COMMUNICATION WITH PATIENTS IN THE CONTEXT OF MEDICAL ERROR

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by

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EXECUTIVE SUMMARY

This report was commissioned by Professor Richard Lilford on behalf of the NPSA in October 2002 to help establish a set of principles to guide communication with patients and their families following medical error and to prioritise an agenda for a focussed research programme in the area.

An initial literature review revealed:-

- Errors are common to all healthcare systems and causes are multi-factorial.
- Communication often has a central role in the origin, exacerbation or amelioration of the effects of medical error.
- Following an adverse patient incident, there is little consensus as to what should be communicated, when communication should take place and who should conduct the discussion with patients and families.
- All communication is influenced by the nature of the error, its outcome for the patient and other moral, ethical and legal imperatives.
- More open communication after an adverse event may lead to improvements in safety and practice. It may allow doctors to:- learn from their errors, ask for support and feel some relief instead of the additional guilt when errors are covered up. It may also promote trust and strengthen the doctor-patient relationship and decrease the likelihood of litigation. For patients open disclosure should relieve uncertainty and help them to make more informed decisions.
- Barriers to open disclosure include fears about litigation and disciplinary action, the prevailing culture of infallibility within the medical profession and deficiencies in communication skills. These could be tackled with increased organisational and professional support and training.
- Improvements in safety will not occur unless there is commitment by top management and an overt, clearly defined, and continuing effort on the part of all personnel and managers.
- Although a valuable literature exists concerning the impact that medical error has on all involved, and initiatives have been developed to help inform and guide practice regarding open disclosure, there is as yet little research evidence available describing the practical problems of implementation and demonstrating measurable benefits.
• Much of the research regarding preferences of both patients and healthcare professionals about communication has methodological limitations or has been conducted in cultures with different healthcare delivery systems.
• There are few data available to inform recommendations about communication with vulnerable groups with special needs.
• In the absence of clear and unambiguous policies about the communication that should occur, there is too much leeway for obfuscation and rationalisation thus denying victims appropriate information, support and recompense.

The report provides elaboration and discussion of all these issues together with relevant references. Suggestions are given, based wherever possible on current research, about the specific types of communication that should take place following different types of medical error.

• It is recognised that no universal formula can be applied to communication about medical errors; the adverse event, suspected cause(s), the level of harm, personnel, needs and preferences of the patient and/or relatives influence - what is said, how it should be said and how much support is necessary.

• A detailed taxonomy derived from a variety of sources has been compiled as a reference tool for use when considering the communication required. Specific suggestions are given about preparations needed prior to and at the conclusion of any discussion about medical error.

• Examples and descriptions of desirable communication strategies are highlighted under the following headings –
  - immediate actions
  - prior to any formal meeting
  - clear description of adverse incident and probable outcome
  - expression of sorrow or regret
  - reassurance about any revisions to the plan of care, eg additional monitoring, treatment and rehabilitation
  - measures being taken to prevent the same thing from happening again
  - opportunities for further discussion
  - procedures and contacts for obtaining compensation
  - information and contacts concerning emotional support
  - details about full inquiry
  - concluding the meeting
The following recommendations are also proposed:

- A broader research programme surrounding medical error in the UK is developed in order to inform and update the content of policy guidelines and training interventions. Close liaison with the Australian Open Disclosure Project coordinators would be useful.
- The views of relevant stakeholders towards a policy of open disclosure are investigated and that the readiness of Trusts to adopt such a policy is canvassed.
- A national scoping exercise is commissioned in order to operationalise good practice in terms of parameters such as: the disclosure policies and practice of teams, the wider organisation and specific communications skills needed by individuals.
- That this exercise is followed by a consensus conference and statement.
- That any new policy initiatives are piloted in a few Trusts. An evaluation should track the changes and monitor indicators over time such as complaint rates, litigation claims etc. in addition to collecting feedback from health care staff and patients.
- That individual institutions must develop clear policies regarding disclosure about adverse events. Consideration should then be given to harmonising these nationally.
- That urgent attention be paid to the design and evaluation of communication skills training in the context of error for individuals and for multi-disciplinary teams.
## SECTION SUMMARIES

### INTRODUCTION

- The causes of error may be multi-factorial but communication often has a central role in its origin, the exacerbation or amelioration of its effects.
- The emphasis placed on the need to communicate well when things are bad or upsetting should not lead to the neglect of the central point that good communication is necessary at all times. More effective dialogue, appropriately tailored to individual patients’ needs, can also help to prevent errors, complications and distress.
- Given the large numbers of errors that occur within healthcare systems including the NHS, there are surprisingly few studies that address and test interventions specifically designed to assist communication after an adverse event.
- There is no clear consensus about how to handle communication with patients about medical error.
- This report concerns medical errors that involve mainly doctors and which occur in hospital but this should not be taken to imply that other healthcare professionals working in other parts of the health service are either error free or do not require guidance. Hopefully the issues discussed will have multi-disciplinary applications.

### DEFINITIONS AND TAXONOMY

- The definitions of errors and related terms may depend on their purpose thus when considering communication with patients, different ways of categorising adverse patient incidents (eg by cause, type of error, outcome, type of setting or staff involved) may be needed.
- Whether an adverse event was caused by an error and who or what caused the error are usually important for the patient and relatives, but it is often difficult to know whether any error(s) occurred, and whether any injury or harm was a direct result of the error(s) and who or what factors were responsible.
- What factors led up to an adverse event and the type of setting or personnel involved are relevant, when deciding who should be involved in the disclosure process.
- Although the putative relationship between error(s) and harm may affect the way an adverse event is disclosed and who is involved, the degree of harm suffered by the patient may be more relevant when deciding whether to disclose the event in the first place.
- The extent of harm or long term impact resulting from an adverse incident will not always be a known quantity immediately and may change over time.
### WHAT IS KNOWN ABOUT THE PRACTICE OF DISCLOSURE

- Research findings demonstrate a tendency for physicians to be less than forthright with patients about adverse events.

- Surveys that used hypothetical scenarios find higher proportions of doctors reporting a willingness to disclose their errors, than those that question doctors or patients about their own experiences.

- The degree of harm or injury resulting from an error may affect disclosure.

- The willingness to disclose the error of another treating physician may be lower than the willingness to admit to one’s own errors.

### REASONS FOR DISCLOSURE

- The majority of the public and doctors believe patients and or their families should be told about errors.

- Disclosure is seen to be ethically appropriate. In general the benefits of disclosure outweigh the negative consequences.

- The popular view that the disclosure of errors is inherently risky and increases the likelihood of being sued is not supported by recent empirical data.

- Liability may be imposed on a physician precisely because of failure to reveal a medical error, especially if it is uncovered later.

### BARRIERS TO DISCLOSURE

- Doctors face conflicting moral dilemmas when deciding whether to reveal their own or a colleague’s error.

- The prevailing legal system does not encourage health professionals to be open after an adverse event. A lack of clear direction, commitment and support from an organisation, institution or trust may impede disclosure.

- Errors are not reported because health professionals fear they will be punished by disciplinary systems.

- The prevailing culture within the medical profession, e.g. infallibility and competitiveness hampers open discussion about errors.

- A lack of communication skills can make talking to patients difficult.
**TRAINING**

- High level communication skills are demanded when discussing any bad, sad or difficult news.

- Doctors need to be equipped with skills to deal with the emotionally charged discussion that surrounds disclosure of error.

- Training videos and workshops have been used to assist and promote open disclosure, but there is a dearth of information as to whether or not these have led to measurable benefits.

- Educational and skills based initiatives alone are not sufficient in themselves to produce behavioural change.

- A training programme to help professionals with disclosure about medical error is proposed and described. The programme which incorporates cognitive, behavioural and affective components is based on a communication skills model shown to be effective for senior doctors in cancer medicine.

**SUPPORT FOR PATIENTS**

- The speed and extent of recovery from an injury depends on many factors, for example, the nature and extent of injury, the personality of the patient, financial security and the support given by family, friends and professionals.

- Support for patients can include information about disability benefits, talking to others who have had similar experience or factual information or it can involve more formal psychological counselling.

- Support after an adverse event should be an integrated part of care.

- More attention should be paid to understanding patients’ psychological and social problems in the aftermath of an adverse event as these are often not recognised by the professionals involved in their care.

- The principal forms of trauma experienced by patients harmed by treatment are chronic pain, bereavement and loss, depression and anxiety and post-traumatic stress is less common.

- Formal psychological or psychiatric treatment should not be offered routinely, but according to need and referrals should be handled with sensitivity.

- In some cases an independent counsellor or professional may be the best person for a patient to talk to after an adverse event.

- Some patients and families may get the emotional support they need via the Action for Victims of Medical Accidents (AMVA).
SUPPORT FOR DOCTORS

- Doctors are often deeply affected emotionally and psychologically if they make an error or are involved in the care of someone harmed by an adverse event.

- Discussing an adverse event with patients may cause additional emotional distress.

- Doctors want emotional support and professional reaffirmation after making an error, but there can be reluctance by them to ask for support and in its provision if they do need help.

- A range of support is needed from a ‘quiet word in the corridor’ to the offer of extended psychotherapy. The choice of intensity of support should be up to the individual who may have changing needs over time.

- Some hospitals employ mentors and it is suggested that a link with a psychiatrist or psychologist, perhaps outside the hospital trust might also be useful in some cases.

- There is little research on what singles out a mistake as being particularly traumatic.

- Offering legal advice and training within the hospital setting may help doctors to understand the legal process and alleviate the stress and fears associated with litigation.

- Telephone support services for doctors such as the Doctors Support Line (DSL) are available.
FURTHER RESEARCH

- As many existing research studies have methodological limitations or emanate from the United States more empirical research in the UK about patient and doctor preferences regarding communication issues and behaviour in the aftermath of an adverse event is recommended.

- Research in this field is difficult to undertake because of the sensitivities that surround discussion about and the acknowledgement of error.

- There is an urgent need for a thorough scoping exercise in the UK in order to identify examples of good practice and initiatives.

- The impact of the outcome of an adverse event on communication preferences should be examined.

- Any special needs or preferences of particular groups with regard to communication after an adverse event should be explored.

- Information about the attitudes of the many interested parties in the UK (eg Trust Boards, organisations representing different groups of healthcare professionals, insurance organisations and consumer representatives) toward open disclosure and their readiness to adopt such a policy is needed.

- If there is support for a national open disclosure policy, it would be essential to conduct pilot studies first in a few trusts.

- There is a real need to invest in the design and evaluation of educational materials and training interventions specifically designed to assist communication after an adverse event. These need to be appropriate for use in a UK healthcare setting.
INTRODUCTION

Errors, mistakes and accidents are an inevitable part of healthcare systems worldwide, consequently many countries have set up national patient safety agencies and institutional review panels to determine the best means of preventing and managing error. The causes of error may be multi-factorial but communication often has a central role in its origin, the exacerbation or amelioration of its effects, and in the prevention of error through staff and patient education and system changes. Effective communication is a core clinical skill\(^1\) shown to have a positive effect on a variety of health outcomes for example hospital stays are shorter, requirements for analgesia and complication rates are lower \(^2\). Good communication increases patient satisfaction, enhances both the professional and personal well-being of health-care professionals \(^3\)\(^4\) and reduces the likelihood of complaints and litigation \(^5\)\(^6\). Thus effective and appropriate exchanges between and within healthcare teams, patients and their relatives should be seen as a vital part of the delivery of all clinical and nursing services.

The education and research literature contains a plethora of papers concerned with communication of bad news \(^7\)-\(^11\). Many of these papers provide helpful guidelines regarding communication in potentially stressful situations. Although useful, there is no clear evidence that mere lists of do’s and don’ts alone can significantly alter healthcare professionals’ behavioural styles in optimal, beneficial ways. Furthermore the undue emphasis placed on the need to communicate well when things are bad or upsetting leads to the neglect of the central point that good communication is necessary at all times. More effective dialogue, appropriately tailored to individual patients’ needs, could help prevent some of the errors, complications and distress seen in our hospitals. Good communication should help patients:- to understand complex information, make appropriate choices between treatment options, be more aware of the side-effects and inherent hazards of some procedures, be clearer about likely therapeutic gains and the intent of treatment regimens, help adherence with drugs and diets and better appreciation of the rationale behind recommendations for life-style changes \(^1\)\(^12\).
Much of the delivery of healthcare services is handled by multidisciplinary teams, consequently communication between and within teams must be clear and unambiguous to help avoid errors and to ensure that accountability for system failures are recognised and acted upon. A recent (2002) report by the independent National Confidential Enquiry into Perioperative Deaths cited poor communication and team work as major contributory factors in the large numbers of deaths that occur within 3 days of a medical intervention. There is some evidence that traditional hierarchical barriers and differing perceptions of informational roles in healthcare teams, make discussion about error problematic. The likelihood that errors will be accurately reported and identified so that individuals and systems can benefit and protect future patients, may be less in dysfunctional teams.

There is a considerable literature about the impact that medical error has on doctors, surveys of the effects that errors have on the victims and the preferences of patients and their families when error has been made. However given the large numbers of errors that occur within healthcare systems including the NHS, there are surprisingly few studies that address and test interventions specifically designed to assist communication in such situations, (although the ‘breaking bad news’ literature does provide some insights). There is not even any clear consensus as to how communication about medical error should be handled. Some countries such as Australia and certain institutions in the US have opted for an open disclosure policy whereas others await more research. ‘Building a Safer NHS for Patients’ sets out the Government’s plans for promoting patient safety following the publication of ‘An Organisation with a Memory’ and the commitment to implement it in the NHS Plan. Included amongst the key questions in the patient safety agenda being developed, is the following: “When something does go wrong, we need to understand what information should be given to the patients who are harmed or their family members, tailored to their particular problems, treatments and interventions, and to develop and test the best ways of imparting this information. This may involve checklists, courses and advanced guidelines for those involved.”

Although valuable initiatives are taking place, researching systems for mandatory reporting of errors and mistakes and into methods for analysing, understanding and preventing future errors, much less work has been conducted to date to evaluate ways
of enhancing communication when an error has occurred. For many years there was an unspoken agreement that open disclosure was unnecessary unless the error was likely to come to light and as long as the patient was unharmed and/or unlikely to die. As the Data Protection Act now gives patients the right of access to their medical records, error could be discovered in an unplanned and inappropriate way, likely to create a great deal of hostility and suspicion.

In the current climate of more openness and honesty, non-disclosure is a position now regarded as untenable by many. Regular columns about error are now found in journals such as the American Family Practitioner and Lancet where clinicians have given very personal accounts of the guilt and aftermath of non-disclosure.

A major initiative is also now underway in Australia, the National Open Disclosure Project (http://www.nsh.nsw.gov.au/teachresearch/cpiu/OD.htm), established by the Australian Council for Safety and Quality in Health Care, which aims to improve the practice of open disclosure by providing health care professionals and health services with the practical tools to adopt good practices. Initial reports include a literature review and legal review an issues paper and the results of a consultation exercise with stakeholders. As a result a draft standard has been prepared, in order to promote a clear and more consistent approach to more open communication following an adverse event. An educational and organisational support package is also being developed to facilitate implementation. Both the draft standard and support package are being piloted to test their practicality in a clinical environment. Although there are cultural differences between the populations of Australia and the UK and the way health services are organised, the preliminary work for the project has provided useful background information for our report.

This report covers important recent background information that impacts upon any recommendations about the disclosure of error to patients and their relatives (in the report the term ‘relatives’ also refers to carers, friends or advocates). It concerns medical errors that involve mainly doctors and which occur in hospital rather than primary care settings, but this should not be taken to imply that other healthcare professionals working in other parts of the health service are either error free or do not
require guidance. Hopefully the issues discussed will have multi-disciplinary applications.

The sources used in the report included electronic databases such as MEDLINE from 1990 - 2003. Search strategies included combinations of the following terms: medical errors, error, mistake, truth disclosure, disclosure, communication, physician-patient relations, breaking bad news and physician-patient. Websites of relevant organisations were also accessed which provided further references, including policy documents. Especially helpful were the systematic literature review conducted by Merrilyn Walton in 2001 for the Open Disclosure Project initiated by the Australian Council for Safety and Quality in Health Care and the National Patient Safety Foundation’s website (www.npsf.org) which contains many references to patient safety materials and resources.
DEFINITIONS AND TAXONOMY

A recent survey of American hospitals has identified various operational barriers to the implementation of a policy of disclosure of medical errors to patients. Amongst the barriers identified are: defining what a mistake is, determining what level of error to disclose and the level of detail. There have been numerous definitions of error and related terms such as adverse events and these definitions vary depending on their purpose. For example in the Havard Medical Practice Study the definition of adverse event was ‘....an injury that was caused by medical management (and not the disease process) that either prolonged the hospitalisation, produced a disability at the time of discharge, or both’. The aim of the study was to detect injuries that would potentially enter the tort system, so errors that did not harm patients and events that caused only minor discomfort were ignored. Mandatory error reporting systems such as that recommended in ‘An Organisation with A Memory’ have a different aim and errors which do not result in any harm to patients need to be included, so that system weaknesses can be identified and corrected. When determining whether all errors need to be communicated to patients, the main consideration should be that the benefits of disclosure outweigh any negative consequences for the patient.

Before considering the different ways of categorising medical errors, the definitions used in this report should be clarified. In a recent US study 68% of the public surveyed reported they did not know what the term ‘medical error’ meant, before they were given a definition of the term. Another recently published US study which used qualitative methods found that patients’ conceived of medical errors broadly. Despite being presented with a standard definition of an error as ‘failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim’, many patients included poor service quality, non-preventable adverse events and deficient interpersonal skills as examples of errors. This differed from the physicians who were frustrated by the breadth of what patients considered to be an error. Even within the published research literature different definitions of medical errors or mistakes incorporate different outcomes: for example some specify unplanned consequences, whereas others stipulate negative consequences and others include potentially negative consequences.

Error has been defined as a generic term encompassing ‘all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended
outcome, and when these failures cannot be attributed to the intervention of some chance agency’. The Institute of Medicine 33 defines error as ‘the failure of a planned action to be completed as intended (ie error of execution) or the use of a wrong plan to achieve an aim (ie error of planning).’ A distinction is sometimes made between errors and mistakes; where mistakes are defined as the subset of errors in which the action is intended, but there is a flaw in the plan 34 35. Some authors do not distinguish between errors and mistakes though, for example 36 who defines a mistake as ‘an unanticipated negative consequence of a medical intervention’. Other definitions exclude cases in which there is reasonable disagreement over whether a mistake occurred, for example 37 ‘...a commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences.’ The difference between errors and deliberate violations has also been described 34 35. The latter are a deliberate deviation from the norm, so are avoidable, whereas errors are never deliberate; they are unintentional, accidental. Other terms such as ‘near miss’ have also been defined in different ways in the clinical context, which can cause confusion 38.

In this report the following NPSA definitions 39 of ‘adverse patient incident’, ‘harm’, ‘adverse event’ and ‘near miss’ are used to describe events according to outcome. Adverse patient incident is defined as any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage. Harm is any injury (physical or psychological), disease, suffering or death. Incidents that lead to harm are referred to as adverse events and those that did not lead to harm, but could have, are referred to as near misses. Precise definitions of ‘error’ or ‘mistake’ are not given by the NPSA, but in our report the term ‘error’ refers to the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. We do not make a distinction between errors and mistakes.

There are many possible ways of categorising adverse patient incidents, for example by cause including the type of error, by the outcome, or by the type of setting or staff involved. When considering communication with patients after an adverse incident, different classifications may suit different purposes.
Adverse events may sometimes be the result of risks inherent in a treatment procedure, bad luck or unique patient factors or due to error(s) or a combination. Whether an adverse event was caused by an error and who or what caused the error are usually important for the patient and relatives who seek to understand what happened and want accountability. The way an event is described may also promote different emotional reactions in patients, carers and medical staff. Merry and McCall Smith state, ‘Event descriptions carry a great deal of moral weight, and our choice of description may well be decisive in determining the outcome of any legal or moral inquiry into the event’.

Disclosing adverse events to patients and apologising if an error has occurred is generally accepted as the ethical way to proceed, for example the General Medical Council states: ‘If a patient under your care has suffered harm, through misadventure or for any other reason, you should act immediately to put matters right, if that is possible. You must explain fully and promptly to the patient what has happened and the likely long- and short-term effects. When appropriate you should offer an apology.’ Similarly in the USA the National Patient Safety Foundation (2000) has declared a statement of principle that ‘when a health care injury occurs, the patient and the family or representative are entitled to a prompt explanation of how the injury occurred and its short- and long-term effects. When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error and the remedies available to the patient. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients’.

Whilst these statements acknowledge the moral obligation to be forthcoming about health care injuries (near misses are not mentioned) and errors, it is in practice, often very difficult to know whether any error(s) occurred, and whether any injury or harm was a direct result of the error(s) and who or what factors were responsible. This is especially true when the initial disclosure to the patient and family needs to be made, before a full investigation into the underlying cause or causes of an adverse event has taken place. Even after analysis the relationship between error and outcome can still be unclear or contentious. An error might be the probable rather than the definite
cause, for example a test result may have been mislaid or overlooked, which delayed a
diagnosis and this may or may not have affected the eventual course of the disease. In
other cases where an error definitely occurred and a poor outcome occurred, any
relationship between error and outcome may be unlikely, for example Vincent describes a case where a woman died suddenly, following a delay in diagnosing
coeliac disease. There had undoubtedly been a failure of care, but it was in fact
unlikely that the delay had worsened her prognosis.

These examples illustrate how complicated the relationship between error and
outcome can be but uncertainty should not be used as an excuse for non-disclosure.
Results of the Bristol Inquiry endorse this view, stating ‘with specific regard to an
unplanned event which results in harm to the patient, the duty of candour should still
apply even when mistakes are not immediately apparent and come to light later.’
Patients should be told that an adverse event has occurred, and they should be given
the details as they come to light. Premature conclusions must be avoided and the
theme of disclosure and all resultant discussions with the patient and/or relative
should be objectivity.

What factors led up to an adverse event and the type of setting or personnel involved
are also relevant, when deciding who should be involved in the disclosure process.
Typically many factors lead to an adverse patient incident, not just the one that
directly gives rise to it. As the Department of Health report, An Organization with a
Memory states: ‘Human error may sometimes be the factor that immediately
precipitates a serious failure, but there are usually deeper, systemic factors at work
which if addressed would have prevented the error or acted as a safety-net to mitigate
its consequences.’ Errors can be categorised according to their genesis; system or
latent errors, which derive primarily from flaws inherent in the system of medical
practice can be distinguished from individual errors, which derive primarily from
deficiencies in the physician’s own knowledge, skill or attentiveness. When a
system error occurs, the physician shares responsibility with other elements of the
health care system, whereas in a case of individual error, the physician has primary
responsibility. Wu and colleagues state that the disclosure of latent errors differs from
the disclosure of individual errors and in the case of the former; disclosure should not
be the sole responsibility of the physician.
Although the putative relationship between error(s) and harm may affect the way an adverse event is disclosed and who is involved, the degree of harm suffered by the patient may be more relevant when deciding whether to disclose the event in the first place. This view is endorsed by the new ethics code adopted in Quebec 47 which does not use the term ‘medical errors’, but states that doctors must tell patients about all ‘incidents’, ‘accidents’ or ‘complications’ that occur during treatment that could have a substantial impact on the patient’s health. Deciding what is substantial and what is trivial or of no consequence needs to be addressed, but assigning some form of objective measurement to subjective expressions of suffering can be difficult 48. A medication index for categorising errors has been produced 49 (see table 1 in appendix) and the Pennsylvania Association for Health Care Risk Management 50 has categorised events by severity of outcome (see table 2 in appendix).

It should be emphasised, however, that the extent of harm or long term impact resulting from an adverse incident will not always be a known quantity and may change over time. For example after orthopaedic or cardiac surgery, where patients need a long recovery period, the effects of an adverse event on outcome may take several months to become apparent. There are many other situations particularly those involving the very young or the seriously ill, when the long term impact of deficient care is not clear 44. In some cases a patient may not show any sign of immediate injury or harm, but the medical error or event has the potential, albeit an infinitesimally small one, for causing later health problems. An example is the recent incident at Middlesbrough General Hospital in 2002, where instruments that were used in a brain biopsy on a patient, who was later found to have the sporadic form of CJD were reused on 24 other patients 51.

We propose the following taxonomy (Table 3) derived from the many sources described previously, which should be regarded as a tool for considering the communication issues required. There is no universal formula that can be applied to communication about adverse events, as the circumstances: the event, the suspected cause(s), the outcome, the personnel involved and above all the needs and preferences of the patient and/or relatives will define what is said, how it should be said and how much communication and support is necessary.
Table 3  Recommendations About the Communication Required According to Outcome of Event

<table>
<thead>
<tr>
<th>LEVEL</th>
<th>DESCRIPTION</th>
<th>EXAMPLES</th>
<th>COMMUNICATION</th>
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| 1     | event did not reach patient | - prescription for incorrect dose noticed, before administered to patient  
- wrong results filed in patient’s notes, but error noticed in time | Discretionary/non-essential but mandatory reporting to institution |
| 2 (a) | event which affected patient, but did not cause harm | - diagnostic test done incorrectly, so needed to be repeated  
- medication administered late | A,B,*D,*E, |
| 2 (b) | event which may cause eventual harm | - the re-use of instruments, used on a patient suffering from CJD  
- risk of contamination from health worker suffering from hepatitis | A,B,C,D,*E,*G, |
| 3 (a) | event which caused temporary harm, resulting in additional monitoring or assessments | - missed dose of medication, requiring change to subsequent dose and increased checks  
- diamorphine administered to patient with respiratory problems, some respiratory distress but no long term harm | A,B,C,D,E, |
| 3 (b) | event which caused temporary harm, resulting in additional treatment or hospitalisation | - patient given medication despite warning in notes which caused a temporary allergic reaction  
- failure of intravenous pump causing overdose of analgesia | A,B,C,D,E,*F, |
| 4     | event which caused permanent harm or nearly led to patient death | - anaphylaxis following incorrect drug  
- removal of organ following incorrect diagnosis  
- malignancy missed when disease still at potentially curable stage | A,B,C,D,E,F,G,H, |
| 5     | event which led to death | - intravenous injection eg vincristine given intrathecally  
- damage to vital organ during surgery  
- incompatible blood administered | A,B,C,D,E,F,G,H, |

Content of Communication Required

A  clear description of adverse incident and probable outcome  
B  expression of sorrow or regret  
C  reassurance about any revisions to the plan of care, eg additional monitoring, treatment, rehabilitation  
D  measures which are being taken to prevent the same thing from happening again  
E  opportunities for further discussion  
F  procedures and contacts for obtaining compensation  
G  information and contacts concerning emotional support  
H  details about full inquiry  
I  ending the interview  

* communication is seen as discretionary/not essential
In general the amount of communication about an event will be related to the severity of the outcome, but other factors may need to be acknowledged, especially the preferences of patients and their relatives. If a decision is taken that no disclosure should take place there should nevertheless be mandatory reporting of adverse patient incidents to the institution’s system for error prevention. Expansion of the actual communication required is provided on pages 39-43 together with recommendations as to who should communicate, how and when this should be done. Whilst it is fairly easy to make apparently reasonable suggestions as to what type of disclosure should take place, their likely implementation and the impact on all concerned needs further examination. There is also a moral, ethical and legal perspective to consider.

WHAT IS KNOWN ABOUT THE PRACTICE OF DISCLOSURE

Research findings have shown a tendency for physicians to be less than forthright with patients about adverse events. In a recent US survey of 831 physicians and 1207 members of the public, only about a third of the respondents who reported experience with an error said that the health professionals involved in the error had told them about it or apologized to them. In an earlier US survey, which used anonymous questionnaires, 114 house officers described their most significant mistake and their response to it. This revealed that they had discussed the mistake with the patient or patient’s family in only 24% of cases. A study on medication errors in a paediatric teaching hospital in the UK found that 48% of the parents of patients involved were not informed about the event.

Other studies, which have used hypothetical scenarios in their surveys, found higher proportions of doctors reporting a willingness to disclose their errors. This difference may be because results using this methodology reflect attitudes rather than actual behaviour. For example, a survey of 106 US medical students, attending officers and house officers, used three case vignettes to assess whether physicians would report an error to the patient and what factors were most influential. In this study 95% of respondents said they would tell a patient of an error when the error led to short-term pain, and 78% indicated that they would report the error when it led to the patient’s death. Despite this hypothetical readiness to admit error, some respondents wondered if they would actually tell the truth if they were really involved in a similar situation.
An earlier US study, which also used hypothetical case scenarios, reported a smaller proportion of doctors willing to disclose an error. Just over half, 54% of the 211 doctors surveyed, said they would report an error that led to a patient’s death and a third indicated they would offer incomplete or misleading information to a patient's family. The difference between these results and those of the more recent study may reflect a trend over time to becoming more candid in discussions with patients in general.

Factors that may affect disclosure include the degree of harm or injury resulting from an error. The study used scenarios with different outcomes and as the severity of the injury increased, the doctors’ willingness to admit an error to the patient decreased correspondingly. The same study also found the willingness to disclose the error of another treating physician was far lower than their willingness to admit their own errors.

**REASONS FOR AND BARRIERS TO DISCLOSURE**

**Preferences of patients and doctors**

Despite some methodological limitations, results from the surveys described below suggest that the majority of the public believe patients and or their families should be told about errors, even when the consequences are minor. Survey results also suggest a difference between perceptions of doctors and patients regarding the need for disclosure.

A small US survey using hypothetical scenarios, which described 3 levels of mistakes (minor, moderate and severe) examined 149 patients’ attitudes towards physicians’ mistakes. The vast majority of respondents (98%) desired some acknowledgement of even minor errors.

In 1999, 48 ophthalmologists and 246 patients responded to a UK survey about their attitudes to the amount of information that should be given after unintended injury during treatment. The questionnaire asked about postoperative information that should be given routinely in a hypothetical situation in which a common complication occurred in cataract surgery with an estimated 10% risk of an adverse effect on vision. The attitudes of the patients differed substantially from those of the ophthalmologists;
92% of patients believed patient should always be told if a complication occurred, whilst only 60% of ophthalmologists thought so. The majority (81%) of patients, but only a third (33%) of the ophthalmologists believed that a patient should not only be informed of a complication, but also given detailed information on possible adverse outcomes.

There have also been two recent US surveys that asked patients whether they would want to be informed if an error occurred. One study, using a convenience sample, questioned 258 patients and families attending an emergency department. Error was not defined, but respondents were told: ‘During the delivery of your health care many things could go wrong. Most would in no way impact on your health. The following survey is designed to determine what your wishes would be if something did go wrong in the administration of your health care.’ A majority (88%) said they would want to know everything about the mistake if a medical mistake did happen, whilst 12% said they would only want to know about the mistake if it did or could affect their health. If a medical mistake did happen to them 76% said they would want to know as soon as it was detected whereas 23% said they would want to know about it as soon as the extent of the mistake was known.

Larger parallel surveys in the US of 831 physicians and 1207 members of the public have also been carried out. Medical error was defined, ‘Sometimes when people are ill and receive medical care, mistakes are made that result in serious harm, such as death, disability or additional or prolonged treatment. These are called medical errors. Some of the errors are preventable, whereas others may not be.’ A larger proportion of the public (89%) than the doctors (77%) believed physicians should be required to tell patients when errors are made in their care. Two vignettes were described in which the same medication error occurred, but with different outcomes, death vs. full recovery. In both cases, the majority of doctors and public thought that the error should be reported to the patient or family, but there were differences between the doctors and the public in the attribution of responsibility for the error and the consequences for those involved.

A European survey using multiple-choice questions, asked doctors practising intensive care medicine what they would tell patients and/or family when an
iatrogenic incident (avoidable mistake) occurred and what they felt that they should do. Most of the doctors reported that they were not completely honest, but felt that they should be giving more information. Almost two-thirds (63%) said they would say that a complication occurred, but would minimise the iatrogenic aspects, 32% said they would tell a patient and/or family exactly what happened, including that the complications were probably due to medical negligence and 4% said they would say nothing about the complication whenever possible. However when asked whether they should give full details, 70% felt they should. This study found variations between the 16 countries surveyed, but the number of doctors responding in each country was relatively small, ranging from 21 to 72. In all countries, doctors felt they should be disclosing more complete information than they were in fact giving.

The recently published US qualitative study which analysed focus group transcripts to determine patients’ and physicians’ attitudes about error disclosure, also found that physicians ‘choose their words carefully’, when telling patients about errors. Separate focus groups of patients and physicians and joint groups of patients and physicians took place and case scenarios and personal experiences were discussed. Although patients’ and physicians’ attitudes had much in common, differences in perspectives between the groups emerged. Patients unanimously wanted disclosure of all harmful errors and wanted information regarding an error’s cause, consequences and future prevention. Physicians agreed in principle that patients should be told about any error which caused harm, but many described specific situations in which they might not disclose an error and they were more circumspect concerning the details they would disclose. For example they would disclose the adverse event, but often avoided stating that an error had occurred, why it happened, or how recurrences would be prevented. Patients stated they desired an apology, following an error, whilst the physicians were concerned that making an apology might create a legal liability. Patients had mixed opinions regarding the disclosure of near misses, while most physicians opposed disclosure of them.

**Ethical considerations**

The ethical obligation to disclose errors to patients and/or families have been discussed in detail by many authors. In general, disclosure of a medical error is seen to be ethically appropriate. In situations in which disclosure of a medical
error might cause serious and irreversible harm to the patient, physicians can exercise “therapeutic privilege” and choose not to disclose, but this ‘should be used rarely and in emergent situations, followed by a commitment to reassess disclosure when the patient is more stable’.

Doctors face conflicting moral dilemmas when deciding whether to disclose an error, such as: their personal values, their professional obligation to prevent a recurrence of the error, the patients right to know the truth, the concern that informing the patient will create more suffering because of the patients knowledge of the avoidabity of the event and the positive or negative effects on the doctor-patient relationship.

Two different theoretical, ethical perspectives have been described in relation to communicating about error: a consequentialist theory which holds that one ought to do the act which will realise the best overall consequences (where the benefits and harms to patients should have greater weight than those to the physician) and a deontological theory which maintains one ought to do that act by which one fulfils one’s duties or obligations. In most cases it would seem that the benefits of disclosure outweigh the harmful consequences, especially from the patient’s perspective. Disclosing an error is also generally supported if one considers the deontological perspective.

From a consequentialist perspective, the importance and potentially beneficial consequences of disclosing an error are real and include the following:- Information about a medical error allows patients to obtain timely and appropriate monitoring or treatment to correct problems resulting from a mistake, thus preventing further harm. Patients may be unwilling to cooperate with new treatment or management plans if unaware of the reason. Being informed about an error also allows patients to resolve any uncertainty about the cause of their condition and provides information to make informed decisions about any further treatment or monitoring. In the case of injury, knowing about an error may allow the patient to obtain compensation. Being told the truth allows patients to develop more realistic expectations about their doctor’s interventions and may even promote trust and strengthen the doctor-patient relationship. The doctor may feel relief and may gain absolution by being forgiven by the patient or family member. Candid disclosure may decrease the likelihood of legal
liability and disclosing mistakes may help physicians to learn and improve their practice.

If one considers the duties or obligations of the doctor (the deontological perspective), disclosure of an error is also generally supported. The doctor-patient relationship relies on principles of beneficence, nonmaleficence, autonomy, and justice in all actions. Respect for patient autonomy means patients have a claim to know their own history and to be free of mistaken beliefs concerning their past, present or future medical condition. As to nonmaleficence and beneficence, disclosure may further the patient’s health. In cases in which harm resulting from a mistake can be reversed or ameliorated, the physician is obligated to do so. Considering justice, if a mistake is not remedial, there is an ethical duty to disclose so that the patient can claim compensation.

The harmful consequences of disclosure might include the following: in some cases patients and their families may be harmed by the knowledge and become alarmed, anxious and discouraged. Their faith and confidence in doctor’s ability to help may be damaged and they could become disillusioned with the medical profession in general, which may lead them to decline beneficial treatments. Some patients might not want to know everything about their medical care and the well-meaning disclosure of potentially serious, but inconsequential mistakes may be unwelcome. Disclosing an error may carry disadvantages for the physician(s) involved. In addition to the psychological stress of facing angry patients, it may lead to a malpractice suit, increased insurance premiums and damage to reputation and status.

From a deontological perspective, disclosure may not be ethically appropriate when the error is inconsequential and disclosure does not empower the patient, when disclosure would likely distress the patient or when disclosure results in unwarranted diminution of patient trust. In these instances promotion of autonomy may not be the overriding obligation.

A different view that supports the disclosure of all errors to patients, irrespective of the outcome is given by Greely 1999 who states ‘the bond between professionals and their clients should require complete honesty and responsibility for errors.”
whether the professional is a physician, a lawyer, or a tax accountant. The fiduciary should disclose what reasonable patients or clients would want to know under the circumstances. Reasonable patients will often want to know about significant problems in their treatment to plan future care, to consider litigation, or just to help decide whether to change doctors.\textsuperscript{61} This view is endorsed by Hebert and colleagues who state that patients are due information about errors out of respect to them as persons, so they have a right to know about critical incidents even if they are not physically harmed by them.\textsuperscript{63}

There is also an emerging literature on the ethical aspects of discussing the mistakes of others. The General Medical Council\textsuperscript{43} tells doctors: 'You must protect patients when you believe that a doctor's or other colleague's conduct, performance or health is a threat to them. Before taking action you should do your best to find out the facts. Then, if necessary, you must follow your employer's procedures or tell someone from the employing authority ...or a regulatory body.... The safety of patients must come first at all times.'

There is a culture of silence though and social norms militate against reporting occasions when a colleague makes a mistake.\textsuperscript{37 56 64-66} Other members of the healthcare team often witness mistakes and agonise over conflicting loyalties to patient, institution, and team. While the position is clear for physicians' obligations to admit their mistakes to their patients, the case of the medical student observing a case is less clear because of dual responsibilities of honesty to patients and their responsibility as a student.\textsuperscript{67} Nonetheless, there are ethical arguments in favour of disclosing to patients possible mistakes made by other medical professionals: first there is the duty to be truthful to patients. Normal care typically includes a discussion of how a condition occurred- silence falsely implies that the doctor believes the patient’s problem occurred by natural means. Second there is the principle of reparations. Most patients will have no way of knowing that they may be entitled to reparations if they are not told the likely cause of their condition. Third, there may be a duty to protect others.
Legal considerations

It is impossible to consider the issue of disclosure without taking litigation into account. Whether or not errors should be communicated to patients and relatives should not however, be determined by legal considerations. As Bark, Vincent, Jones and Savory 1994 state69 ‘If litigation is a real fear a clear policy must be agreed between managers and clinical staff that explanations to patients are justifiable on clinical and humanitarian grounds, even at the risk of ensuing litigation.’

It should also be emphasised that medical errors, though common, rarely lead to litigation70 71 and that fears about exposure to legal liability as a result of admitting an error may be founded on incorrect premises about the law72. Indeed the Legal Review25 which examined the relevant law in Australia that may affect the implementation of a national standard on open disclosure, concluded that concerns about an explanation and apology amounting to an admission of liability in negligence are overstated. Nevertheless litigation is increasing and the fear of litigation is often cited as a barrier to the reporting of errors26 56 73. Some doctors report they feel torn between their own wish for an open approach and what they perceive to be their defence societies’ directives27 74.

The popular view that the disclosure of errors is inherently risky and increases the likelihood of being sued is not supported by recent empirical data. Preliminary data are available from a Veterans Affairs medical centre in Lexington, Kentucky, which has adopted a policy of full factual disclosure and apology75. Unexpectedly, the policy has not caused an onslaught of litigation, and overall the institution has realised cost savings, in part because of reduced legal expenses. This is believed to be due to the fact that the facility honestly informs patients of substandard care and offers timely and comprehensive help in obtaining compensation, thus defusing the anger and desire for revenge that often motivates litigation. The authors recognise that the results of their study may not be generalisable.

Liability may be imposed on a physician precisely because of failure to reveal a medical error, especially if it is uncovered later. Witman and colleagues found that for both moderate and severe mistakes, patients would be significantly more likely to consider litigation if the physician did not disclose the error. In the moderate mistake
scenario, 12% of patients would sue if informed by the physician vs. 20% if the physician failed to disclose the error and they discovered it by some other means. Results of studies of why patients sue doctors or hospitals suggest that deficient communication about the adverse event is a common cause. A study of 227 patients and relatives in the UK found that the decision to take legal action was determined not only by the original injury, but also by the insensitive handling and poor communication after the original incident. When the researchers asked the respondents whether anything could have been done following the incident that would have eliminated their need to take legal action, more than a third (37%) responded that an explanation and an apology would have made a difference. Similar results were found in another US survey. Of 127 families in Florida, who sued after perinatal injuries, 24% were motivated by the suspicion of a cover up and a further 20% said they needed information. Both these surveys had low response rates, but they demonstrate that patients and relatives who sue are not only motivated by the desire for financial compensation. A survey of senior clinicians in the UK also identified poor communication between staff and patients as a significant reason for litigation.

Although the pre-action protocol for the resolution of clinical disputes, which followed on from Lord Woolf’s ‘Access to Justice’ report supports an increase in openness when something has ‘gone wrong’, the prevailing legal system does not encourage health professionals to be open after an adverse event. This is recognised by the Department of Heath, for example in its response to recommendations resulting from the Bristol Inquiry; ‘We agree that staff should be open and candid about errors..... Whether or not patients wish to pursue complaints or clinical negligence claims, they are entitled to a proper explanation and apology when things go wrong. However, the current system of clinical negligence litigation can act as a barrier to full and frank disclosure....’

Despite the many deficiencies of the current tort system, a few valuable features have been highlighted; both for the patients and the health professionals involved. Patients often appreciate the chance to have their case reviewed by an independent expert, if they proceed beyond the initial stages of litigation and they welcome the access to
more information than they might otherwise have had. An additional benefit of the tort system for the defendant is that it allows a defendant to protect his or her reputation from a suggestion of incompetence or negligence.

Alternative procedures for settling medical disputes are being considered and tested. A no-fault compensation system is one option which might be less adversarial, as it severs the link between perceived negligence and compensation, but other problems would remain and the issue of accountability would not be resolved. This type of system would not necessarily address patients’ concerns about receiving an adequate explanation of the events that led to injury. Although mediation is not intended to replace litigation, it is one process of alternative dispute resolution which enables a wide variety of settlement solutions to be offered to the patient and family for consideration beyond simple monetary transfer. For example the process addresses patient concerns, including facilitation of communication, resolution of uncertainty, and acknowledgment of suffering.

Organisational/institutional considerations

The Institute of Medicine’s report stresses the central role that an organisation or institution must take in improving patient safety: ‘Chief executive officers and boards of trustees must make a serious and ongoing commitment to creating safe systems of care. Other high-risk industries have found that improvements in safety do not occur unless there is commitment by top management and an overt, clearly defined, and continuing effort on the part of all personnel and managers.’ Results of the consultation exercise carried out for the Australian open disclosure project endorse this view, with stakeholders regarding the role of hospital managers and boards as fundamental.

Indeed the communication of errors to patients depends to some extent on whether other parts of the patient safety system are working and there is a need for both leadership and organizational commitment. The openness and sensitivity of individual clinicians will be completely undermined if there is not a collaborative approach between clinicians and management with a basic strategy agreed by the hospital trust board.
To assist organisations and leaders to promote the importance of patient safety, create awareness and act as a catalyst for change, a self-assessment tool has been developed at the Dana-Farber Cancer institute in Boston, Massachusetts specifically for executives' personal use and reflection on their efforts to develop a culture of safety. The tool, ‘Strategies for Leadership: Hospital Executives and Their Role in Patient Safety’ aims to give individuals and groups of leaders a range of choices to consider, periodically revisit, and use to trigger action. Although it is designed for an American audience, it includes useful background references and strategies for implementing and maintaining a culture of safety throughout an organisation. Also useful is the material being produced for the Australian Open Disclosure Project which will include the following support package: a document setting out responsibilities of professionals and managers and practical implementation measures, advice on how to incorporate open disclosure into operational systems, advice on documentation, reporting and review systems, suggestions for privacy, advice on lines of responsibility, guidance on notification to insurers and regulators, advice on the role of complaints systems and suggestions on how to provide support for patients and providers.

A vast number of errors are not reported either internally to an institution or disclosed to patients because health professionals fear they will be punished. Particular attention should therefore be paid to the disciplinary procedures within an organisation. A report by Marx 2001 advises health executives to re-evaluate the role of their disciplinary system as it relates to system safety and asks them to consider whether their current disciplinary policy is supportive of or detrimental to system safety efforts? Current disciplinary systems often prohibit human error and this can create a reluctance to come forward and admit to errors. An error that causes harm may not always warrant punitive sanctions. The interests of communication should be balanced with those of deterrence. Disciplining employees in response to honest mistakes does little to improve overall system safety. A blame-free system, in which any conduct can be reported with impunity, is not advocated though, as disciplinary action is warranted when errors are caused by irresponsible, negligent, malicious or unethical behaviour.
Institutions may also facilitate the communication about errors by ensuring staff are well supported in the aftermath of an adverse event and the ways a well organised trust can alleviate the stress encountered by staff involved in serious incidents or litigation have been outlined. This can be achieved by practical interventions operating at the organisational level and action towards supporting individuals. Results from a UK study examining the level of reporting of errors to internal systems discuss the ways an organisation can encourage error reporting, for example: support from management, cultural change to make clear what is acceptable or not in terms of behaviour, improving leadership generally and in terms of safety and error, listening and action on the part of management seen to bring about useful change and training on safety and the handling of error for doctors, nurses and management. If these recommendations were implemented, communication about the same events to patients might also be facilitated. All institutions need to establish a clear and unambiguous disclosure policy for their employees.

Professional Considerations
Professional societies, groups, and associations can play an important role in improving patient safety by contributing to the creation of a culture that encourages the identification and prevention of errors. Several studies have demonstrated the reluctance of doctors to talk about errors, even amongst themselves. One reason for this is the culture of infallibility within the medical profession. Medical school training encourages doctors to have high expectations. They are expected to function without error, which many of them translate into a need to be infallible and as a result errors come to be viewed as a failure of character. Role models in medical education reinforce the idea of infallibility, and as a result errors are rarely talked about, either to doctors or patients. Competitiveness, the fear of damage to reputation and loss of respect from peers also inhibits communication.

An open acknowledgment of the inevitability of medical errors and the need for practitioners to be trained in their management is essential if successful communication with patients about adverse events is to take place. Physicians individually and within groups need to be encouraged to foster an environment in which errors are openly acknowledged, analysed and managed. Role modelling and professional training that address medical error may help to encourage a more
open climate and attempts should also be made to regularly include a discussion of medical errors in formal meetings with colleagues, such as medical group sessions or committee conferences.

A survey by Lefevre et al showed the dire lack of training programmes that exist in risk management and communication. Improvements in communication skills training may help to overcome the difficulties health professionals have in talking to patients after an adverse event, which is another barrier to disclosure. Members of staff often do not possess the crucial communication skills to help them handle these incidents. It is particularly difficult to communicate the uncertainty that surrounds many adverse events, especially if the causes are not immediately obvious. There is also a general reluctance to discuss another health professional’s behaviour with a patient following an error. Empathy, sympathy and the ability to admit to mistakes are attributes that need to be acquired and maintained and there is a need for training in communication skills, both pre- and post- qualification for coping with and helping dissatisfied, distressed or injured patients and their relatives.

The background studies described in this section of the report generally support the disclosure of errors to patients or their relatives, but they also demonstrate that this does not yet happen routinely and there are many barriers to disclosure. The practical issues such as: whether, who, and when to tell patients about errors will be discussed in the next section. Consideration will also be given to the need for support and resources for doctors, patients and their families and the areas that need further research.

**PRACTICAL ISSUES TO CONSIDER**

**Which incidents should be disclosed**

We await with interest publication of results from the Australian Open Disclosure Project to further inform this issue but feel on balance, that the situations when disclosure of an adverse patient incident is not recommended are likely to be rare. We suggest (Table 3) that patients should be informed after all adverse incidents except ‘near misses’. However in view of the evidence that individuals may consciously or unwittingly rationalise decisions not to discuss error fully with patients and their relatives, institutions need to have established policies providing clear...
and specific guidance to encourage compliance. A consensus needs to be reached, as opinions will differ as to whether all incidents should be disclosed, including near misses, and even whether all adverse events should be discussed. For example Cantor asks whether a patient, who has a temporary drop in blood pressure after receiving the wrong medication, has suffered enough harm to have the event disclosed. If a patient has not been seriously harmed, he or she may be unaware that an adverse incident has occurred and the first decision for the clinical team (not just the individual doctor) will be whether it is in that individual patient’s best interest to be told. Similarly in controversial cases, for example when there is legitimate uncertainty as to whether an adverse outcome was the result of an error, an opinion on the need for disclosure should come also come from an experienced institutional body rather than the individual caregiver who may be biased. In the short term it may be necessary for individual institutions to establish clear guidelines of their own, but consideration should also be given to harmonising these nationally, given that staff, particularly junior doctors, move posts frequently.

Who should communicate about an adverse event?
There appears to be little general consensus that the person deemed primarily responsible for an error should be present when the adverse event is disclosed to the patient and or relatives.

Results from one US study which asked patients with whom they would like to speak further after a mistake found that many wished to discuss the matter further with their physician if the error was minor, but only half wished to do so when the consequences were severe. The number desiring to speak to another physician rose with increasing severity of the mistake. Only a small proportion (3%) of respondents wished to speak to a nurse regardless of the severity of the error.

It has been reported that for the majority of victims of medical accidents, compensation is secondary to accountability and many people want a face to face meeting and apology from the person responsible and not a letter from a ‘faceless’ bureaucrat. A UK study, which explored the scope for mediation as an appropriate alternative to litigation in the resolution of clinical disputes, found that claimants’ satisfaction with the mediation process was sometimes, although not
always, contingent on the presence of the clinician they blamed for inadequate medical treatment. Some expressed the opinion that they must be present if the claimant’s sense of a ‘day in court’ was to be created, although this view was not necessarily reflected in satisfaction levels. Others felt that the level of distrust and anger was so great between the claimant and doctor that to bring them together could serve no useful purpose.

Some authorities have instigated systems based on models proposed by Liang that remove the clinician from the disclosure procedure altogether, at least initially, and employ a disclosure team instead 46 75. Others have guidelines that state explicitly that the attending physician should be responsible for communicating about error with the patient and/or family96. This appears to be the current recommendation of the GMC 43 which states ‘You must explain fully and promptly to the patient what has happened and the likely long- and short-term effects. When appropriate you should offer an apology.’ There are some reasons why this latter policy might not be appropriate. If the adverse event is the result of a whole sequence of mistakes and misunderstandings, if responsibility is still unclear or if the emotional state of all the people involved is still somewhat volatile, then probably another well-informed clinician, such as the multidisciplinary team leader or senior consultant, should be the primary informant.

Stakeholders consulted about the Australian Open Disclosure Project27 indicated that “a primary consideration for deciding who should speak with the consumer at different stages of discussion is the consumer’s needs and wishes. Consumers should be dealing with someone they trust and someone they feel reflects that the incident has been taken seriously and will be accountable. This could include senior management in some circumstances.”

A very junior doctor or nurse should always have a senior member of staff present who is able to provide support for all the damaged parties 54. A recent UK study highlighted the difficulties junior doctors face coping with disclosure of bad news to patients or relatives 97. More relevant sometimes than seniority however is the communication ability of the doctor involved and the relationship that the doctor already has with the patient and family members. Breaking bad news after an adverse
event can be a particularly difficult task for emergency physicians, whose contact with the patient and family is invariably brief and lacks the benefit of an ongoing relationship 19.

Clinicians have very different communication styles and skills and studies have shown that ability is not necessarily related to experience. Interestingly there are some suggestions in the literature that the communication styles of doctors who are most likely to be sued differ from those who are not sued 6 98. In the US, physicians who invested time in orienting the patient as to what was likely to happen to them, used humour appropriately, actively sought the patient’s opinions and finally checked their understanding, had lower litigation rates than those who did not employ such patient centred techniques. While the purpose of a disclosure interview about an adverse event is not necessarily to avoid litigation, arguably the types of skills needed in these circumstances such as empathy, patient-centeredness and the ability to handle emotionally charged interactions might make the perpetrator of the error quite the worst person to then discuss what has happened with the victims. If the communication skills of the doctor are known to be poor a difficult situation might escalate further and remain unresolved, so another person should be asked to do it.

As far as the initial disclosure of a very serious adverse event or an unexpected death is concerned, there is evidence that the ability of relatives to cope and adjust to this may be related to the skill of the person breaking the news 7. In one such study of the reactions of 120 bereaved parents told that their child had died, police officers’ skills were rated more positively than were those of doctors or nurses 99. Especially valued were unhurried interviews with parents’ questions encouraged and the informant overtly displaying an understanding and caring attitude. In contrast a cool, detached appearance gave great offence especially if parents’ questions were evaded suggesting a cover-up. These dissatisfied parents said that litigation seemed like their only means of obtaining information.

What information should be provided and how should error be disclosed?
Clinicians find it very difficult to conduct a relationship with patients, harmed as a result of a medical error 100 as they generally receive little training not only in the communication skills demanded but in the handling of their own emotions 91. There
are a large number of models within the general communication skills literature about breaking bad news, explaining complex information, and conflict resolution. There is less specifically aimed at communication about error although there are several papers that suggest useful principles and guidelines. Little attention has been paid to communication with groups of patients who may be more vulnerable to error than others, for example older patients. Patients of different ethnic backgrounds vary in their preferences about how to hear about bad news such as a cancer diagnosis, but there is virtually no literature available on discussions about medical error with patients from different cultural backgrounds.

When should discussions take place?

A recent US survey of patients reported that if a medical mistake did happen to them, 76% would want to know as soon as it was detected. A smaller proportion (23%) said they would want to know about it as soon as the extent of the mistake was known.

The classification of adverse incidents shown in Table 3 (p21) provides a summary of the stages of disclosure that might be needed depending on the type of event and type of outcome that has occurred. In general terms stages A, B & C should take place as soon as the patient is medically stable enough to assimilate the information, any delay can encourage impressions that there is a cover-up. If the adverse event has had dire consequences such as death, then the grieving relatives should at least be invited to discussions about the nature of the incident as soon as they feel able, followed by others at a later date.
SUGGESTIONS FOR EFFECTIVE COMMUNICATION ABOUT ADVERSE EVENTS

What follows is a synthesis of the skills needed to handle the stages of communication delineated in Table 3. This has been derived from a variety of sources including the authors’ experience from their own research observing the practice of doctors and nurses breaking bad news and its impact on patients, and from some of the many guidelines proposed for the breaking of bad, sad and difficult news \(^7\) \(^{10}\) \(^{28}\) \(^{101}\).

**Immediate Actions**

In the immediate aftermath of an adverse event, communication needs to be handled very carefully as all parties are likely to be in a highly charged emotional state. Relatives could be distressed, anxious and angry and the healthcare professionals involved could feel panic, guilt, uncertainty and anxiety. The latter might also be involved in remedial actions to try and rectify or ameliorate the worst effects of the error. Such a potentially volatile cocktail of emotions is not conducive to easy communication. Things said or omitted in the heat of the moment may leave lasting impressions and hamper a satisfactory outcome for all concerned. The most reasonable advice is to stay calm, enlist the help and support of an appropriate colleague quickly, especially if more than one other person is involved, provide a brief statement of the situation with an apology that something amiss has occurred and reassure the patient/relatives that as soon as the facts can be assembled a more formal meeting will be convened. Whenever bad news is given, the recipients should be offered privacy, access to phones, and especially in the case of a person alone, offers to call another family member or friend. The patient and or relatives should be given a contact number and name of a person who will be able to liaise with them about any future meeting required.

**Prior to convening any meeting**

The doctor and other institutional representatives need to :-

- Ensure that all facts regarding clinical situation are available together with any other important information about the patient/relatives who will be attending the meeting
• Give parents the option of including their child in the meeting, in the case of the patient being a minor
• Make arrangements for patients with any special needs, for example organise advocates or interpretation services
• Pick a mutually convenient appointment for the meeting and allow sufficient time
• Chose a comfortable, private environment with no interruptions from other staff members, telephones etc

(A) Clear description of adverse event and probable outcome

Beginning the interview
• Introduce yourself and anyone else present
• Establish who is the patient (if present) and/or what is the relationship of those present to the injured party
• Explain how the meeting will progress eg “first I shall explain what we believe has happened, how we think this will affect you/your relative and what we wish to do to help you”
• Encourage those present to takes notes, ask questions or interrupt if something is said that they do not understand

Explaining what happened
• A clear jargon-free description of the facts as known should be given
• Unresolved issues should be identified and patient and relatives assured that these are being investigated further
• The patient’s current condition and what the probable outcome will be should be described as honestly as possible. False or premature reassurance is not likely to be helpful
• Check on understanding and note any queries or concerns that are raised for which further information has to be sought

(B) Expression of sorrow or regret and genuine apology

Apologising
• It is probably wise initially not to attribute blame to specific individuals unless the error has a manifestly obvious cause
• State quite clearly that all concerned genuinely regret that the event(s) occurred e.g. “We are extremely sorry that events have led to your current problems/continued ill-health/father’s death and appreciate the unnecessary distress/pain that has been caused”

• Avoid comments such as “I understand how angry/upset you must be” Use instead “In similar circumstances I think most people would react/feel as you do now, but can I assure you that we want to help you to deal with this”

• The person apologising on behalf of the institution and or healthcare professional(s) involved should be prepared for a variety of emotional reactions to this which might include anger, tears or even gratitude

(C) Revisions to care plan, rehabilitation etc.

Explanation as to what needs to be done for patient

• Outline in clear jargon-free terms what new treatment, extra monitoring, tests etc are being done or need to be done

• Reassure patient/relatives that all possible measure are being taken to try and resolve the harm done if possible

• The patient/relatives might well demand that another doctor, team or hospital takes over further treatment and this possibility should have been discussed with doctor(s) institutions concerned

• Allow time for patient/relative(s) to assimilate information given and ask questions

(D) Measures being taken to prevent similar occurrence

• Explain what is being done to prevent same event from happening again

• Be prepared for questions as to whether or not similar events have happened before within the hospital or to patients under the care of doctor, nurse or team involved

• Open disclosure is probably the best policy and institution’s risk manager should have already instigated an appropriate enquiry as to why event has happened again if that is the case
(E) Opportunities for further discussion

- Even if event was not serious and patient has experienced little if any harm, opportunity for further meeting should be offered
- In the case of serious medical error where patient’s condition is still uncertain or if full facts of event are still unknown, then further meeting must be arranged
- If a great deal of information has been given or the patient and relative(s) are very distressed by the meeting then offer of a break or another meeting should be made

(F) Procedures for compensation

- Patient and relatives should be given all necessary information regarding complaints procedures and contact names and numbers of people who can offer help and guidance with this and compensation claims

(G) Emotional support

- Information and contacts about internal and external sources for emotional help and support should be provided. This might include names and telephone numbers of bereavement counsellors, social services, chaplains, patient advocates, the Patient Liaison Advisory Service (PALS), the Patient and Public Involvement team at the NPSA and support groups such as Action for Victims of Medical Accidents (AVMA)

(H) Details about full inquiry

- Patient and relatives must be told, who will conduct a full inquiry, how and when this will be done
- Explain how they will be kept informed about progress
**Concluding the meeting**

At the conclusion of any meeting another opportunity should be given to ask any questions. A further expression of regret should be made and all should be thanked for attending. What was said and agreed should be clearly documented for use by the institution’s risk manager, patient and relatives and the patient’s primary health care team.

**TRAINING**

High level communication skills are demanded when discussing any bad, sad or difficult news and most clinicians would agree that their medical training has not equipped them adequately to deal with the emotionally charged discussion that surrounds disclosure of error.

A support package for the Australian Open Disclosure Project\(^{27}\) is being developed, but it aims simply to provide effective information about the standard and how to adopt it in practice, rather than a program to implement widespread attitudinal change in the health sector or communication skills training. A variety of training videos have also been produced such as the Institute for Safe Medication Practice’s ‘Beyond Blame’ (http://www.ismp.org/Pages/Blame.htm) and the NPSF’s ‘Let's Talk: (http://www.npsf.org/html/letstalkvideo.html). References to workshops aimed at improving communication about medical error can be found\(^{93,106}\), and include the ‘Apologizing for Error’ run by the AMA in 2002. (http://www.healthcaremediations.com/hm/recent.htm) and ‘Avoiding a Communications Crisis: Planning and Preparing Communications about Errors’ (http://www.npsf.org/congress_archive/2001/workshops.html). Other training programmes are planned, for example the National Patient Safety Foundation will launch in 2003 the Training Institute for Patient Safety\(^{SM}\) (TIPS). TIPS programs will educate and train physicians, nurses, and other healthcare professionals and one of the planned courses is ‘Disclosing Medical Errors to Patients and their Families’. (http://www.npsf.org/html/education.html). There is a clear need for the development of further programmes to assist healthcare professionals working within a UK setting but these also need to be evaluated.
Despite the seemingly valuable initiatives run in countries elsewhere there is unfortunately a dearth of information as to whether or not any of these have led or will lead to measurable benefits. In common with much of the literature that exists on communication skills courses designed to help when breaking bad news, the outcomes are customarily subjective reports from participants who rate the intervention as having been interesting and very useful. A recent, as yet unpublished systematic review commissioned by the National Institute for Clinical Excellence (NICE) (http://www.nice.org.uk/cat.asp?c=20102) to inform its Supportive and Palliative Care strategy, shows that evaluations of outcomes following training programmes rarely examine objective improvements in communication skills and in particular their transfer into clinical practice (Higginson personal communication). There are some important exceptions cited in the review including a randomised controlled trial of a 3 day residential, general communication skills training programme. This trial was conducted in 34 cancer centres throughout the UK and involved more than 3,000 patients at all stages of the disease trajectory seeing 160 doctors about their test results or treatment options, so many of these consultations included breaking bad news. The study utilised multiple outcomes and the results provided good evidence for the efficacy of courses incorporating cognitive, behavioural and affective components. The intervention significantly changed attitudes and beliefs towards the importance of effective communication and led to measurable and sustained changes in doctors’ communication skills which transferred into the clinical setting. This approach is therefore recommended for a training programme to help healthcare professionals with disclosure about medical error.

Suggestions for a UK training programme about medical error

Any training initiatives in the UK should be informed by the outcome of some of the research suggested on pp 50 - 51, but course methods and content might include:-

**Cognitive component**: This would comprise some didactic presentation of evidence-based practice together with prepared annotated bibliographies of key readings about communication skills, perspectives of patients and relatives about preferences for disclosure as well as legal and ethical issues.

**Behavioural component**: This would involve 1) review and group discussion about trigger videotapes of healthcare professionals discussing error with patients and
relatives, 2) interactive, demonstration role-plays and 3) videotaped role-play of participants with simulated patients followed by review and constructive feedback.

**Affective component:** Doctors would be encouraged to discuss errors that they have made or witnessed, how these were dealt with and how they affected the individuals concerned. Barriers to disclosure would be discussed as well as appropriate ways to overcome some of these.

Groups would have to be led by experienced facilitators skilled at creating safe, supportive and non-judgmental environments that assist in personal disclosure and self-awareness. Participants on any training initiatives do need to have the objectives of such courses articulated clearly. The different elements of the course need to be designed to link up with specific desirable outcomes if there is to be transfer of skills into the hospital setting. For example, worthy outcomes such as helping the patient and/or family to feel acknowledged, respected and supported or promotion of trust and strengthening of the doctor-patient relationship sound laudable enough, but participants require illustrative examples of which actual phrases and techniques promote such things if learning is to occur. In the general communication skills model shown to be effective for senior doctors in cancer medicine, an important course element, apart from increasing doctors’ competence and confidence in communicating well, was changing attitudes and beliefs about the necessity of applying certain skills. Educational and skills based initiatives alone are not sufficient in themselves to produce behavioural change.

**SUPPORT**

**Support for patients and their relatives**

The speed and extent of recovery from an injury depends on many factors, for example, the nature and extent of injury, the degree of pain and the degree of subsequent disability. Subsequent adjustment is also influenced by the personality of the affected patient, any history of trauma and loss in their life, financial security and employment prospects and the support given by family, friends and health professionals.
Support for patients can include information about disability benefits, talking to others who have had similar experience or factual information or it can involve more formal psychological counselling. The Bristol Inquiry\textsuperscript{45} has highlighted the need for support for patients and families after a serious adverse event. ‘To meet these needs for an integrated system of support, a hospital must have a well-developed system and a well-trained group of professionals whose task it is to provide counselling and support and to make the links to various other forms of support (such as that provided by voluntary and social services) which patients may need.’ The report stresses that these type of needs have to be met in an integrated part of care, not on an ad hoc basis or solely by untrained volunteers or whoever’s available.

Vincent and colleagues\textsuperscript{12 41 109} recommend more attention to understanding patients’ psychological and social problems in the aftermath of an adverse event. A study of patients injured during surgical accidents\textsuperscript{94} found that the average levels of distress were considerably higher than those of people who had experienced bereavements or serious accidents and their psychosocial adjustment was considerably worse than that of seriously ill patients. The principal forms of trauma experienced by patients harmed by treatment are chronic pain, bereavement and loss, depression and anxiety. Post-traumatic stress is less common. Formal psychological or psychiatric treatment should not be offered routinely, but according to need. For example bereavement may be particularly severe if the loss is untimely or unexpected\textsuperscript{41 109}.

Vincent and colleagues have recommended basic principles for helping patients and families who have been injured or seriously distressed by treatment\textsuperscript{12 44 109}. They emphasise: commitment to openess by the organisation, believing people who say their treatment has harmed them, the continuing duty of care (or referral), honesty and openness and early explanation, asking specific questions about emotional trauma and the consideration of counselling or psychotherapy and financial assistance and practical help.

Regarding the need for counselling or psychotherapy, overt psychiatric disorders within the health service often go unrecognised and therefore untreated\textsuperscript{110} and some injured patients have stated that none of the professionals involved in their care appreciated the depth of their distress\textsuperscript{109}. The circumstances after an adverse event in

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which error has played a part may be rather different from other traumatic situations in medicine, but meta-analyses of the benefits of counselling and other psychotherapeutic interventions attest to their value 111-113. However not everyone will necessarily accept counselling. Results of a UK study of perinatal bereavement examining the benefits of routine versus selective counselling114, suggested that women often felt daunted at the prospect of attending a counselling session with someone they had never met. In addition the women who were less able to adjust to bereavement were also those less likely to accept counselling.

Following an adverse event only a proportion of patients and their relatives are likely to be sufficiently anxious or depressed to warrant a referral, but this must be carefully handled. Injured patients are understandably very wary of their problems being seen as “psychological” or “all in the mind” and may be especially suspicious if a referral to a psychiatrist or specialist counsellor is suggested. Nevertheless in some cases an independent counsellor or professional may well be the best person for a patient or relative to talk to if they do have intense emotional reactions after an adverse event. Firstly the health care team involved in looking after the patient’s remedial medical treatment may not have the time or necessary training 109. Secondly patients or their relatives may find it difficult to express their anger or rage to the professionals who have been involved in their care, especially if the latter have been very sympathetic and supportive 115. So although not all people either need or necessarily benefit from counselling after traumatic events, there is still a good case for it being made available. Some patients and families may get the emotional support they need via the Action for Victims of Medical Accidents (AVMA), the only charity supporting people injured by medical accidents. AVMA provide a support network accessible on (http://www.avma.org.uk/) and can put patients and their families in contact with other people in their area or with alternative organisations and support groups

Support for doctors

Doctors are often deeply affected emotionally and psychologically if they make an error or are involved in the care of someone harmed by an adverse event 36 53 54 87 89. Feelings of fear, guilt, anger, embarrassment and humiliation are often unresolved, which can lead to poor or maladaptive coping strategies, such as denial, discounting or distancing 36. One US study 54 found that the house officers who accepted
responsibility for mistakes were more likely to report constructive changes to practice, but accepting responsibility was strongly associated with emotional distress. The study therefore concluded ‘supervising physicians who encourage house officers to accept responsibility for their mistakes need to respond sensitively to the distress those house officers experience’. Undoubtedly talking to patients about an error is part of taking responsibility and support must be offered to the staff involved.

Doctors want emotional support and professional reaffirmation after making an error, but there can be a reluctance both to ask for and to provide support. In one study almost all the clinicians stated a need for support after a serious error, but only one-third would unconditionally help a colleague with identical needs for support. Discussions with colleagues may not always be helpful though, as emotional concerns are often avoided or ignored and discussion can be restricted to technical issues or to problem-solving aspects. The tendency to ‘minimise’ the problem has been discussed.

Wu and colleagues suggest emotional support can be provided in several settings including house officer support groups and discussions of mistakes at departmental retreats. Small group discussions of mistakes are also recommended. Crisis counselling and emotional support on a one-to-one basis might also be applicable in some cases and therapeutic referrals should be offered when needed. There is little research on what singles out a mistake as being traumatic, but usually the outcome is severe, the mistake is a clear departure from the clinician’s usual practice, there is the potential for criticism from others, or there has been a long therapeutic relationship beforehand. A highly self-critical person may also find errors and mistakes extremely disturbing.

Several authors have discussed the negative effects complaints and litigation can have on doctors. Whilst these processes put doctors under extra stress, many of the feelings experienced, for example depression, anger, shame and loss of confidence are common to all those involved in an adverse event. Vincent, discussing doctors involved in complaints or litigation, suggests a range of support is needed from a ‘quiet word in the corridor’ to the offer of extended psychotherapy and states that the choice of intensity should be up to the individual who may have changing needs over
Managers tempted to provide “stress counselling”, especially from paid sources outside the organisation, should remember that support from immediate colleagues is usually much more welcome and appropriate. People are resilient, but anyone might be vulnerable because of personality, position or circumstance, to distressingly severe reactions. Some hospitals employ recently retired consultants as mentors and it is suggested that a link with a psychiatrist or psychologist, perhaps outside the hospital trust might also be useful in some cases. Indeed in one study, over a quarter (29%) of the British hospital senior doctors surveyed about the impact of litigation suggested the formal provision of a counselling service and nominated mentor to whom they could refer.

There is also a demand for legal advice and training within the hospital setting. Education about medical law and the legal process, for example teaching sessions or seminars by hospital solicitors or doctors who act as expert witnesses in litigation cases may help doctors to understand the legal process and alleviate the stress and fears associated with litigation. The consultation exercise conducted for the Australian Open Disclosure Project also found considerable support for a targeted education program to address the difference between an apology and explanation and an admission of liability.

Telephone support services for doctors also exist. The BMA’s stress counselling service is a confidential national service, set up for doctors, medical students and their families. It is run by First Assist where a team of 8 trained counsellors deals with calls. The largest number of calls relate to emotional issues with anxiety, stress and depression heading the list. The Doctors’ Support Line (DSL) is a new peer support help line which offers informal support for doctors with any concerns, for example burnout, depression, and anxiety to work difficulties and family worries. It has been set up jointly by the charity Primary Care Mental Health and Education and the self-help group Doctors’ Support Network, with a grant from the Department of Health. Volunteer doctors, many of whom have experienced problems in their own lives, staff the help line. Calls are confidential and anonymous and unconditional listening rather than counselling, therapy or advice is offered.
FURTHER RESEARCH

There is a clear need for more empirical research about patient and doctor preferences regarding communication issues and behaviour in the aftermath of an adverse event. Although the research studies reported provide preliminary, descriptive evidence about the practice of disclosure and the preferences of doctors and patients, many of these studies have methodological limitations, such as poor response rates, unrepresentative samples, the reliance on retrospective data and hypothetical scenarios. The results from some studies might also not be generalisable because samples are too small. Much of the published research emanates from the US and the results from these may not always be transferable because of their country’s different organisation and provision of health services and levels of litigation. Thus there are many reasons for undertaking more research in the UK.

The dearth of research concerning communication interventions in the context of error is perhaps understandable. The work is difficult to undertake because of the sensitivities that surround discussion about and the acknowledgement of error. There may also be reluctance by some patients, their relatives or doctors to participate in research if they are already involved in litigation or other procedures resulting from an adverse event. Despite these difficulties, there is a need for a broader research programme in the UK. This should include empirical data from observational studies and surveys in order to inform and update the content of policy guidelines and training interventions. Other forms of consultation such as workshops, meetings and teleconferences used in the Australian Open Disclosure Project should also be used to collect information. Without more research appropriate to the culture in which UK health services are delivered, recommendations would have to be derived from sources summarised in this report and be predominantly opinion based rather than evidence based.

We recommend the following: more research on the preferences of healthcare staff and the public and in particular whether the views about communication of both differ according to the outcome of an adverse event. There is an urgent need for a thorough nationwide scoping exercise in order to identify good practice and initiatives. Studies
should not only question patients and others who were dissatisfied with the communication after an adverse event, but also those who felt well informed. Studies are also required to investigate the impact that receipt of information that they would rather not have known about, had on patients. Any special needs or preferences of particular groups, for example the elderly or patients from different cultural backgrounds also need to be explored.

Close liaison with the Australian Open Disclosure Project co-ordinators about their consultation exercise might be useful as information about the attitudes of the many other interested parties in the UK towards open disclosure and their readiness to adopt such a policy, is needed. This might include canvassing the views of the members of Trust Boards, the British Medical Association, the Royal Colleges (including Royal College of Nursing), the Medical Defence Union, Medical Protection Society, groups representing consumers and other relevant organisations. Once this information is available a consensus conference could be held to formulate a national policy regarding disclosure about adverse events. If there is support for an open disclosure policy, it would be essential to carry out a pilot in a few Trusts, tracking the changes and monitoring indicators over time such as complaint rates, litigation claims etc. in addition to collecting feedback from health care staff and patients.

Finally there needs to be substantial investment in the design and evaluation of educational materials and training interventions specifically designed to assist communication after an adverse event. These need to be appropriately tailored for use in a UK healthcare environment.
### APPENDIX

#### Table 1  Medication Error Index for Categorizing Errors

<table>
<thead>
<tr>
<th>Type of Error</th>
<th>Category</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Error</td>
<td>Category A</td>
<td>Circumstances or events that have the potential to cause error</td>
</tr>
<tr>
<td>No Harm</td>
<td>Category B</td>
<td>An error occurred but the medication did not reach the patient</td>
</tr>
<tr>
<td></td>
<td>Category C</td>
<td>An error occurred that reached the patient but did not cause patient harm</td>
</tr>
<tr>
<td></td>
<td>Category D</td>
<td>An error occurred that resulted in the need for increased patient monitoring but no patient harm</td>
</tr>
<tr>
<td>Harm</td>
<td>Category E</td>
<td>An error occurred that resulted in the need for treatment or intervention and caused temporary patient harm</td>
</tr>
<tr>
<td></td>
<td>Category F</td>
<td>An error occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm</td>
</tr>
<tr>
<td></td>
<td>Category G</td>
<td>An error occurred that resulted in permanent patient harm</td>
</tr>
<tr>
<td></td>
<td>Category H</td>
<td>An error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest)</td>
</tr>
<tr>
<td>Death</td>
<td>Category I</td>
<td>An error occurred that resulted in patient death</td>
</tr>
</tbody>
</table>

Source:49

#### Table 2  Adverse patient incidents categorised by severity of outcome

<table>
<thead>
<tr>
<th>Level 1</th>
<th>An event occurred, but the patient was not harmed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 2</td>
<td>An event occurred that resulted in the need for increased patient assessments, but there was no change in vital signs and no patient harm.</td>
</tr>
<tr>
<td>Level 3</td>
<td>An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient harm.</td>
</tr>
<tr>
<td>Level 4</td>
<td>An event occurred that resulted in initial or prolonged hospitalisation and caused temporary patient harm.</td>
</tr>
<tr>
<td>Level 5</td>
<td>An event occurred that resulted in permanent patient harm or near-death event, such as anaphylaxis.</td>
</tr>
<tr>
<td>Level 6</td>
<td>An event occurred that resulted in patient death.</td>
</tr>
</tbody>
</table>

Source: Pennsylvania Association for Health Care Risk Management 50
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