

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

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Scientific summary

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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.

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