj2 (event$ or incident or incidents or outcome$)).ti,ab. (82,145)
22. (safety adj2 (incident or incidents)).ti,ab. (178)
23. (serious adj2 (incident or incidents)).ti,ab. (173)
24. (sentinel adj2 event$).ti,ab. (564)
25. ((critical or clinical or medical or healthcare) adj2 (incident or incidents)).ti,ab. (1729)
26. ((harm or harms or harmful) adj3 (event$ or incident or incidents or outcome$)).ti,ab. (591)
27. (unexpected adj2 (event$ or incident or incidents or outcome$)).ti,ab. (1151)
28. (unintended adj2 (event$ or incident or incidents or outcome$)).ti,ab. (121)
29. (unintentional$ adj2 (event$ or incident or incidents or outcome$)).ti,ab. (67)
30. (unanticipated adj2 (event$ or incident or incidents or outcome$)).ti,ab. (156)
31. ((unexpected or unintended or unintentional$ or unanticipated) adj2 injur$).ti,ab. (1281)
32. (medical adj (accident$ or injur$)).ti,ab. (321)
33. (surgical adj (accident$ or injur$)).ti,ab. (703)
34. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 adverse).ti,ab. (10,028)
35. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (harm or harms or harmful)).ti,ab. (2763)
36. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (mistake$ or error or errors)).ti,ab. (3712)

37. ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or surgeon$ or surgical$ or surger$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthe$ or anesthe$ or GP) adj3 (mistake$ or error or errors)).ti,ab. (4085)
38. ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or hospital$ or system$) adj3 (mistake$ or error or errors)).ti,ab. (17,663)
39. misdiagnosis.ti,ab. (6617)
40. (iatrogenic or iatrogenesis).ti,ab. (18,465)
41. (negligence or negligent).ti,ab. (3159)
42. malpractice.ti,ab. (7847)
43. litigat$.ti,ab. (4718)
44. (legal adj (action$ or proceeding$)).ti,ab. (857)
45. (lawsuit$ or law suit$).ti,ab. (2425)
46. near miss.ti,ab. (688)
47. near misses.ti,ab. (402)
48. err is human.ti,ab. (249)
49. things go wrong.ti,ab. (63)
50. or/16-49 (213,095)
51. 15 and 50 (3156)
52. open disclosure.ti,ab. (42)
53. ((communicat$ or discuss$ or convers$ or talk$ or explain$ or explanation$ or tell$ or told or acknowledg$ or consult$ or inform$ or notif$) adj3 (patient$ or family or families or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj3 (adverse or harm$ or error or errors or mistake$ or incident or incidents)).ti,ab. (301)
54. 51 or 52 or 53 (3423)
55. limit 54 to yr="1980 -Current" (3222)

Key

/ = indexing term [medical subject heading (MeSH)]
exp = exploded MeSH
$ = truncation
.ti,ab. = terms in either title or abstract fields
adj2 = terms within two words of each other (any order)

EMBASE

OvidSP, http://ovidsp.ovid.com/

1980 to week 45, 2011.

Searched on 18 November 2011; 3655 records were retrieved.

1. *interpersonal communication/ (29,453)
2. disclos$.ti,ab. (50,225)
3. (nondisclos$ or undisclos$).ti,ab. (683)
4. (candour or candor or candid).ti,ab. (434)
5. duty of care.ti,ab. (573)
6. duty to advise.ti,ab. (8)
7. apolog$.ti,ab. (801)
8. sorry.ti,ab. (367)
9. openness.ti,ab. (2813)
10. being open.ti,ab. (317)
11. ((express$ or show$ or communicat$ or convey$) adj2 regret$).ti,ab. (129)
12. ((express$ or show$ or communicat$ or convey$) adj2 remorse).ti,ab. (12)
13. ((express$ or show$ or communicat$ or convey$) adj2 sympathy).ti,ab. (47)

14. or/1-13 (83,329)
15. exp medical error/ (66,530)
16. exp *iatrogenic disease/ (124,806)
17. sentinel event/ (118)
18. malpractice/ (28,065)
19. negligence/ (2761)
20. lawsuit/ (7778)
21. (adverse adj2 (event$ or incident or incidents or outcome$)).ti,ab. (108,362)
22. (safety adj2 (incident or incidents)).ti,ab. (216)
23. (serious adj2 (incident or incidents)).ti,ab. (245)
24. (sentinel adj2 event$).ti,ab. (653)
25. ((critical or clinical or medical or healthcare) adj2 (incident or incidents)).ti,ab. (2047)
26. ((harm or harms or harmful) adj3 (event$ or incident or incidents or outcome$)).ti,ab. (714)
27. (unexpected adj2 (event$ or incident or incidents or outcome$)).ti,ab. (1400)
28. (unintended adj2 (event$ or incident or incidents or outcome$)).ti,ab. (132)
29. (unintentional$ adj2 (event$ or incident or incidents or outcome$)).ti,ab. (70)
30. (unanticipated adj2 (event$ or incident or incidents or outcome$)).ti,ab. (198)
31. ((unexpected or unintended or unintentional$ or unanticipated) adj2 injur$).ti,ab. (1330)
32. (medical adj (accident$ or injur$)).ti,ab. (342)
33. (surgical adj (accident$ or injur$)).ti,ab. (779)
34. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 adverse).ti,ab. (13,061)
35. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (harm or harms or harmful)).ti,ab. (3311)
36. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (mistake$ or error or errors)).ti,ab. (4391)
37. ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or surgeon$ or surgical$ or surger$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthe$ or anesthe$ or GP) adj3 (mistake$ or error or errors)).ti,ab. (4883)
38. ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or hospital$ or system$) adj3 (mistake$ or error or errors)).ti,ab. (19,843)
39. misdiagnosis.ti,ab. (7808)
40. (iatrogenic or iatrogenesis).ti,ab. (21,661)
41. (negligence or negligent).ti,ab. (3538)
42. malpractice.ti,ab. (8078)
43. litigat$.ti,ab. (5423)
44. (legal adj (action$ or proceeding$)).ti,ab. (962)
45. (lawsuit$ or law suit$).ti,ab. (2480)
46. near miss.ti,ab. (808)
47. near misses.ti,ab. (516)
48. err is human.ti,ab. (280)
49. things go wrong.ti,ab. (97)
50. or/15-49 (386,847)
51. 14 and 50 (3407)
52. open disclosure.ti,ab. (44)
53. ((communicat$ or discuss$ or convers$ or talk$ or explain$ or explanation$ or tell$ or told or acknowledg$ or consult$ or inform$ or notif$) adj3 (patient$ or family or families or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj3 (adverse or harm $ or error or errors or mistake$ or incident or incidents)).ti,ab. (400)
54. 51 or 52 or 53 (3776)
55. limit 54 to yr="1980 -Current" (3655)

Key

/ = indexing term (EMTREE heading)
* = focused EMTREE heading
exp = exploded EMTREE heading
$ = truncation
.ti,ab. = terms in either title or abstract fields
adj2 = terms within two words of each other (any order)

PsycINFO

OvidSP, http://ovidsp.ovid.com/

1806 to November week 3, 2011.

Searched on 18 November 2011; 697 records were retrieved.

1. interpersonal communication/ (12,219)
2. disclos$.ti,ab. (15,916)
3. (nondisclos$ or undisclos$).ti,ab. (388)
4. (candour or candor or candid).ti,ab. (732)
5. duty of care.ti,ab. (176)
6. duty to advise.ti,ab. (4)
7. apolog$.ti,ab. (1521)
8. sorry.ti,ab. (234)
9. openness.ti,ab. (6694)
10. being open.ti,ab. (197)
11. ((express$ or show$ or communicat$ or convey$) adj2 regret$).ti,ab. (120)
12. ((express$ or show$ or communicat$ or convey$) adj2 remorse).ti,ab. (50)
13. ((express$ or show$ or communicat$ or convey$) adj2 sympathy).ti,ab. (125)
14. or/1-13 (37,231)
15. Errors/ (6987)
16. Misdiagnosis/ (333)
17. professional liability/ (1723)
18. litigation/ (919)
19. (adverse adj2 (event$ or incident or incidents or outcome$)).ti,ab. (8032)
20. (safety adj2 (incident or incidents)).ti,ab. (43)
21. (serious adj2 (incident or incidents)).ti,ab. (97)
22. (sentinel adj2 event$).ti,ab. (53)
23. ((critical or clinical or medical or healthcare) adj2 (incident or incidents)).ti,ab. (2099)
24. ((harm or harms or harmful) adj3 (event$ or incident or incidents or outcome$)).ti,ab. (292)
25. (unexpected adj2 (event$ or incident or incidents or outcome$)).ti,ab. (531)
26. (unintended adj2 (event$ or incident or incidents or outcome$)).ti,ab. (90)
27. (unintentional$ adj2 (event$ or incident or incidents or outcome$)).ti,ab. (12)
28. (unanticipated adj2 (event$ or incident or incidents or outcome$)).ti,ab. (101)
29. ((unexpected or unintended or unintentional$ or unanticipated) adj2 injur$).ti,ab. (416)
30. (medical adj (accident$ or injur$)).ti,ab. (34)
31. (surgical adj (accident$ or injur$)).ti,ab. (6)
32. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 adverse).ti,ab. (771)
33. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (harm or harms or harmful)).ti,ab. (881)
34. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (mistake$ or error or errors)).ti,ab. (767)

35. ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or surgeon$ or surgical$ or surger$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthe$ or anesthe$ or GP) adj3 (mistake$ or error or errors)).ti,ab. (1063)
36. ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or hospital$ or system$) adj3 (mistake$ or error or errors)).ti,ab. (2637)
37. misdiagnosis.ti,ab. (903)
38. (iatrogenic or iatrogenesis).ti,ab. (1173)
39. (negligence or negligent).ti,ab. (906)
40. malpractice.ti,ab. (1104)
41. litigat$.ti,ab. (2642)
42. (legal adj (action$ or proceeding$)).ti,ab. (649)
43. (lawsuit$ or law suit$).ti,ab. (807)
44. near miss.ti,ab. (147)
45. near misses.ti,ab. (114)
46. err is human.ti,ab. (45)
47. things go wrong.ti,ab. (56)
48. or/15-47 (31,213)
49. 14 and 48 (620)
50. open disclosure.ti,ab. (27)
51. ((communicat$ or discuss$ or convers$ or talk$ or explain$ or explanation$ or tell$ or told or acknowledg$ or consult$ or inform$ or notif$) adj3 (patient$ or family or families or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj3 (adverse or harm$ or error or errors or mistake$ or incident or incidents)).ti,ab. (92)
52. 49 or 50 or 51 (722)
53. limit 52 to yr="1980 -Current" (697)

Key
/ = subject heading
$ = truncation
.ti,ab. = terms in either title or abstract fields
adj2 = terms within two words of each other (any order)

Health Management Information Consortium (HMIC)

OvidSP, http://ovidsp.ovid.com/

1979 to September 2011.

Searched on 18 November 2011; 236 records were retrieved.

1. "disclosure of information"/ (401)
2. "duty of care"/ (2)
3. openness/ (23)
4. disclos$.ti,ab. (947)
5. (nondisclos$ or undisclos$).ti,ab. (18)
6. (candour or candor or candid).ti,ab. (21)
7. duty of care.ti,ab. (127)
8. duty to advise.ti,ab. (1)
9. apolog$.ti,ab. (48)
10. sorry.ti,ab. (52)
11. openness.ti,ab. (391)
12. being open.ti,ab. (33)
13. ((express$ or show$ or communicat$ or convey$) adj2 regret$).ti,ab. (7)
14. ((express$ or show$ or communicat$ or convey$) adj2 remorse).ti,ab. (1)

15. ((express$ or show$ or communicat$ or convey$) adj2 sympathy).ti,ab. (5)
16. or/1-15 (1803)
17. exp errors/ (910)
18. iatrogenic disease/ (39)
19. exp medical malpractice/ (1085)
20. clinical negligence/ (94)
21. legal proceedings/ (480)
22. litigation/ (351)
23. adverse events/ (420)
24. (adverse adj2 (event$ or incident or incidents or outcome$)).ti,ab. (1413)
25. (safety adj2 (incident or incidents)).ti,ab. (113)
26. (serious adj2 (incident or incidents)).ti,ab. (73)
27. (sentinel adj2 event$).ti,ab. (20)
28. ((critical or clinical or medical or healthcare) adj2 (incident or incidents)).ti,ab. (326)
29. ((harm or harms or harmful) adj3 (event$ or incident or incidents or outcome$)).ti,ab. (49)
30. (unexpected adj2 (event$ or incident or incidents or outcome$)).ti,ab. (23)
31. (unintended adj2 (event$ or incident or incidents or outcome$)).ti,ab. (16)
32. (unintentional$ adj2 (event$ or incident or incidents or outcome$)).ti,ab. (0)
33. (unanticipated adj2 (event$ or incident or incidents or outcome$)).ti,ab. (8)
34. ((critical or clinical) adj2 (incident or incidents)).ti,ab. (297)
35. ((unexpected or unintended or unintentional$ or unanticipated) adj2 injur$).ti,ab. (64)
36. (medical adj (accident$ or injur$)).ti,ab. (72)
37. (surgical adj (accident$ or injur$)).ti,ab. (5)
38. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 adverse).ti,ab. (191)
39. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (harm or harms or harmful)).ti,ab. (276)
40. ((patient$ or inpatient$ or outpatient$ or consumer$ or citizen$ or public or user$) adj3 (mistake$ or error or errors)).ti,ab. (165)
41. ((professional$ or worker$ or dentist$ or nurs$ or doctor$ or physician$ or surgeon$ or surgical$ or surger$ or pharmac$ or human or practitioner$ or psychiatrist$ or psychologist$ or anaesthe$ or anesthe$ or GP) adj3 (mistake$ or error or errors)).ti,ab. (245)
42. ((medical or diagnos$ or treatment$ or medication$ or healthcare or care or hospital$ or system$) adj3 (mistake$ or error or errors)).ti,ab. (681)
43. misdiagnosis.ti,ab. (54)
44. (iatrogenic or iatrogenesis).ti,ab. (101)
45. (negligence or negligent).ti,ab. (587)
46. malpractice.ti,ab. (200)
47. litigat$.ti,ab. (566)
48. (legal adj (action$ or proceeding$)).ti,ab. (134)
49. (lawsuit$ or law suit$).ti,ab. (38)
50. near miss.ti,ab. (32)
51. near misses.ti,ab. (80)
52. err is human.ti,ab. (24)
53. things go wrong.ti,ab. (72)
54. or/17-53 (5580)
55. 16 and 54 (207)
56. open disclosure.ti,ab. (12)
57. ((communicat$ or discuss$ or convers$ or talk$ or explain$ or explanation$ or tell$ or told or acknowledg$ or consult$ or inform$ or notif$) adj3 (patient$ or family or families or inpatient$ or outpatient$ or consumer$ or citizen$ or public or carer$ or caregiver$ or user$) adj3 (adverse or harm$ or error or errors or mistake$ or incident or incidents)).ti,ab. (38)
58. 55 or 56 or 57 (236)
59. limit 58 to yr="1980 -Current" (236)

Key
/ = subject heading
exp = exploded subject heading
$ = truncation
.ti,ab. = terms in either title or abstract fields
adj2 = terms within two words of each other (any order)

The Cochrane Library
Wiley, http://onlinelibrary.wiley.com/

- Cochrane Database of Systematic Reviews (CDSR), Issue 11, November 2011
- Database of Abstracts of Reviews of Effects (DARE), Issue 4, October 2011
- Health Technology Assessment (HTA) Database, Issue 4, October 2011
- Cochrane Central Register of Controlled Trials (CENTRAL), Issue 4, October 2011.

The above four databases were searched on 22 November 2011, via The Cochrane Library.

Ninety-three records were retrieved in total: 10 from CDSR, 1 from DARE, 0 from HTA, 82 from CENTRAL.

ID	Search	Hits
#1	MeSH descriptor Disclosure, this term only	80
#2	MeSH descriptor Truth Disclosure, this term only	167
#3	disclos*:ti,ab	1409
#4	(nondisclos* or undisclos*):ti,ab	27
#5	(candour or candor or candid):ti,ab	10
#6	"duty of care":ti,ab	0
#7	"duty to advise":ti,ab	0
#8	apolog*:ti,ab	11
#9	sorry:ti,ab	4
#10	openness:ti,ab	69
#11	being NEXT open:ti,ab.	4
#12	((express* or show* or communicat* or convey*) NEAR/2 regret*):ti,ab	3
#13	((express* or show* or communicat* or convey*) NEAR/2 remorse):ti,ab	0
#14	((express* or show* or communicat* or convey*) NEAR/2 sympathy):ti,ab	2
#15	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)	1680
#16	MeSH descriptor Medical Errors, this term only	82
#17	MeSH descriptor Diagnostic Errors, this term only	211
#18	MeSH descriptor Medication Errors explode all trees	147
#19	MeSH descriptor Iatrogenic Disease, this term only	61
#20	MeSH descriptor Malpractice, this term only	10
#21	(adverse NEAR/2 (event* or incident or incidents or outcome*)):ti,ab	24,785
#22	(safety NEAR/2 (incident or incidents)):ti,ab	2
#23	(serious NEAR/2 (incident or incidents)):ti,ab	6
#24	(sentinel NEAR/2 event*):ti,ab	9
#25	((critical or clinical or medical or healthcare) NEAR/2 (incident or incidents)):ti,ab	55
#26	((harm or harms or harmful) NEAR/3 (event* or incident or incidents or outcome*)):ti,ab	62

APPENDIX 2

ID	Search	Hits
#27	(unexpected NEAR/2 (event* or incident or incidents or outcome*)):ti,ab	200
#28	(unintended NEAR/2 (event* or incident or incidents or outcome*)):ti,ab	7
#29	(unintentional* NEAR/2 (event* or incident or incidents or outcome*)):ti,ab	2
#30	(unanticipated NEAR/2 (event* or incident or incidents or outcome*)):ti,ab	19
#31	((unexpected or unintended or unintentional* or unanticipated) NEAR/2 injur*):ti,ab	46
#32	(medical NEXT (accident* or injur*)):ti,ab	1
#33	(surgical NEXT (accident* or injur*)):ti,ab	31
#34	((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) NEAR/3 adverse):ti,ab	2215
#35	((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) NEAR/3 (harm or harms or harmful)):ti,ab	162
#36	((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) NEAR/3 (mistake* or error or errors)):ti,ab	149
#37	((professional* or worker* or dentist* or nurs* or doctor* or physician* or surgeon* or surgical* or surger* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or anaesthe* or anesthe* or GP) NEAR/3 (mistake* or error or errors)):ti,ab	93
#38	((medical or diagnos* or treatment* or medication* or healthcare or care or hospital* or system*) NEAR/3 (mistake* or error or errors)):ti,ab	401
#39	misdiagnosis:ti,ab	43
#40	(iatrogenic or iatrogenesis):ti,ab	287
#41	(negligence or negligent):ti,ab	18
#42	malpractice:ti,ab	12
#43	litigat*:ti,ab	50
#44	(legal NEXT (action* or proceeding*)):ti,ab	7
#45	lawsuit*:ti,ab.	8671
#46	law NEXT suit*:ti,ab	1
#47	"near miss":ti,ab	11
#48	"near misses":ti,ab	6
#49	"err is human":ti,ab	1
#50	"things go wrong":ti,ab	0
#51	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50)	35,181
#52	(#15 AND #51)	103
#53	(open NEXT disclosure):ti,ab	0
#54	((communicat* or discuss* or convers* or talk* or explain* or explanation* or tell* or told or acknowledg* or consult* or inform* or notif*) NEAR/3 (patient* or family or families or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*) NEAR/3 (adverse or harm* or error or errors or mistake* or incident or incidents)):ti,ab	6
#55	(#52 OR #53 OR #54) limited to CDSR, DARE, HTA, CENTRAL	94
#56	(#52 OR #53 OR #54), from 1980 to 2011 limited to CDSR, DARE, HTA, CENTRAL	93

MeSH descriptor = indexing term (MeSH).
* = truncation.
:ti,ab = terms in either title or abstract fields.
NEAR/2 = terms within two words of each other (any order).
NEXT = terms are next to each other.
" " = phrase search.

Cumulative Index to Nursing and Allied Health Literature (CINAHL)

Via EBSCO*host*.

Inception to 9 December 2011.

Searched on 21 December 2011; 1300 records were retrieved.

#	Query	Results
S62	S59 or S60 or S61 Limiters - Published Date from: 19800101-	1300
S61	TI ((communicat* or discuss* or convers* or talk* or explain* or explanation* or tell* or told or acknowledg* or consult* or inform* or notif*) N3 (patient* or family or families or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*) N3 (adverse or harm* or error or errors or mistake* or incident or incidents)) OR AB ((communicat* or discuss* or convers* or talk* or explain* or explanation* or tell* or told or acknowledg* or consult* or inform* or notif*) N3 (patient* or family or families or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*) N3 (adverse or harm* or error or errors or mistake* or incident or incidents))	183
S60	TI "open disclosure" OR AB "open disclosure"	26
S59	S53 and S58	1165
S58	S10 or S54 or S55 or S56 or S57	11,431
S57	TI ((express* or show* or communicat* or convey*) N2 sympathy) OR AB ((express* or show* or communicat* or convey*) N2 sympathy)	28
S56	TI ((express* or show* or communicat* or convey*) N2 remorse) OR AB ((express* or show* or communicat* or convey*) N2 remorse)	4
S55	TI ((express* or show* or communicat* or convey*) N2 regret*) OR AB ((express* or show* or communicat* or convey*) N2 regret*)	29
S54	TI "being open" OR AB "being open"	67
S53	S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52	60,878
S52	TI "things go wrong" OR AB "things go wrong"	59
S51	TI "err is human" OR AB "err is human"	124
S50	TI "near misses" OR AB "near misses"	194
S49	TI "near miss" OR AB "near miss"	234
S48	TI (lawsuit* or "law suit*") OR AB (lawsuit* or "law suit*")	1609
S47	TI ("legal action*" or "legal proceeding*") OR AB ("legal action*" or "legal proceeding*")	295
S46	TI litigat* OR AB litigat*	1731
S45	TI malpractice OR AB malpractice	2361
S44	TI (negligence or negligent) OR AB (negligence or negligent)	1625
S43	TI (iatrogenic or iatrogenesis) OR AB (iatrogenic or iatrogenesis)	1587
S42	TI misdiagnosis OR AB misdiagnosis	765
S41	TI ((medical or diagnos* or treatment* or medication* or healthcare or care or hospital* or system*) N3 (mistake* or error or errors)) OR AB ((medical or diagnos* or treatment* or medication* or healthcare or care or hospital* or system*) N3 (mistake* or error or errors))	5467

#	Query	Results
S40	TI ((professional* or worker* or dentist* or nurs* or doctor* or physician* or surgeon* or surgical* or surger* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or anaesthe* or anesthe* or GP) N3 (mistake* or error or errors)) OR AB ((professional* or worker* or dentist* or nurs* or doctor* or physician* or surgeon* or surgical* or surger* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or anaesthe* or anesthe* or GP) N3 (mistake* or error or errors))	1521
S39	TI ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 (mistake* or error or errors)) OR AB ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 (mistake* or error or errors))	1332
S38	TI ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 (harm or harms or harmful)) OR AB ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 (harm or harms or harmful))	1281
S37	TI ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 adverse) OR AB ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) N3 adverse)	2580
S36	TI ("surgical accident*" or "surgical injur*") OR AB ("surgical accident*" or "surgical injur*")	35
S35	TI ("medical accident*" or "medical injur*") OR AB ("medical accident*" or "medical injur*")	79
S34	TI ((unexpected or unintended or unintentional* or unanticipated) N2 injur*) OR AB ((unexpected or unintended or unintentional* or unanticipated) N2 injur*)	611
S33	TI (unanticipated N2 (event* or incident or incidents or outcome*)) OR AB (unanticipated N2 (event* or incident or incidents or outcome*))	80
S32	TI (unintentional* N2 (event* or incident or incidents or outcome*)) OR AB (unintentional* N2 (event* or incident or incidents or outcome*))	27
S31	TI (unintended N2 (event* or incident or incidents or outcome*)) OR AB (unintended N2 (event* or incident or incidents or outcome*))	45
S30	TI (unexpected N2 (event* or incident or incidents or outcome*)) OR AB (unexpected N2 (event* or incident or incidents or outcome*))	281
S29	TI ((harm or harms or harmful) N3 (event* or incident or incidents or outcome*)) OR AB ((harm or harms or harmful) N3 (event* or incident or incidents or outcome*))	268
S28	TI ((critical or clinical or medical or healthcare) N2 (incident or incidents)) OR AB ((critical or clinical or medical or healthcare) N2 (incident or incidents))	1083
S27	TI sentinel N2 event* OR AB sentinel N2 event*	399
S26	TI (serious N2 (incident or incidents)) OR AB (serious N2 (incident or incidents))	68
S25	TI (safety N2 (incident or incidents)) OR AB (safety N2 (incident or incidents))	145
S24	TI (adverse N2 (event* or incident or incidents or outcome*)) OR AB (adverse N2 (event* or incident or incidents or outcome*))	16,562
S23	(MH "Legal Procedure+")	3916
S22	(MH "Negligence")	3985
S21	(MH "Malpractice")	6020
S20	(MH "Iatrogenic Disease")	1129
S19	(MH "Sentinel Event")	631
S18	(MH "Adverse Drug Event")	2596
S17	(MH "Adverse Health Care Event")	2237
S16	(MH "Failure to Diagnose")	1025

#	Query	Results
S15	(MH "Human Error")	454
S14	(MH "Diagnostic Errors")	4111
S13	(MH "Medication Errors")	7424
S12	(MH "Treatment Errors")	4066
S11	(MH "Health Care Errors")	1914
S10	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9	11,321
S9	TI openness OR AB openness	814
S8	TI sorry OR AB sorry	245
S7	TI apolog* OR AB apolog*	391
S6	TI "duty to advise" OR AB "duty to advise"	8
S5	TI "duty of care" OR AB "duty of care"	333
S4	TI (candour or candor or candid) OR AB (candour or candor or candid)	132
S3	TI (nondisclos* or undisclos*) OR AB (nondisclos* or undisclos*)	167
S2	TI disclos* OR AB disclos*	5581
S1	(MH "Truth Disclosure")	5370

MH = indexing term (CINAHL heading).
+ = exploded CINAHL heading.
* = truncation.
TI = words in the title.
AB = words in the abstract.
" " = phrase search.
N2 = terms within two words of each other (any order).

Science Citation Index (SCI)
Social Sciences Citation Index (SSCI)
Conference Proceedings Citation Index – Science (CPCI-S)
Conference Proceedings Citation Index – Social Science & Humanities (CPCI-SSH)

Web of Science – ISI Web of Knowledge, www.isinet.com/

SCI, 1899 to present; SSCI, 1956 to present; CPCI-S, 1990 to present; CPCI-SSH, 1990 to present.

The above four databases were searched together with the strategy as set out below on 6 December 2011; 3778 records were retrieved in total.

Query number	Results	Query
# 45	3778	#44 *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=1980-2011*
# 44	3785	#43 OR #42 OR #41 *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 43	2145	TS=((communicat* or discuss or discussed or convers* or talk* or explain* or explanation* or tell* or told or acknowledg* or consult* or inform or informs or informed or informing or notif*) SAME (patient* or family or families or inpatient* or outpatient* or consumer* or citizen* or public or carer* or caregiver* or user*) SAME (adverse or harm or harms or harmful or error or errors or mistake* or incident or incidents)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 42	43	TS="open disclosure" *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 41	1724	#40 AND #12 *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 40	> 100,000	#39 OR #38 OR #37 OR #36 OR #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 39	112	TS="things go wrong" *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 38	195	TS="err is human" *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 37	2818	TS=(lawsuit* or "law suit*") *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 36	948	TS=("legal action*" or "legal proceeding*") *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 35	10,948	TS=litigat* *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 34	5625	TS=malpractice *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 33	3358	TS=(negligence or negligent) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*

Query number	Results	Query
# 32	13,183	TS=(iatrogenic or iatrogenesis) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 31	5123	TS=misdiagnosis *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 30	82,099	TS=((medical or diagnos* or treatment* or medication* or healthcare or care or hospital* or system*) SAME (mistake* or error or errors)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 29	12,738	TS=((professional* or worker* or dentist* or nurs* or doctor* or physician* or surgeon* or surgical* or surger* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or anaesthe* or anesthe* or GP) SAME (mistake* or error or errors)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 28	17,176	TS=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) SAME (mistake* or error or errors)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 27	6815	TS=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) SAME (harm or harms or harmful)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 26	42,210	TS=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) SAME adverse) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 25	448	TS=("surgical accident*" or "surgical injur*") *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 24	272	TS=("medical accident*" or "medical injur*") *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 23	1680	TS=((unexpected or unintended or unintentional* or unanticipated) SAME injur*) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 22	437	TS=(unanticipated SAME (event* or incident or incidents or outcome*)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 21	237	TS=(unintentional* SAME (event* or incident or incidents or outcome*)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 20	462	TS=(unintended SAME (event* or incident or incidents or outcome*)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 19	2944	TS=(unexpected SAME (event* or incident or incidents or outcome*)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 18	2159	TS=((harm or harms or harmful) SAME (event* or incident or incidents or outcome*)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*
# 17	4755	TS=((critical or clinical or medical or healthcare) SAME (incident or incidents)) *Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years*

APPENDIX 2

Query number	Results	Query
# 16	407	TS=(sentinel SAME event*)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 15	486	TS=(serious SAME (incident or incidents))
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 14	1242	TS=(safety SAME (incident or incidents))
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 13	82,616	TS=(adverse SAME (event* or incident or incidents or outcome*))
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 12	59,602	#11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 11	188	TS=((express* or show* or communicat* or convey*) SAME sympathy)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 10	42	TS=((express* or show* or communicat* or convey*) SAME remorse)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 9	386	TS=((express* or show* or communicat* or convey*) SAME regret*)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 8	8673	TS=openness
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 7	618	TS=sorry
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 6	2060	TS=apolog*
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 5	6	TS="duty to advise"
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 4	452	TS="duty of care"
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 3	775	TS=(candour or candor or candid)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 2	763	TS=(nondisclos* or undisclos*)
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years
# 1	46,329	TS=disclos*
		Databases=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=All Years

TS = topic tag; searches terms in title, abstract, author keywords and keywords plus fields.
* = truncation.
" " = phrase search.
SAME = terms within same sentence.

Latin American and Caribbean Health Sciences Literature (LILACS)

http://bases.bireme.br/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&base=LILACS&lang=i

Searched on 20 December 2011; 83 records were retrieved.

disclos$ or nondisclos$ or undisclos$ or candour or candor or candid or apolog$ or sorry or openness [Words field]

934 records

AND

error$ or mistake$ or adverse or harm$ or misdiagnosis or sentinel or safety or iatrogenic or iatrogenesis or negligence or negligent or malpractice or litigat$ or "NEAR-MISS" or "NEAR-MISSES" [Words field]

42,474 records

83 records

Key

$ = truncation

PASCAL

Dialog, www.dialog.com/

1973 to December week 3, 2012.

Searched on 9 January 2012; 921 records were retrieved.

Set	Items	Description
1	16,404	DISCLOS?/TI,AB,DE
2	243	(NONDISCLOS? OR UNDISCLOS?)/TI,AB,DE
3	173	(CANDOUR OR CANDOR OR CANDID)/TI,AB,DE
4	0	DUTY(W)OF(W)CARE/TI,AB,DE
5	0	DUTY(W)TO(W)ADVISE/TI,AB,DE
6	286	APOLOG?/TI,AB,DE
7	63	SORRY/TI,AB,DE
8	2026	OPENNESS/TI,AB,DE
9	73	BEING(W)OPEN/TI,AB,DE
10	76	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REGRET?/TI,AB,DE
11	9	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REMORSE/TI,AB,DE
12	21	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)SYMPATHY/TI,AB,DE
13	19,178	S1:S12

Set	Items	Description
14	39,042	ADVERSE(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
15	109	SAFETY(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
16	97	SERIOUS(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
17	151	SENTINEL(2N)EVENT?/TI,AB,DE
18	750	(CRITICAL OR CLINICAL OR MEDICAL OR HEALTHCARE)(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
19	321	(HARM OR HARMS OR HARMFUL)(3N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
20	745	UNEXPECTED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
21	61	UNINTENDED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
22	31	UNINTENTIONAL?(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
23	89	UNANTICIPATED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
24	452	(UNEXPECTED OR UNINTENDED OR UNINTENTIONAL? OR UNANTICIPATED)(2N)INJUR?/TI,AB,DE
25	78	MEDICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
26	216	SURGICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
27	6560	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)ADVERSE/TI,AB,DE
28	986	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(HARM OR HARMS OR HARMFUL)/TI,AB,DE
29	2779	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
30	8055	(PROFESSIONAL? OR WORKER? OR DENTIST? OR NURS? OR DOCTOR? OR PHYSICIAN? OR SURGEON? OR SURGICAL? OR SURGER?

Set	Items	Description
		OR PHARMAC? OR HUMAN OR PRACTITIONER? OR PSYCHIATRIST? OR PSYCHOLOGIST? OR ANAESTHE? OR ANESTHE? OR GP)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
31	24,079	(MEDICAL OR DIAGNOS? OR TREATMENT? OR MEDICATION? OR HEALTHCARE OR CARE OR HOSPITAL? OR SYSTEM?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
32	2086	MISDIAGNOSIS/TI,AB,DE
33	21,351	(IATROGENIC OR IATROGENESIS)/TI,AB,DE
34	2975	(NEGLIGENCE OR NEGLIGENT)/TI,AB,DE
35	1937	MALPRACTICE/TI,AB,DE
36	1605	LITIGAT?/TI,AB,DE
37	194	LEGAL(W)(ACTION? OR PROCEEDING?)/TI,AB,DE
38	390	(LAWSUIT? OR LAW(W)SUIT?)/TI,AB,DE
39	302	NEAR(W)MISS/TI,AB,DE
40	165	NEAR(W)MISSES/TI,AB,DE
41	48	ERR(W)IS(W)HUMAN/TI,AB,DE
42	23	THINGS(W)GO(W)WRONG/TI,AB,DE
43	105153	S14:S42
44	431	S13 AND S43
45	15	OPEN(W)DISCLOSURE/TI,AB,DE
46	514	(COMMUNICAT? OR DISCUSS? OR CONVERS? OR TALK? OR EXPLAIN? OR EXPLANATION? OR TELL? OR TOLD OR ACKNOWLEDG? OR CONSULT? OR INFORM? OR NOTIF?)(3N)(PATIENT? OR FAMILY OR FAMILIES OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR CARER? OR CAREGIVER? OR USER?)(3N)(ADVERSE OR HARM? OR ERROR OR ERRORS OR MISTAKE? OR INCIDENT OR INCIDENTS)/TI,AB,DE
47	924	S44:S46
48	921	S47/1980:2012

? = truncation.
/TI,AB,DE = terms in title, abstract or descriptor fields.
(W) = terms adjacent to each other (same order).
(2N) = terms within two words of each other (any order).
S1:S12 = S1 OR S2 OR S3 OR S4 . . . S12.
S47/1980:2012 = limits set 47 to those records published between1980 and 2012.

Health Systems Evidence
www.mcmasterhealthforum.org/healthsystemsevidence-en

Searched on 6 January 2012; 13 records were retrieved.

Using the open search box the following terms were entered:

disclos* OR nondisclos* OR undisclos* OR candour OR candor OR apolog* OR sorry OR openness

Key
* = truncation

Social science databases

Applied Social Sciences Index and Abstracts (ASSIA)
CSA Illumina, www.csa.com/csaillumina/

1987 to December 2011.

Searched on 20 December 2011; 199 records were retrieved.

((DE="disclosure") or(DE="truth telling") or(DE="duty of care") or(DE="apologies") or(DE="openness") or(DE="regret") or(DE="remorse") or(DE="sympathy") or(KW=disclos*) or(KW=(nondisclos* or undisclos*)) or(KW=(candour or candor or candid)) or(KW="duty of care") or(KW="duty to advise") or (KW=apolog*) or(KW=sorry) or(KW=openness) or(KW="being open") or(KW=((express* or show* or communicat* or convey*) WITHIN 2 regret*)) or(KW=((express* or show* or communicat* or convey*) WITHIN 2 remorse)) or(KW=((express* or show* or communicat* or convey*) WITHIN 2 sympathy))) and ((DE=("errors" or "human error" or "near misses")) or(DE=("misdiagnosed" or "misdiagnosis")) or (DE="iatrogenic effects") or(DE="medical malpractice") or(DE="medical negligence") or(DE="critical incidents") or(DE="harm") or(DE="mistakes") or(DE=("litigation" or "claims" or "class action suits")) or (KW=(adverse WITHIN 2 (event* or incident or incidents or outcome*))) or(KW=(safety WITHIN 2 (incident or incidents))) or(KW=(serious WITHIN 2 (incident or incidents))) or(KW=(sentinel WITHIN 2 event*)) or (KW=((critical or clinical or medical or healthcare) WITHIN 2 (incident or incidents))) or(KW=((harm or harms or harmful) WITHIN 3 (event* or incident or incidents or outcome*))) or(KW=(unexpected WITHIN 2 (event* or incident or incidents or outcome*))) or(KW=(unintended WITHIN 2 (event* or incident or incidents or outcome*))) or(KW=(unintentional* WITHIN 2 (event* or incident or incidents or outcome*))) or(KW=(unanticipated WITHIN 2 (event* or incident or incidents or outcome*))) or(KW=((unexpected or unintended or unintentional* or unanticipated) WITHIN 2 injur*)) or(KW="medical accident*" or "medical injur*") or(KW="surgical accident*" or "surgical injur*") or(KW=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) WITHIN 3 adverse)) or(KW=((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) WITHIN 3 (harm or harms or harmful))) or(KW= ((patient* or inpatient* or outpatient* or consumer* or citizen* or public or user*) WITHIN 3 (mistake* or error or errors))) or(KW=((professional* or worker* or dentist* or nurs* or doctor* or physician* or surgeon* or surgical* or surger* or pharmac* or human or practitioner* or psychiatrist* or psychologist* or anaesthe* or anesthe* or GP) WITHIN 3 (mistake* or error or errors))) or(KW=((medical or diagnos* or treatment* or medication* or healthcare or care or hospital* or system*) WITHIN 3 (mistake* or error or errors))) or(KW=misdiagnosis) or(KW=(iatrogenic or iatrogenesis)) or(KW=(negligence or negligent)) or (KW=malpractice) or(KW=litigat*) or(KW=("legal action*" or "legal proceeding*")) or(KW=(lawsuit* or "law suit*")) or(KW=("near miss" or "near misses")) or(KW="err is human") or(KW="things go wrong"))

Key
DE = subject heading
KW = searches the title, abstract, descriptor and identifier fields
WITHIN 2 = terms within two words of each other (any order)
* = truncation
" " = phrase search

Law databases

Lawtel

Westlaw

Lexus

Reports/conference proceedings/grey literature

National Technical Information Service (NTIS)
Dialog, www.dialog.com/

1964 to January week 1, 2012.

Searched on 9 January 2012; 217 records were retrieved.

Set	Items	Description
1	9931	DISCLOS?/TI,AB,DE
2	58	(NONDISCLOS? OR UNDISCLOS?)/TI,AB,DE
3	168	(CANDOUR OR CANDOR OR CANDID)/TI,AB,DE
4	0	DUTY(W)OF(W)CARE/TI,AB,DE
5	0	DUTY(W)TO(W)ADVISE/TI,AB,DE
6	51	APOLOG?/TI,AB,DE
7	10	SORRY/TI,AB,DE
8	379	OPENNESS/TI,AB,DE
9	25	BEING(W)OPEN/TI,AB,DE
10	2	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REGRET?/TI,AB,DE
11	0	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REMORSE/TI,AB,DE
12	5	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)SYMPATHY/TI,AB,DE
13	10,604	S1:S12
14	516	ADVERSE(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
15	192	SAFETY(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE

Set	Items	Description
16	72	SERIOUS(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
17	40	SENTINEL(2N)EVENT?/TI,AB,DE
18	246	(CRITICAL OR CLINICAL OR MEDICAL OR HEALTHCARE)(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
19	36	(HARM OR HARMS OR HARMFUL)(3N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
20	145	UNEXPECTED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
21	12	UNINTENDED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
22	10	UNINTENTIONAL?(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
23	57	UNANTICIPATED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
24	100	(UNEXPECTED OR UNINTENDED OR UNINTENTIONAL? OR UNANTICIPATED)(2N)INJUR?/TI,AB,DE
25	34	MEDICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
26	4	SURGICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
27	242	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)ADVERSE/TI,AB,DE
28	131	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(HARM OR HARMS OR HARMFUL)/TI,AB,DE
29	604	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
30	1536	(PROFESSIONAL? OR WORKER? OR DENTIST? OR NURS? OR DOCTOR? OR PHYSICIAN? OR SURGEON? OR SURGICAL? OR SURGER? OR PHARMAC? OR HUMAN OR PRACTITIONER? OR PSYCHIATRIST? OR PSYCHOLOGIST? OR ANAESTHE? OR ANESTHE? OR GP)(3N)(MISTAKE?

Set	Items	Description
		OR ERROR OR ERRORS)/TI,AB,DE
31	7343	(MEDICAL OR DIAGNOS? OR TREATMENT? OR MEDICATION? OR HEALTHCARE OR CARE OR HOSPITAL? OR SYSTEM?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
32	20	MISDIAGNOSIS/TI,AB,DE
33	61	(IATROGENIC OR IATROGENESIS)/TI,AB,DE
34	220	(NEGLIGENCE OR NEGLIGENT)/TI,AB,DE
35	462	MALPRACTICE/TI,AB,DE
36	1877	LITIGAT?/TI,AB,DE
37	207	LEGAL(W)(ACTION? OR PROCEEDING?)/TI,AB,DE
38	320	(LAWSUIT? OR LAW(W)SUIT?)/TI,AB,DE
39	63	NEAR(W)MISS/TI,AB,DE
40	47	NEAR(W)MISSES/TI,AB,DE
41	11	ERR(W)IS(W)HUMAN/TI,AB,DE
42	4	THINGS(W)GO(W)WRONG/TI,AB,DE
43	13,784	S14:S42
44	117	S13 AND S43
45	1	OPEN(W)DISCLOSURE/TI,AB,DE
46	144	(COMMUNICAT? OR DISCUSS? OR CONVERS? OR TALK? OR EXPLAIN? OR EXPLANATION? OR TELL? OR TOLD OR ACKNOWLEDG? OR CONSULT? OR INFORM? OR NOTIF?)(3N)(PATIENT? OR FAMILY OR FAMILIES OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR CARER? OR CAREGIVER? OR USER?)(3N)(ADVERSE OR HARM? OR ERROR OR ERRORS OR MISTAKE? OR INCIDENT OR INCIDENTS)/TI,AB,DE
47	260	S44:S46
48	217	S47/1980:2012

? = truncation.
/TI,AB,DE = terms in title, abstract or descriptor fields.
(W) = terms adjacent to each other (same order).
(2N) = terms within two words of each other (any order).
S1:S12 = S1 OR S2 OR S3 OR S4 . . . S12.
S47/1980:2012 = limits set 47 to those records published between1980 and 2012.

Dissertation Abstracts

Dialog, www.dialog.com/

1861 to December 2011.

Searched on 9 January 2012; 411 records were retrieved.

Set	Items	Description
1	10,298	DISCLOS?/TI,AB,DE
2	169	(NONDISCLOS? OR UNDISCLOS?)/TI,AB,DE
3	332	(CANDOUR OR CANDOR OR CANDID)/TI,AB,DE
4	0	DUTY(W)OF(W)CARE/TI,AB,DE
5	0	DUTY(W)TO(W)ADVISE/TI,AB,DE
6	1799	APOLOG?/TI,AB,DE
7	73	SORRY/TI,AB,DE
8	4576	OPENNESS/TI,AB,DE
9	160	BEING(W)OPEN/TI,AB,DE
10	50	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REGRET?/TI,AB,DE
11	12	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REMORSE/TI,AB,DE
12	108	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)SYMPATHY/TI,AB,DE
13	17,191	S1:S12
14	1189	ADVERSE(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
15	26	SAFETY(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
16	41	SERIOUS(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
17	24	SENTINEL(2N)EVENT?/TI,AB,DE
18	1655	(CRITICAL OR CLINICAL OR MEDICAL OR HEALTHCARE)(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
19	111	(HARM OR HARMS OR HARMFUL)(3N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
20	391	UNEXPECTED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
21	108	UNINTENDED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE

Set	Items	Description
22	14	UNINTENTIONAL?(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
23	116	UNANTICIPATED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
24	133	(UNEXPECTED OR UNINTENDED OR UNINTENTIONAL? OR UNANTICIPATED)(2N)INJUR?/TI,AB,DE
25	11	MEDICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
26	11	SURGICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
27	217	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)ADVERSE/TI,AB,DE
28	225	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(HARM OR HARMS OR HARMFUL)/TI,AB,DE
29	572	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
30	669	(PROFESSIONAL? OR WORKER? OR DENTIST? OR NURS? OR DOCTOR? OR PHYSICIAN? OR SURGEON? OR SURGICAL? OR SURGER? OR PHARMAC? OR HUMAN OR PRACTITIONER? OR PSYCHIATRIST? OR PSYCHOLOGIST? OR ANAESTHE? OR ANESTHE? OR GP)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
31	3906	(MEDICAL OR DIAGNOS? OR TREATMENT? OR MEDICATION? OR HEALTHCARE OR CARE OR HOSPITAL? OR SYSTEM?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
32	170	MISDIAGNOSIS/TI,AB,DE
33	150	(IATROGENIC OR IATROGENESIS)/TI,AB,DE
34	573	(NEGLIGENCE OR NEGLIGENT)/TI,AB,DE
35	336	MALPRACTICE/TI,AB,DE

Set	Items	Description
36	2536	LITIGAT?/TI,AB,DE
37	361	LEGAL(W)(ACTION? OR PROCEEDING?)/TI,AB,DE
38	812	(LAWSUIT? OR LAW(W)SUIT?)/TI,AB,DE
39	54	NEAR(W)MISS/TI,AB,DE
40	42	NEAR(W)MISSES/TI,AB,DE
41	22	ERR(W)IS(W)HUMAN/TI,AB,DE
42	16	THINGS(W)GO(W)WRONG/TI,AB,DE
43	13,285	S14:S42
44	280	S13 AND S43
45	9	OPEN(W)DISCLOSURE/TI,AB,DE
46	133	(COMMUNICAT? OR DISCUSS? OR CONVERS? OR TALK? OR EXPLAIN? OR EXPLANATION? OR TELL? OR TOLD OR ACKNOWLEDG? OR CONSULT? OR INFORM? OR NOTIF?)(3N)(PATIENT? OR FAMILY OR FAMILIES OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR CARER? OR CAREGIVER? OR USER?)(3N)(ADVERSE OR HARM? OR ERROR OR ERRORS OR MISTAKE? OR INCIDENT OR INCIDENTS)/TI,AB,DE
47	414	S44:S46
48	11,296	47/1980:2012
49	411	S47/1980:2012

? = truncation.
/TI,AB,DE = terms in title, abstract or descriptor fields.
(W) = terms adjacent to each other (same order).
(2N) = terms within two words of each other (any order).
S1:S12 = S1 OR S2 OR S3 OR S4 . . . S12.
S47/1980:2012 = limits set 47 to those records published between1980 and 2012.

Inside Conferences

Dialog, www.dialog.com/

1993 to 6 January 2012.

Searched on 9 January 2012; 29 records were retrieved.

Set	Items	Description
1	1049	DISCLOS?/TI,AB,DE
2	11	(NONDISCLOS? OR UNDISCLOS?)/TI,AB,DE
3	30	(CANDOUR OR CANDOR OR CANDID)/TI,AB,DE
4	0	DUTY(W)OF(W)CARE/TI,AB,DE
5	0	DUTY(W)TO(W)ADVISE/TI,AB,DE
6	244	APOLOG?/TI,AB,DE
7	49	SORRY/TI,AB,DE
8	230	OPENNESS/TI,AB,DE
9	2	BEING(W)OPEN/TI,AB,DE
10	1	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REGRET?/TI,AB,DE
11	0	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)REMORSE/TI,AB,DE
12	0	(EXPRESS? OR SHOW? OR COMMUNICAT? OR CONVEY?)(2N)SYMPATHY/TI,AB,DE
13	1608	S1:S12
14	668	ADVERSE(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
15	91	SAFETY(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
16	6	SERIOUS(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
17	2	SENTINEL(2N)EVENT?/TI,AB,DE
18	166	(CRITICAL OR CLINICAL OR MEDICAL OR HEALTHCARE)(2N)(INCIDENT OR INCIDENTS)/TI,AB,DE
19	9	(HARM OR HARMS OR HARMFUL)(3N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
20	28	UNEXPECTED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
21	6	UNINTENDED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE

continued

Set	Items	Description
22	0	UNINTENTIONAL?(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
23	6	UNANTICIPATED(2N)(EVENT? OR INCIDENT OR INCIDENTS OR OUTCOME?)/TI,AB,DE
24	11	(UNEXPECTED OR UNINTENDED OR UNINTENTIONAL? OR UNANTICIPATED)(2N)INJUR?/TI,AB,DE
25	9	MEDICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
26	5	SURGICAL(W)(ACCIDENT? OR INJUR?)/TI,AB,DE
27	68	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)ADVERSE/TI,AB,DE
28	27	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(HARM OR HARMS OR HARMFUL)/TI,AB,DE
29	149	(PATIENT? OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR USER?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
30	673	(PROFESSIONAL? OR WORKER? OR DENTIST? OR NURS? OR DOCTOR? OR PHYSICIAN? OR SURGEON? OR SURGICAL? OR SURGER? OR PHARMAC? OR HUMAN OR PRACTITIONER? OR PSYCHIATRIST? OR PSYCHOLOGIST? OR ANAESTHE? OR ANESTHE? OR GP)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
31	1542	(MEDICAL OR DIAGNOS? OR TREATMENT? OR MEDICATION? OR HEALTHCARE OR CARE OR HOSPITAL? OR SYSTEM?)(3N)(MISTAKE? OR ERROR OR ERRORS)/TI,AB,DE
32	54	MISDIAGNOSIS/TI,AB,DE
33	219	(IATROGENIC OR IATROGENESIS)/TI,AB,DE
34	181	(NEGLIGENCE OR NEGLIGENT)/TI,AB,DE
35	227	MALPRACTICE/TI,AB,DE

Set	Items	Description
36	1198	LITIGAT?/TI,AB,DE
37	23	LEGAL(W)(ACTION? OR PROCEEDING?)/TI,AB,DE
38	72	(LAWSUIT? OR LAW(W)SUIT?)/TI,AB,DE
39	54	NEAR(W)MISS/TI,AB,DE
40	29	NEAR(W)MISSES/TI,AB,DE
41	8	ERR(W)IS(W)HUMAN/TI,AB,DE
42	19	THINGS(W)GO(W)WRONG/TI,AB,DE
43	5214	S14:S42
44	16	S13 AND S43
45	1	OPEN(W)DISCLOSURE/TI,AB,DE
46	12	(COMMUNICAT? OR DISCUSS? OR CONVERS? OR TALK? OR EXPLAIN? OR EXPLANATION? OR TELL? OR TOLD OR ACKNOWLEDG? OR CONSULT? OR INFORM? OR NOTIF?)(3N)(PATIENT? OR FAMILY OR FAMILIES OR INPATIENT? OR OUTPATIENT? OR CONSUMER? OR CITIZEN? OR PUBLIC OR CARER? OR CAREGIVER? OR USER?)(3N)(ADVERSE OR HARM? OR ERROR OR ERRORS OR MISTAKE? OR INCIDENT OR INCIDENTS)/TI,AB,DE
47	29	S44:S46
48	29	S47/1980:2012

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(W) = terms adjacent to each other (same order).
(2N) = terms within two words of each other (any order).
S1:S12 = S1 OR S2 OR S3 OR S4 . . . S12.
S47/1980:2012 = limits set 47 to those records published between1980 and 2012.

Ongoing research resources

PROSPERO

www.crd.york.ac.uk/prospero/

Searched on 6 January 2012; 0 records retrieved.

disclos* OR nondisclos* OR undisclos* OR candour OR candor OR apolog* OR sorry OR openness

Key
* = truncation

Health Services Research Projects in Progress (HSRProj)

www.cf.nlm.nih.gov/hsr_project/home_proj.cfm

Searched on 9 January 2012; 33 project records retrieved.

Using the advanced search with 'project status' set to 'all' and 'states' set to 'all'.

(((disclose or discloses or disclosure or disclosures or disclosed or disclosing or nondisclose or nondisclosure or nondisclosures or nondisclosed or undisclose or undisclosed or candour or candor or candid or apology or apologies or apologise or apologize or apologised or apologized or apologising or apologizing or sorry or openness) AND (adverse OR harm OR harms OR harmful OR mistake OR mistakes OR error or errors OR misdiagnosis OR iatrogenic OR iatrogenesis OR negligence OR negligent OR malpractice OR litigate OR litigates OR litigation OR miss OR misses OR err OR incident OR incidents)))

National Research Register Archive

www.nihr.ac.uk/Pages/NRRArchiveSearch.aspx (contains records of projects from 2000 to 2007 only).

Searched on 6 January 2012; 63 records retrieved.

(disclos* or nondisclos* or undisclos* or candour or candor or apolog* or sorry or openness or communicat* or discuss* or convers* or talk* or explain* or explanation* or tell* or told or acknowledge* or consult* or inform* or notif*) all fields

AND

(adverse or harm or harms or harmful or mistake* or error or errors or misdiagnosis or iatrogen* or negligence or negligent or malpractice or litigat* or miss or misses or err or incident or incidents) in title field

Key
* = truncation

ClinicalTrials.gov

http://clinicaltrials.gov/ct2/search

Searched on 5 January 2012; 125 records retrieved.

disclose OR discloses OR disclosure OR disclosures OR disclosed OR disclosing OR "duty of candour" OR "duty of candor" OR apology OR apologies OR apologise OR apologize OR apologised OR apologized OR apologising OR apologizing OR sorry OR openness | received on or after 01/01/1980 | updated on or after 01/01/1980

Clinical Controlled Trials

www.controlled-trials.com/mrct/searchform

Searched the *meta*Register (including all active and archived registers) on 9 January 2012; 245 records retrieved.

(disclos* OR candour OR candor OR candid OR apolog* OR sorry) AND (adverse OR sentinel OR harm* OR mistake* OR error OR errors OR misdiagnosis OR iatrogen* OR negligence OR negligent OR malpractice OR litigat*)

Key

* = truncation

World Health Organization (WHO) International Clinical Trials Registry Platform Search Portal (ICTRP)

http://apps.who.int/trialsearch/Default.aspx

Searched on 6 January 2012; 54 records retrieved.

disclos* OR candour OR candor OR candid OR apolog* OR sorry OR openness

Key

* = truncation

Appendix 3 Databases searched

The following databases were searched.

Health related

- MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations.
- EMBASE.
- PsycINFO.
- HMIC.
- The Cochrane Library:
  - CDSR.
  - DARE.
  - HTA Database.
  - CENTRAL.
- CINAHL.
- SCI.
- LILACS.
- PASCAL.
- Health Systems Evidence.

Social science

- ASSIA.
- SSCI.

Law

- Lawtel.
- Westlaw.
- Lexus.

Reports/conference proceedings/grey literature

- NTIS.
- CPCI-S.
- CPCI-SSH.
- Dissertation Abstracts.
- Inside Conferences.

Ongoing research

- PROSPERO.
- HSRProj.
- National Research Register Archive.
- ClinicalTrials.gov.
- Current Controlled Trials.
- WHO ICTRP.
- The websites and databases of relevant organisations [e.g. AHRQ, Canadian Patient Safety Institute (CPSI), Institute for Healthcare Improvement (IHI), NPSA, National Patient Safety Foundation (NPSF), Alexandria Patients Safety Alliance (APSA), Action Against Medical Accidents (AvMA), Joint Commission Journal on Quality and Patient Safety (JCJQS), Sorry Works in the USA, Safety Improvement for Patients in Europe (SIMPATIE)].
- Personal contact with key personnel in organisations that are actively developing work to involve patients in efforts to improve their own safety (e.g. AHRQ, CPSI, IHI, NPSA, NPSF).

Appendix 4 Ethical permission

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Bradford
Yorkshire & Humber REC Office
Millside
Mill Pond Lane
Meanwood
Leeds
LS6 4RA

Telephone: 0113 30 50128
Facsimile: 0113 85 56191

13 February 2012

Dr Yvonne Birks
Senior Research Fellow
University of York
York Trials Unit
York
YO10 5DD

Dear Dr Birks

Study title: **Being Open: An exploration of the implementation of open disclosure of adverse events in the UK**

REC reference: **11/YH/0427**

Thank you for your letter of 7 February 2012 responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

A Research Ethics Committee established by the Health Research Authority

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/YH/0427 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Ian Woollands
Chair

Email: sinead.audsley@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Sue Final, University of York*
Mrs Jane Dennison, Bradford Institute for Health Research

A Research Ethics Committee established by the Health Research Authority

Appendix 5 Example topic guide

Topic guide

Health professional interviews

Outline of the project. Define adverse event.

General awareness of disclosure and current practice

Can you talk to me about open disclosure in health care – what does this term mean to you?

Personal experiences of disclosure

If an adverse event occurred in your ward/unit what role might you expect to play in its disclosure?

How would you feel about disclosing an adverse event?

How well-prepared do you feel if that situation was to arise now?

What would you want to achieve through the disclosure?

What do you think the patients would want from the disclosure?

What factors do you think might influence your approach to the disclosure or the things you might say?

What would your main concerns be about disclosing an event to patients or their friends or relatives?

Have you had any experience of disclosing an adverse event to a patient or their friends or relatives?
If yes go to Q4.

Can you tell me a bit about your experience?

What role did you play in the disclosure?

How did you feel about disclosing the event?

How well-prepared did you feel for that situation?

What did you want to achieve through the disclosure?

What do you think the patient wanted from the disclosure?

What factors do you feel influenced your approach to the disclosure or the things that you said?

What challenges did you face, if any?

How did you feel after the disclosure – would you have done anything differently?

Knowledge and perceptions of open disclosure policy

You might be aware of the Being Open framework which relates to the policy of open disclosure in the NHS. The framework sets out 10 key principles of open disclosure that NHS staff should use when communicating with patients, their families and carers about a patient safety incident. Are you aware of the being open policy or framework?
If yes go to 6.
If no go to 8.

Can you tell me a bit about the policy and how it works in practice from your own experiences?

What do you consider to be the main challenges in its use?

What kinds of things might you expect to see in the 10 key principles that you might need to consider in the process of disclosing an incident?

SHOW PARTICIPANTS THE FRAMEWORK

What are your initial thoughts about this framework?

Do you see any parts that you think might raise some challenges or are there any things that you would feel concerned about looking at this?

Disclosure, quality and patient safety

Can you tell me a bit about the disclosure policy that operates in your trust?

What are you required to do, when and who is responsible for disclosing what types of incidents?

How does it link into the incident reporting system, if at all?

Do you think there is a link between disclosing adverse events to patients and enhancing the quality or safety of their care?

Appendix 6 Coding framework

Why Being Open is important: for and against (including consequences) – BRIEF ONLY

- Respect for the patient as a person.
- Showing trustworthiness of professional, organisation or profession.
- Implications for ongoing care relationship.
- What matters to the patient/family (including implications for them going forward).
- Impact on the professional going forward.

Uncertainties/complexities of what and whether to disclose

- 'The problem' – definitions and thresholds.
- Who might be responsible – error or not.
- Patient and their likely response.
- 'Salience' of the event – is it important to tell.

Whether and where disclosure is done and not done (descriptive/epidemiology)

- Relationship, history, context.
- Setting/specialty.

How it's done (descriptive including examples)

What makes for better and worse disclosure (evaluative comments)

- Medium – person, letter, phone.
- Person – involved with incident, seniority, experience, role.
- Where.
- When.
- If in person – sincerity, genuine.
- Relationship history.
- Ongoing process of disclosure.
- Flexibility, subtlety, sensitivity – attitude, sincerity.
- Formality/formulaic.
- Resultant feelings – patient – clinician.

Issues influencing whether, how, when and awareness of it (all include what's missing and what's needed)

- National policy on Being Open.
- Local policy on Being Open.
- Health professional
    - hearing mixed messages (or consistent messages) about value/appropriateness of being open
    - vulnerability to/trust of patient
    - vulnerability to/trust of employing organisation
    - tension between requirement/pressures of employing organisation and professional body
    - place in hierarchy/seniority/experience
    - perceptions of expectations on you and perceived norms (profession, organisation, team, patient)
    - concerns re difficult conversations and personal ability to conduct and handle them well
    - attitudes to open disclosure (normative beliefs?)
    - past personal experiences of open disclosure
    - awareness of others' experiences of open disclosure (or not)
    - concern for self (including reputation, job security)
    - education/training on open disclosure.
- Professional organisations
    - principle of being open
    - specific guidance/policy – awareness of and driving force behind.
- NHS organisations
    - processes for disclosure/follow-up post event
    - resources/staff allocated to it
    - reporting for learning
    - (whose) awareness/promotion of principle/policy of being open
    - support for staff involved in adverse outcomes/errors
    - reputation concerns
    - litigation concerns
    - costs/financial issues relating to being open or not and the consequences.
- Policy framework
    - forked tongues (policies that pull in different directions)
    - measurement of effective disclosure and of patient safety problems/success in addressing these
    - reporting for learning.
- Legal framework
    - duty of candour.

Suggestions or solutions to improve open disclosure

- Duty of candour.
- Training/education.

Appendix 7 Key characteristics and numbers of study participants by stakeholder group

Group	Salient characteristics	Recruitment	Sampling notes
Policy-makers ($n = 7$)	Individuals who had been involved in health at political policy level, with an interest in open disclosure of adverse events currently or in the recent past	Targeted letters to those involved in health policy with a role in patient safety or the Being Open guidance	Deliberately identified those involved in the development or implementation of Being Open
Representatives from professional organisations ($n = 16$)	Organisations which regulate or indemnify health professionals in the UK	Targeted letters to leaders of 23 professional organisations in the UK	
NHS managers and health professionals ($n = 54$)	NHS managers working in clinical or non-clinical roles. Included risk managers Some managers have both clinical and non-clinical roles 13 doctors; 22 nurses; two pharmacists 17 NHS managers	Targeted letters to senior managers in the five recruited trusts, and information disseminated through them to health professionals with our contact details	Efforts were made to recruit from a variety of ranks and professions but junior doctors were difficult to recruit
Patients and patient organisations ($n = 5$)	Individuals either represented patient organisations or had experienced error or harm	Information distributed to patient organisations and sent out to patients via the organisations with contact information Targeted letters to leaders of patient organisations	Patients with positive experiences of disclosure were sought through health-care trusts but none were identified
Other relevant individuals ($n = 2$)		Targeted letters to those identified as potentially suitable by other respondents	

Appendix 8 Detailed statement for reflexivity

Team data analysis

At significant points during the process of data analysis, the researchers most closely involved in data collection and the early stages of analysis (YB, RH, KB) met with members of the wider research team with extensive qualitative (VE) and clinical (IW) experience, to discuss emerging codes and categories, the interpretation of key texts and potential new lines of enquiry, thereby drawing on the combined insights of those 'handling' the data closely and members of the team with a wider perspective of methodological and open disclosure issues.

Reliability of coding

Towards the end of the analysis of the qualitative data, a member of the wider research team (VE) examined five transcripts which had been coded by the members of the team most closely involved in data collection and analysis (YB, RH, KB), as an independent check on the assignment of codes to data.

Comparison of data within and across cases in the data set

This was facilitated by the use of the analytic matrix which forms the basis of the framework approach. Comparing data within cases allowed for the exploration of contextual meaning, while comparing cases across the data set facilitated the search for regularities (key themes) and exceptions (negative cases).

Use of memos

The careful use of memos (by the prime analysts) during initial stages of analysis provided a visible 'audit trail' as the analysis moved from 'raw' data, through interpretation, to the production of findings.

Attention to 'negative' cases

Analysis included a search across the data set for 'negative' cases (evidence that contradicts, or appears to contradict, the explanations being developed) and alternative ways of explaining the data were considered. Systematic searching for negative cases or 'outliers' can help illuminate the connections that link the other cases together.

Reflexivity

Reflexivity relates to sensitivity to the ways in which the researcher and the research process may shape the data collected, including the role of prior assumptions and experience.

Prior assumptions and experience

Within the context of the current study, the members of the research team involved in face-to-face contact with study participants needed to consider the ways in which their interactions with participants might be influenced by their own professional background, experiences and prior assumptions. The two interviewers (RH and KB) were both academic research fellows from non-clinical backgrounds. An important question we needed to address in drawing conclusions from the data concerned whether or not knowing about our

professional background could have impacted on participants' willingness to talk openly about experiences, or how this knowledge might have shaped what was said.

Awareness of social setting and the social 'distance' between the researcher and the researched

The majority of interviews were conducted in participants' workplaces or homes (for patients), either face to face or over the telephone, as this was usually more convenient for them. Although we were invited in as researchers, we were also mindful that we were guests in the participants' work or living spaces; respondents were therefore given the lead in 'setting the pace' of the interview. By deliberately adopting a 'back seat' approach in setting the scene for the interview to take place, the researchers hoped that participants would feel they were exercising a measure of control over the interview process.

Fair dealing

Dingwall[247] has suggested that one way of reducing bias in qualitative research is to ensure that the research design explicitly incorporates a wide range of different perspectives, so that the viewpoint of one group is never presented as if representing the sole truth about any situation, an analytic technique he has referred to as 'fair dealing'.

Our study was designed to elicit contributions from a broad range of stakeholders in open disclosure. During the analytic process no particular group's views were 'privileged' over those of others; that is to say, data analysis included a process of constant comparison between accounts of each group of participants, to uncover similarities and differences, which were subsequently highlighted (for example, health professionals identified a lack of certainty around what should be disclosed to a patient or carer, more so than other participants).

A main goal of data analysis was the identification of common themes that emerged from comparison across cases (individual interviews). However, equal importance was attached to focusing on the minutiae of individuals' accounts relating to specific incidents of disclosure; in the analysis, we sought to identify the views and experiences of individuals, as well as the majority, where these were divulged.

Awareness of wider social and political context

As a research team, we discussed the fact that participants recruited from a policy level, professional organisation or national 'consumer' group might show a strong commitment to a particular personal or political agenda, or wish to raise particular issues during group discussions which may relate only tangentially, or not at all, to the main purpose of the discussion. We discussed how we might handle this situation if it arose and decided to emphasise the purpose of the research prior to interview and through the questions and probes used. This strategy appeared to be successful in keeping participants engaged in the research process.

The role of the research team as collaborators in knowledge production

Collaborative research is highly valued for its ability to bring together multiple researchers with distinctive and specialist perspectives to tackle large or complex research problems, though frequently the 'putting together' of multiple perspectives in the construction of knowledge is not described.[248]

Within the Being Open research team, there was a strong commitment from the outset to work collaboratively in the collection, analysis, interpretation and reporting of the qualitative data, though individual involvement with the various stages of the research process necessarily varied. The three team members most closely involved in fieldwork (YB, RH, KB) met frequently (on average at least once per week) to discuss the progress of fieldwork and reflect on data collection; meetings intensified during the early stages of analysis, when themes and codes were beginning to be identified. At this crucial stage, input was sought from other members of the research team with extensive experience of qualitative research and a broad knowledge of patient safety research (VE, IW) to assist with 'firming up' the coding framework. During the early stages of analysis, an all-day meeting was convened in a location away from the

interruptions of the office environment, which served as a kind of 'interpretative retreat'. Throughout the day, we explored a sample of transcripts to gain a sense of the data that were emerging, the effectiveness of the topic guides and whether or not there may be additional participants who we wanted to invite to take part. A more intense focus on a subset of transcripts (which had been sent to VE in advance) in a further half-day analysis session was used to draw up the coding framework that would serve to underpin the analysis (and interpretation) of all the interview data. This endeavour resulted in an analytic strategy that was informed by insights from team members with a broad understanding of the research field and methodological issues, and those with field-based contextual and experiential understanding.

Potential for psychological harm

Members of the research team involved in fieldwork (RH, KB) were acutely sensitive to the possibility that focusing on the research topic could potentially provoke anxiety in the research participants concerning the disclosure of adverse events. At the end of each interview, researchers took time to ensure that participants were not feeling distressed by their participation; in these interviews, none of the participants expressed such concerns or appeared to be distressed or uneasy.

Appendix 9 Reference list of included literature for reviews

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Appendix 10 Studies excluded at second stage

Author and year	Title	Reason for exclusion
Barrios 2009[220]	Framing family conversation after early diagnosis of iatrogenic injury and incidental findings	Study not a controlled design or uncontrolled before and after
Bell 2010[221]	Improving the patient, family, and clinician experience after harmful events: the 'when things go wrong' curriculum	Study not a controlled design or uncontrolled before and after
Daud-Gallotti 2011[222]	A new method for the assessment of patient safety competencies during a medical school clerkship using an objective structured clinical examination	Study not a controlled design or uncontrolled before and after
Gillies 2011[223]	Teaching medical error apologies: development of a multi-component intervention	Study not a controlled design or uncontrolled before and after
Hannawa 2009[224]	When the truth hurts: toward a validation of the physician mistake disclosure (PMD) model	Study not a controlled design or uncontrolled before and after
Keller 2009[98]	An effective curriculum for teaching third year medical students about medical error and disclosure	Study not a controlled design or uncontrolled before and after
Kim 2011[225]	A web-based team-oriented medical error communication assessment tool: development, preliminary reliability, validity, and user ratings	Intervention not open disclosure or intervention to support open disclosure
Wu 2009[226]	Disclosing medical errors to patients: it's not what you say, it's what they hear	Study not a controlled design or uncontrolled before and after

Appendix 11 Patient and public involvement

The majority of this work was directed at exploring implementation of policy and stakeholders were varied. We had the expertise of Peter Walsh as a leading national patient representative who was able to ensure representation for patients and the public as part of this work. Peter advised on patient and public involvement at a national level.

Peter Walsh is the chief executive of AvMA and brings a wealth of experience from both the voluntary sector and the patient perspective to this project. He is also a WHO-appointed patient safety champion, a member of the National Patient Safety Forum and an executive member of the Clinical Disputes Forum. He has been involved in several research projects looking at patient perspectives on patient involvement in safety in health care and is well networked with the NPSA and WHO.

Peter was involved in this work from its inception. He helped to write the grant proposal and was an applicant for the funding. Peter has been involved in managing the delivery of the research, assisting with recruitment of stakeholders, designing recruitment materials and writing the final report, and will be involved in future dissemination of the findings of this report to both lay and professional organisations.

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