Communicating With Patients About Medical Errors

A Review of the Literature

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Background: Ethical and professional guidelines recommend disclosure of medical errors to patients. The objective of this study was to review the empirical literature on disclosure of medical errors with respect to (1) the decision to disclose, (2) the process of informing the patient and family, and (3) the consequences of disclosure or nondisclosure.

Methods: We searched 4 electronic databases (MEDLINE, CINAHL, PsycINFO, and Social Sciences Citations Index) and the reference lists of relevant articles for English-language studies on disclosure of medical errors. From more than 800 titles reviewed, we identified 17 articles reporting original empirical data on disclosure of medical errors to patients and families. We examined methods and results of the articles and extracted study designs, data collection procedures, populations sampled, response rates, and definitions of error.

Results: Available research findings suggest that patients and the public support disclosure. Physicians also indicate support for disclosure, but often do not disclose. We found insufficient empirical evidence to support conclusions about the disclosure process or its consequences.

Conclusions: Empirical research on disclosure of medical errors to patients and families has been limited, and studies have focused primarily on the decision stage of disclosure. Fewer have considered the disclosure process, the consequences of disclosure, or the relationship between the two. Additional research is needed to understand how disclosure decisions are made, to provide guidance to physicians on the process, and to help all involved anticipate the consequences of disclosure.

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When medical errors occur, effective physician-patient communication is critical. Ethical and professional guidelines make clear that physicians have a responsibility to disclose medical errors, and recent standards link disclosure of unexpected outcomes to hospital accreditation. The National Patient Safety Foundation’s statement of principle on disclosure of health care injuries urges health care professionals and institutions to be forthcoming about health care injuries and errors and to provide truthful and compassionate explanations to patients and families when errors occur. The literature is replete with discussions, commentaries, letters, and editorials on disclosure of medical errors to patients, many of which argue for disclosure on ethical and pragmatic grounds.

The objective of this study was to review the empirical literature on disclosure of medical errors to patients. We also examined the evidence regarding the decision to disclose, the process of disclosing the error to the patient and family, and the consequences of disclosure or nondisclosure.
STUDY SELECTION

Articles reporting original empirical results of systematic research relating to disclosure of medical errors to patients and families were selected. We used 3 selection criteria. First, we required content on disclosure of medical error to patients or families, using the Institute of Medicine’s definition of medical error.20 If it was not clear whether the event or item considered in the study met this definition (eg, if it was not explicitly stated that the event was preventable), we included the study if the researchers or participants referred to the event as an error, mistake, accident, or negligence. We excluded studies of disclosure if the focus was nonpreventable adverse events, as well as studies of disclosure of other sorts of information, such as human immunodeficiency virus status or genetic testing results. This criterion (disclosure to patients and families) also excluded studies of internal reporting, public reporting, or reporting to professional or regulatory organizations. Our second criterion was that the study report original empirical data; this excluded personal accounts, reviews, letters, editorials, opinion pieces, and commentaries. Finally, we excluded articles in veterinary, dentistry, trade, or medical technicians’ journals; unpublished manuscripts; legal decisions; and popular press articles.

SYNTHESIS OF THE LITERATURE

Included studies were abstracted for study design, data collection procedures, study population, and response rate, where applicable. Evaluations of interventions were classified using the rubric described by Campbell and Stanley.21 We also abstracted whether medical error was defined and, if so, how.

Our initial review of the studies led us to conceptualize disclosure as consisting of 3 stages: (1) the decision to disclose that an error occurred, (2) the process of disclosing the error to the patient and family (given the decision to disclose), and (3) the consequences of disclosure or nondisclosure. We therefore categorized each study as providing evidence on 1 or more of these stages.

RESULTS

Of the 825 articles identified through searches of the electronic databases, 9 met our inclusion criteria.22-30 Eight additional articles were identified through hand searching.31-38 Key characteristics of the 17 articles reviewed are summarized in the Table. All studies were primarily descriptive. With one exception,29 the studies used cross-sectional designs. One study32 also incorporated an experimental component: 2 versions of a vignette were developed and randomly assigned to respondents. Only one study25 considered the effect of an intervention (a change in organizational policy on disclosure). This study involved a static group comparison and was classified as preexperimental.

Definitions of medical error varied across studies. Seven of the studies incorporated 1 or more vignettes describing a medical error and associated outcome.23,26,29,32,34,35,37 In these studies, the medical error was defined by the vignette. Alternatively (or, in some cases, additionally), researchers provided explicit definitions of medical error or adverse event22,23,30,32,35 or used terms such as mistake or error in the questionnaire item or stem.24,28 One study36 defined medical error in the article, but did not provide the definition of medical error used with participants. Studies27,31,33,34,38 of patients and relatives seeking advice or legal action presume that the respondent believes that a negligent event occurred, and negligent events are considered a subset of preventable adverse events.20 Finally, for the intervention study,23 the policy under study explicitly referred to medical error.

Several of the studies have significant methodological weaknesses related to response rates and sampling. Of the 13 studies reporting response rates, 6 reported rates less than 50%.22,28-30,33,38 In addition, most studies drew samples from highly constrained populations; only 3 studies randomly sampled from state37 or national22,25 lists. The findings from the reviewed studies are summarized herein, organized by stage of disclosure.

DECIDING TO DISCLOSE

Studies using retrospective self-report by physicians and trainees suggest that disclosure often does not occur. During interviews about how mistakes were handled, trainees mentioned the patient or family in only 6% of the cases.36 When queried about their most significant medical mistake in the last year, 24% of trainees had discussed the error with the patient or family,26 and a similar rate (21%) was found in a later study37 of physicians. A survey of hospital risk managers in the United States found that disclosure of adverse events (preventable and nonpreventable) occurred a mean of 7.4 times per 10,000 admissions; 65% of managers indicated that hospital practice was always to disclose death or serious injury, and 37% indicated that their practice was always to disclose serious short-term harm.35 Reports of patients and relatives also suggest low rates of disclosure. A recent national survey found that, of those who believed that they had experienced an error in their care or in the care of a family member, approximately 30% had been told by the health professional involved that an error had been made.32

When asked to predict whether they would disclose under different circumstances, physicians’ responses are variable. Physician focus group participants described specific situations in which they would not disclose; some indicated that there was no need to disclose if the harm was trivial or if the patient was unaware of the error.23 A study28 that queried European physicians on whether they would disclose an “iatrogenic incident (avoidable mistake)” found that 32% would disclose what happened, while 63% would minimize the incident. In response to vignettes describing medical errors, 95% of physicians and physician trainees predicted that they would disclose a medication error that resulted in injury, while 84% would disclose the same error if it resulted in death.26 In a separate study37 using a different medication error vignette also resulting in death, approximately 50% of physicians indicated that they would admit the error. Hospital risk managers reported that disclosure would be more likely to occur for a medical error leading to a serious adverse event than for an error resulting in a minor adverse event (90% vs 80%).35 In addition, 53% of risk managers reported a lower likelihood of disclosing preventable harm than nonpreventable harm.
Physicians agree that patients should be informed about medical errors. With respect to the iatrogenic incident (avoidable mistake) noted in the previous paragraph, 70% of responding European physicians believed that they should provide details of such an event. In a survey of US physicians, 77% responded that physicians should be required to tell patients when errors are made in their care. The same survey presented respondents with 1 of 2 vignettes. One vignette described a prescribing error resulting in death. In this instance, 90% of physicians believed that the prescribing physician should disclose the error; fewer thought that the nurse involved (70%) or the hospital (71%) should disclose. In response to the same error resulting in a rash but with full recovery, 85% believed that the physician should disclose, while 75% thought that the nurse should disclose and 60% believed that the hospital should disclose.

Studies of patient and family preferences for disclosure have found strong support for disclosure. In focus group discussions, patients were unanimous in their desire to be told about any error that caused harm, although not all would want to know about errors that did not cause harm. A national survey found that 89% of the public believed that physicians should be required to tell patients when errors are made in their care. A smaller study of emergency department patients found that 76% would want to be informed immediately if “something did go wrong in the administration of [their] health care” and 88% favored full disclosure of the error’s extent.

Similar results have been reported with respect to patients’ responses to vignettes. When presented with a

<table>
<thead>
<tr>
<th>Source</th>
<th>Data Collection Method</th>
<th>Subjects (Location)</th>
<th>Sample Size (Response Rate)</th>
<th>Definition of Error or Adverse Event</th>
<th>Stages of Disclosure Findings Are Applicable to</th>
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<tr>
<td>Allman,1998</td>
<td>Questionnaire</td>
<td>Physicians (United States)</td>
<td>39 (18%)</td>
<td>An act or omission for which the house officer felt responsible that had serious or potentially serious consequences for the patient, and that would have been judged wrong by knowledgeable peers.</td>
<td>Decision</td>
</tr>
<tr>
<td>Beckman et al,1994</td>
<td>Review of depositions</td>
<td>Plaintiffs (United States)</td>
<td>45 (NA)</td>
<td>Adverse outcome.</td>
<td>Process, consequences</td>
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<tr>
<td>Blendon et al,2002</td>
<td>Questionnaire</td>
<td>Members of the public and physicians (United States)</td>
<td>1207 (67%); 831 (62%)</td>
<td>“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 these errors are preventable, whereas others may not be.” Also specific vignettes.</td>
<td>Decision, process, process</td>
</tr>
<tr>
<td>Gallagher et al,2003</td>
<td>Focus group</td>
<td>Patients and physicians (United States)</td>
<td>52 (NA); 46 (NA)</td>
<td>Error: “failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.” Adverse event: “injury that was caused by medical management and resulted in measurable disability.” Also specific vignettes.</td>
<td>Decision, process, process</td>
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<tr>
<td>Hickson et al,1992</td>
<td>Questionnaire</td>
<td>Malpractice claimants (United States)</td>
<td>127 (35%)</td>
<td>Care deviated from the community standards of care; deviations caused death or permanent injury. Also specific vignettes.</td>
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<td>Hingorani et al,1999</td>
<td>Questionnaire</td>
<td>Patients and physicians (United Kingdom)</td>
<td>246 (81%); 48 (100%)</td>
<td>Specific vignette.</td>
<td>Decision</td>
</tr>
<tr>
<td>Hobgood et al,2002</td>
<td>Questionnaire</td>
<td>Patients and relatives (United States)</td>
<td>258 (80%)</td>
<td>“If something did go wrong in the administration of your health care”; “medical mistake.”</td>
<td>Decision</td>
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<td>Kraman and Hamm,1999</td>
<td>Claims records</td>
<td>Veterans Affairs medical center (United States)</td>
<td>NA</td>
<td>Malpractice or substantial error resulting in loss of a patient’s function, earning capacity, or life.</td>
<td>Consequences</td>
</tr>
<tr>
<td>Lamb et al,2003</td>
<td>Questionnaire</td>
<td>Hospital risk managers (United States)</td>
<td>245 (51%)</td>
<td>“Unexpected harm that occurs as a result of treatment or care, not directly because of a patient’s illness or underlying condition.” Plus specific vignettes.</td>
<td>Decision, process</td>
</tr>
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(continued)
Eighty-two percent of risk managers reported that hospitals were offering to share the results of the investigation (66%), an acknowledgment of harm (66%). Less frequently reported were investigating the incident (87%), an apology (68%), and an undertaking to repair the process (92%), an undertaking to explain (89%), and an undertaking to compensate (92%).

In response to a national survey, hospital risk managers reported that the most common elements of the disclosure process were explanations (92%), an undertaking to investigate the incident (87%), an apology (68%), and an acknowledgment of harm (66%). Less frequently reported were offering to share the results of the investigation (41%) and assuming responsibility for harm (33%). Eighty-two percent of risk managers reported that hospitals offered to pay the costs of associated care.

In a national survey of physicians and the public, approximately one third (34% of physicians and 33% of the public) of all respondents who had experienced an error in their care or in the care of a family member reported receiving an apology from the health care professional involved. Of patients who believed that they had been injured as a result of their medical treatment, 21% reported that staff accepted responsibility for what had happened, and 27% reported that they had been offered an apology. Somewhat lower rates were reported in a subsequent study of patients and relatives pursuing medical negligence claims, in which 13% reported that the responsibility for the incident was fully or partly accepted and 15% reported a full or partial apology. A review of depositions of malpractice plaintiffs found that failure to provide an explanation was cited as a reason for pursuing legal action in 10% of the depositions.

Explanations did not necessarily result in patient satisfaction. Among patients who believed that they had been injured and were seeking advice, 82% were dissatisfied with the amount of information they received, 67% were dissatisfied with the clarity, and 63% were dissatisfied with the accuracy. In addition, 63% believed that the explanation had been given unsympathetically, and 44% indicated that they had had no opportunity to ask questions. Similar rates were found among patients and family members pursuing medical negligence claims: 61% of those who had received an explanation of the incident reported that the explanation had been given unsympa-
that they had received explanations within a few days of pursuing medical negligence claims, only 21% reported waiting longer than 6 months for an explanation. Of those resulting from medical treatment, 20% reported that they had received explanations within a few days of the incident, and 37% never received an explanation.27

There are few data from physicians on the disclosure process. Physician focus group participants reported that they would be likely to choose their words carefully and to avoid explicitly stating that an error had taken place.23 Most indicated that they would want to apologize, but would worry that an expression of regret might be construed as admission of legal liability. In contrast, patients in focus groups expressed a desire to be told what had happened and why, the implications of the error for their health, how the problem would be corrected, and how future errors would be prevented. Furthermore, they would want the physician to be forthcoming about the error, rather than have to ask a lot of questions to get the information. Patients also wanted assurances that they would not incur financial liabilities because of error. Vignette-based surveys have also assessed patient preferences. When presented with vignettes of error resulting in no harm or moderate harm, more than 70% of patients indicated that they would want to discuss the error with the physician involved; for the serious error vignette, 80% would want to discuss it with another physician.29

Fourteen percent indicated that they would want a referral to another physician if the error did not result in injury; this percentage increased as the injury became more serious, to approximately 40% for a moderate error and approximately 65% for a severe error. Fewer than 10% reported that they would want financial compensation following an error without harm; this increased to approximately 20% following a moderate error and to nearly 60% following a severe error.

CONSEQUENCES OF DISCLOSURE

None of the studies examined herein provided evidence of a causal relationship between the occurrence (or nonoccurrence) of disclosure and litigation, or between specific elements of the disclosure process and litigation. Given that caveat, studies of those taking or considering legal action provide some insight. Of family members involved in malpractice claims alleging perinatal injury, 20% indicated that they were seeking information, and 24% indicated that they sought legal action when they perceived that there had been a cover-up or that the physician had failed to be completely honest, had allowed them to believe things that were not true, or had intentionally misled them; 32% had believed that the physician involved would not talk to them or answer their questions.33 A study31 of malpractice plaintiffs’ depositions identified physician-patient relationship issues in 71% of the depositions. Although it is not clear whether issues with the physicians existed before the adverse outcome, 32% of depositions referred to physician desecration or failure to be available, 26% referred to dysfunctional delivery of information, and 13% referred to failure to solicit or hear patients’ requests for information, opinions, or expressions of discomfort. Of those pursuing medical negligence claims, 91% of respondents reported that desire for an explanation was a reason for their pursuing legal action.38 When asked whether anything could have been done once the incident occurred that would have prevented the need for legal action, 41% responded affirmatively; many suggested explanation and apology (39%). Of patients who believed that they had been injured through medical treatment, lower frequencies of explanations were associated with greater distress and greater difficulty with adjustment.27 These relationships were not attributable to an overall negative attitude toward physicians or pain levels. In addition, although all of the patients in the study had considered litigation, those who had decided to go forward with litigation were more dissatisfied with the explanations that they had received than those who had chosen not to proceed.

Patients’ predictions about their behavior in response to vignettes suggest that disclosure by the physician may result in more positive consequences than learning of the error from another source; patients indicated that they would be more likely to continue to see the physician, less likely to report the physician, and less likely to file a lawsuit if the physician informed them of the error.29 In focus group discussions, patients predicted that disclosure would be reassuring and would enhance their trust in the physician’s honesty.23

In the study25 that examined the effects of an intervention (implementation of a policy of “extreme honesty”), the claims experience of the facility implementing the new policy, a Veterans Affairs (VA) medical center in Lexington, Ky, was compared with 35 other VA facilities without such a policy. The findings suggest that, although the number of claims against the Lexington facility was high (only 5 facilities had more claims), the total amount of payments was low (only 7 facilities reported lower payments).

Ethical and professional guidelines,1-3 credentialing organizations,4 patient safety organizations,5 and experts on medical errors advocate disclosure of medical errors to patients and families,6-19 but there is little empirical evidence to guide practitioners. We found empirical support for concluding that disclosure often does not occur.22,28,30,32,34 that patients and the public favor disclosure,23,24,20,32,34 and that physicians support disclosure,23,28,32 but we found no empirical results to guide practitioners with respect to the practical questions of who, what, when, and how to disclose. Because best process is defined by best outcomes, answers to these questions await an understanding of the relationship between the process and consequences of disclosure. Insufficient empirical data exist to evaluate whether full disclosure results in benefits for patients, providers, and organizations or whether expectations of negative consequences are unfounded. Medical malpractice litigation provides an example of a potential negative consequence. Fear of litigation has been
Studies of patients and families considering or in- ers within that system make it questionable whether simi- tem, the patients served, and the legal status of provid- encouragement, but the unique characteristics of the VA sys- treme honesty policy at the Lexington VA facility are estab- lished. The results of the implementation of the ex- actual errors, and such a link has not yet been estab- lished. Other research findings suggest that the characteristics of the injury, the phy- sician-patient relationship before the adverse event, the physicians’ communication skills, and the patients’ fi- nancial status are influential in litigation decisions. Evaluation of the relative importance of each of these fac- tors and the specific components of disclosure should be a goal for future research. Fear of malpractice litigation is not the only barrier to disclosure; physicians may also anticipate patient distress, patient attrition, damage to their reputation, license revocation, loss of privileges, and other consequences. Future research should seek to determine the extent to which such concerns are in fact barriers and then evaluate methods for minimizing the likelihood of anticipated negative consequences.

Accompanying the need for research on the relation- ship between decision, process, and consequences is the necessity to investigate the circumstantial variables that affect all 3 stages of disclosure. Vincent et al have proposed a framework for understanding and respond- ing to adverse events, suggesting the headings of institutional, organization and management, work environ- ment, team, individual staff member, task, and patient. Other researchers have stressed the importance of the national, regional, and professional culture. We believe that variables in all of these categories are important to disclosure and that further work is needed to develop a coherent framework for investigating the influence of these types of variables on disclosure. Such a framework will facilitate systematic examination of the interrelationships between variables and will help in the development of guidelines for practitioners.

The Institute of Medicine’s report defines an ad- verse event as “an injury caused by medical manage- ment rather than the underlying condition of the pa- tients.” Adverse events attributable to error are considered preventable (although by definition not all medical errors result in adverse events), and negligent adverse events are a subset of preventable adverse events. In practice, there is likely to be considerable uncertainty as to causality and preventability. Trained physi- cians reviewing medical records have displayed poor to moderate agreement on whether an adverse event occurred and whether that occurrence was prevent- able. Although a treating physician may have greater knowledge of the patient’s condition than a reviewer working from the medical record, determination of causality and preventability may be as difficult or more so. In prac- tice, such uncertainty complicates the disclosure deci- sion. Premature disclosure may cause unnecessary dis- tress, but waiting for an investigation to be completed may increase patient anger and frustration, especially when causality is obscure to the patient and family.

Difficulties in defining and identifying medical errors in practice are paralleled by the different definitions of medical errors used in the studies reviewed herein. Each definition or lack of definition of medical error in a questionnaire or interview study must be considered in interpreting results. If the term medical error is not def- ined, inferences about group differences may not be valid. For instance, some patients include rudeness or poor service quality as medical errors, events that most physi- cians would not include. The use of clear, explicit defi- nitions should increase the likelihood that all respondents are referring to the same class of events. Case vignettes ensure that all respondents are referring to the same event and eliminate the need for the respondent to decide whether an error has occurred. However, the case de- tails will influence responses, so that conclusions based on a specific vignette are not necessarily generalizable, and inferences about attitudes or behaviors regarding disclosure in general may not be justified. Future research should attempt to identify which components of case vignettes influence responses, not only to facilitate cross- study comparisons but also to better understand and pre- dict responses to disclosure of actual errors.

One important limitation to the research consid- ered herein is that most of the studies reported partici- pants’ recollections of behaviors or events or predic- tions about future behaviors. The conclusions of such studies are predicated on the assumption that reports or predictions are related to participants’ behavior in circum- stances of actual errors, but we found no tests of this assumption. Researchers should examine the extent to which errors in recall or prediction occur, as well as whether the study setting introduces a bias. Patients and physicians are likely to have strong emotions and be- liefs about disclosure of medical errors and are likely to be sensitive to the explicit or implicit social context of data collection. Respondents are likely to filter their re- sponses to meet social norms, especially in the context of focus groups or nonanonymous interviews or ques- tionnaires. For physicians, knowledge of ethical stand- ards may result in reporting more “correct” behavior; for patients, especially those involved in legal action, ex- pectations and beliefs about the legal process may influ- ence reporting. Future research should examine the accuracy of self-reports and predictions in this area.

Many of the studies reviewed herein drew from small, circumscribed populations, and many reported poor re- sponse rates; both issues need to be addressed in future research. When the study population is limited (eg, drawn from a single medical center, geographic region, medi-
cal specialty, or organization), results may not be generalizable to other populations. Similarly, self-selection and nonresponse biases limit generalizability; these effects are likely to be most problematic when response rates are low.

Although traditional randomized controlled trials are not feasible or ethically appropriate for studying disclosure of medical error, this review found an overreliance on cross-sectional designs and direct self-report measures. We suggest 2 avenues for future research. First, the use of vignette-based studies in experimental designs provides a means of efficiently and systematically examining multiple variables and allows manipulation of these variables in ways that would be unethical in the clinical setting. This approach will be especially useful for identifying a smaller set of variables for further study. Greater realism can be introduced through videotaped simulations (rather than written vignettes), although the link between behavior in the hypothetical situation and real life must be addressed, as noted herein. The second avenue that researchers should be alert to is the potential for capitalizing on naturally occurring changes in health care organizations. As organizations institute new policies on disclosure of error, opportunities for conducting “natural experiments” may occur. The report on the experience of the Lexington VA facility describes one such effort, but there is a need for additional rigorous evaluations in different settings. Studies conducted at the organizational level, with organizations rather than individual patients assigned to intervention conditions, may also avoid some of the ethical and practical difficulties inherent in research in this area.

The prevalence of discussion papers, commentaries, and editorials on disclosure of errors to patients is evidence of the importance of the topic of disclosure for clinicians; the dearth of empirical research is a barrier to improvements in practice. Without empirical data to provide guidance on how to disclose well and without a better understanding of the relationship between the disclosure process and the consequences of disclosure, clinicians can only guess at what is most effective in this difficult situation. This lack of knowledge may lead to suboptimal outcomes for the patient and the physician and thereby discourage disclosure in future cases. With respect to the decision stage of disclosure, future research should examine what influences this decision, focusing on barriers and how these might be reduced. With respect to process, researchers should seek to develop answers to the many practical questions faced by practitioners, such as who should disclose, what information should be provided, and when disclosure should occur. Answers to these questions will require a greater knowledge of the consequences of disclosure and how specific process components affect the consequences. Finally, future research must consider the many levels of variables that may influence all stages of disclosure, from the cultural context at the national level to the characteristics of the individual patient and physician.

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