

## DISCLOSURE OF ADVERSE EVENTS: ANNOTATED BIBLIOGRAPHY

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Compiled by Judy Johnson, JD

### I. Background and Incidence of Medical Error

Altman DE, Clancy C, Blendon RJ. Improving patient safety—five years after the IOM report. *N Engl J Med* 2004;351(20):2041-3.

*In this brief update, the authors summarize early reactions to the 1999 Institute of Medicine Report entitled “To Err is Human,” and note some of the advances that have been made since then toward safer health care. However, they conclude that further progress requires changing the health care culture to one that encourages sharing information about error. Absent such a change, the authors predict continued lack of confidence in the safety of the health care system.*

Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Institute of Medicine. Washington D.C.: National Academy Press, 1999.

*This landmark report provided the impetus for the growth of the patient safety movement of the 21<sup>st</sup> Century. It reports evidence on the frequency and cost of medical error which, while contested as to the actual figures, was widely-accepted in substance. The Report examines the nature of error and concludes that much error in medicine is systems-based and must be addressed on a system-wide basis. The Report promotes error reporting and protection of information voluntarily reported. It offers numerous specific recommendations for creating safer systems in health care.*

Committee on Quality of Health Care in American. *Crossing the quality chasm: a new health system for the 21<sup>st</sup> century*. Institute of Medicine. Washington D.C.: National Academy Press, 2001.

*This Report, which follows the Institute’s ground-breaking “To Err is Human,” provides a comprehensive overview of how the health care system can fundamentally be redesigned to improve quality of care. After examining the reasons for inadequate quality of care (Chapter 1), the Report recommends changes for the 21<sup>st</sup> century, including the adoption of 6 aims for improvement (Chapter 2); proposes 10 general rules or guidelines for the transition (Chapter 3); addresses priorities and first steps (Chapter 4); recommends building organizational supports for change (Chapter 5), using evidence based medicine (Chapter 6) and information technology (Chapter 7), aligning payment policies with improvements in care (Chapter 8), and preparing the workforce (Chapter 9). Appendices include a review of articles on quality of health care since 1987.*

Leonard M, et al., eds. *Achieving Safe and Reliable Healthcare*. Chicago: Health Administration Press, 2004.

*This collection focuses on what constitutes a safe environment – or a “highly reliable organization” (“HRO”). Sections of the text deal with: (1) the components of a safe*

*environment, (2) establishing a culture of safety, and (3) putting theory into practice. It includes a chapter addressing disclosure of error as an essential component of a safe culture.*

Reason J. Human error. Cambridge: Cambridge University Press, 1990.

*Reason's classic text on human error has three major subdivisions: an introduction to the concepts and research regarding human error; a presentation of basic error mechanisms (including error types and error forms); and a review of the consequences of human error (including error detection, accident contribution and remedial measures). Reason's detailed study of human error and its consequences in complex systems informs much of the later work on medical error.*

Sharpe VA, ed. Accountability: patient safety and policy reform. Hastings Center Studies in Ethics. Washington D.C.: Georgetown University Press, 2004.

*This collection is the result of a 2 year project conducted by the Hastings Institute, which convened an interdisciplinary group (including patients, clinicians, ethicists, other health care leaders, and safety experts from other fields) to address patient safety and reform. Sharpe's introduction describes the impetus for and findings and recommendations of the 1999 IOM Report, as well as some of the ethical principles underlying these recommendations. She notes that the shift from focusing on individual responsibility to emphasizing the role of systems in human error requires corresponding changes in an understanding of how errors occur, how they can be prevented, when and to whom errors should be reported or disclosed, who should be held accountable, and how compensation for harm can best be handled. The remaining essays in the collection include accounts of patient and family experiences of medical error as well as discussions of the roles of professional and organizational cultures, ethical and religious theories/beliefs (such as justice and forgiveness) and approaches to compensation for harm, such as malpractice, mediation, and no fault liability.*

Spath PL, ed. Error reduction in health care: A systems approach to improving patient safety. Chicago: AHA Press/Jossey-Bass Publications, 2000.

*Spath has gathered together a collection of articles that combine theories, illustrations, and suggestions regarding reduction of error in health care. In a forward to the collection, Lucien Leape highlights the complex causes of error in health care, and posits that reducing error depends on a significant change in how such errors are conceptualized and addressed. The various chapters in the collection offer different ways of understanding and responding to medical error. The topics include systems analysis; human factors engineering; cognitive psychology and its insights into error; the human side of human-system "misfits;" accident investigation and analysis, proactive error-reduction; and performance measurement.*

## **II. Disclosure**

Banja J. Persisting problems in disclosing medical error. *Harvard Health Policy Review* 2004;5(1):14-20.

*Banja notes that by 2004, disclosure of medical error had become more common than in the past. However, research reveals that many errors remain undisclosed and, even when physicians do disclose, they may not acknowledge error or accept responsibility. No guidelines are available to help professionals in the disclosure process. Banja points out persistent problems with the disclosure process. One is uncertainty over whether to admit mistake, which is fueled in part by fear of voiding malpractice insurance. Another is perceived inability to determine conclusively whether an error actually caused the patient's adverse outcome. These problems relate primarily to fears of increasing malpractice liability -- a problem that, Banja suggests, should be amenable to empirical research. At that time, Banja reports, the few studies available suggest that error concealment might result in greater liability than disclosure would. Even if research ultimately shows otherwise, Banja believes that the ethical mandates flowing from the fiduciary nature of the physician-patient relationship should prevail over cost. Another problem he notes is the lack of a shared, satisfactory definition of "error." While no completely satisfying definition may exist, Banja advises linking "error" to failure to meet a standard of reasonable care. Assuming such a standard exists and can reasonably be known to the physician, then failure to meet the standard would constitute "error."*

Banja J. *Medical errors and medical narcissism*. Sudbury: Jones and Bartlett Pub., 2005.

*In this work, Banja focuses on responses of health care professionals/organizations to error, and the degree of -- and reasons for -- non-disclosure. While Banja acknowledges that fear of litigation has contributed to non-disclosure, he also introduces, as another factor, a type of narcissism that may be fostered by medical training and practice. Using a case study, Banja notes certain reactions that may characterize the health professional's experience of error: shock, concern, rationalization, avoidance and minimization (SCRAM). In his chapter on "Forgiveness," Banja explores the psychological and moral characteristics of forgiveness and its place in the aftermath of a harmful error (meaning, in Banja's view, those rare occasions in which harm is caused by practice that does not meet the standard of care). He also suggests three kinds of support that would contribute to a change in practice regarding disclosure: a structured teaching curriculum (including role-modeling); the bolstering of the moral environment within which clinicians practice; and tort reform. Finally, he examines the nature and role of empathy in professional-patient interactions, giving examples of empathic techniques and responses. He provides suggestions for, and examples of, the content and process of disclosure.*

Baylis F. Errors in medicine: nurturing truthfulness. *J Clin Ethics* 1997;8(4):336-40.

*In one of several articles on medical error published in this volume of JCE (prior to the IOM report), Baylis examines and responds to commonly expressed justifications for not*

*disclosing (or only partially disclosing) medical error. First, physicians face uncertainty about whether an error has occurred. This problem cannot be eliminated, but the complexity and subjectivity of determining “error” can be acknowledged. Second, physicians express the belief that disclosure is not useful, but only increases patients’ suffering. This belief, however, may stem in whole or part from self-interest. The third reason is fear of litigation; however, such fear is overstated, given the research available at the time. According to Baylis, an even more encompassing reason can be found in the culture of medicine: health care institutions, colleagues, and liability insurers accept (and may even encourage) non disclosure. Disclosing medical error to patients may seem to be a superogatory act, rather than an ethical obligation (as Baylis believes it is). Baylis recommends that the profession encourage disclosure by developing a more open, supportive environment among clinicians; emphasizing truthfulness as the foundation of the patient-physician relationship; working to support appropriate tort reform; and acknowledging that medical professionals (like other humans) are fallible. To Baylis, truth-telling should a characteristic of all physicians, not just those with unusual courage.*

Berlinger N. *After Harm: Medical error and the ethics of forgiveness.* Johns Hopkins University Press, 2005.

*Berlinger’s work examines the emotional and psychological aftermaths of medical harm using concepts derived from religious tradition, in particular, “confession” (disclosure), repentance and forgiveness. (The author offers evidence that such concepts have become part of our secular culture.) Eschewing a detailed examination of the various definitions of “medical error,” Berlinger talks about “mistakes” that lead to harm to a patient or patient’s family. Her focus is on how the patient (family) and physician experience the medical harm and on the subsequent steps that occur, from disclosure to apology to repentance and forgiveness. This book draws on major works in narrative ethics, Christian ethics, feminist ethics, legal scholarship, philosophy and sociology. Building on her theoretical analysis, the author presents, in the final chapter, concrete recommendations for acting ethically in the face of medical error.*

Bonacum D, et al. *Communicating about episodes of harm to patients.* In: Leonard M, et al. *Achieving Safe and Reliable Healthcare.* Chicago: Health Administration Press, 2004.

*This chapter in the collection edited by Leonard et al. focuses on the role of disclosure in a safe environment or “highly reliable organization” (“HRO”). The authors point out the benefits of disclosure to patients, providers, and the health care system as a whole. They note that three components have been shown by numerous studies to be important for effective disclosure: honest and straightforward explanation; acknowledgement of suffering (sympathy, empathy and, if appropriate, apology); and assurance that the adverse event will not recur. The article supports local, institutional efforts to develop disclosure policies, which represent a step in creating an HRO; describes elements of such a policy; and supports education and training for disclosure.*

Boyle D, O'Connell D, Platt FW, Albert RK. Disclosing errors and adverse events in the intensive care unit. *Crit Care Med* 2006;34(5):1532-37.

*This review article summarizes key studies showing the incidence of errors, particularly in the ICU; physicians' attitudes and practices regarding disclosure of errors; patients' desires regarding disclosure; definitions of "error;" the benefits of disclosure; and barriers to disclosure. The authors propose a definition of "harm" and recommend that disclosures be limited to situations in which harm has occurred and in which professional standards would indicate that the treatment decision or action was incorrect (with "near misses" being reviewed for quality improvement purposes only). In the authors' views, disclosure of errors in the ICU, using a coordinated response, is necessary to protect the integrity of the patient-physician relationship and to support a culture focused on patient safety. Citing supporting literature, the authors make specific recommendations about how to disclose error, and provide an example of a disclosure conversation. .*

Chan DK, Gallagher TH, Reznick R, Levinson W. How surgeons disclose medical errors to patients: a study using standardized patients. *Surgery* 2005;138(5):851-8.

*Recognizing the pressure for medical error disclosure, and the evidence that such disclosure is erratic, the authors performed what they believe to be the first study of how surgeons disclose medical error. Thirty surgeons were randomly assigned to meet with experienced standardized patients (either face to face or by videoconference) to discuss 2 of 3 hypothetical errors. The surgeons' performance was rated by an error disclosure scale developed by the authors based on their previous work and on a literature review. Reflecting the results of prior research, the scale contains 5 elements: (1) explanation of medical facts, (2) honesty, (3) empathy, (4) reference to prevention of future error, and (5) general communication skills. Scores varied widely: out of a possible score of 50, 23% of the surgeons performed at 40 or above and 23% performed below 32. The surgeons scored highest on explaining the medical facts, and second highest in honesty. They scored lower in empathy and discussion of prevention of future error. Based on the results of the study, which added evidence of the gap between patients' preferences and actual disclosure communications, the authors advocate the development of evidence-based disclosure guidelines and disclosure training.*

Gallagher TH. Medical errors in the outpatient setting: ethics in practice. *J Clin Ethics* 2002;13(4):291-300.

*Gallagher uses an example of a medical error to introduce basic terms, concepts, and ethical principles relevant to disclosure of medical error and the patient safety movement. He then specifically addresses medical errors in the outpatient setting, including ways to reduce error; barriers to disclosure of error; the essential elements of disclosure; and criteria for evaluating whether to disclose the error of another physician.*

Gallagher TH, Studdert D, Levinson W. Disclosing harmful medical errors to patients. *N Engl J Med* 2007; 356(26):2713-19.

*This article provides an update and overview of the practice of disclosure of medical error to patients. It offers a succinct summary of the prevalence of medical error; the history and current status of the practice of disclosure; regulatory responses in the U.S. as well as in several other countries; guidance from accrediting agencies (with special attention to the NQF safe practices guidelines); legal issues and developments; and important on-going disclosure programs. The authors note that additional research is needed in a number of areas (including patient preferences, training interventions for providers, and the medical and legal consequences of disclosure) and that until more research results are available, disclosure standards will probably remain advisory. Nonetheless, the authors predict that disclosure programs will continue to expand, and within a decade, disclosure will be the norm.*

Gallagher TH, Levinson W. Disclosing harmful medical errors to patients: a time for professional action. *Arch Intern Med* 2005;165(16):1819-24.

*This commentary proposes specific, positive steps that can be taken by those within the health care profession to increase disclosure of medical error. Gallaher and Levinson set the stage by summarizing evidence that patients desire disclosure that meets certain basic criteria, and that patient care could benefit from making full disclosure an integral part of the patient safety movement. However, they note that evidence shows that physicians are concerned that disclosure may lead to liability (and other sanctions); that institutions send “mixed messages” about disclosure; and that physicians lack training in how and what to disclose. Given the desired end and the barriers to getting there, the authors suggest the following steps. First, the relationship between error disclosure and malpractice needs to be clarified. While not downplaying the risks and costs of litigation for clinicians, the authors cite research showing that: (1) physicians overestimate the likelihood of litigation, and (2) disclosure is likely to reduce litigation and awards. While not sanguine about other tort reform efforts, the authors encourage medical groups to urge passage of “apology laws” based on the Colorado model and elimination of language in malpractice policies that tends to inhibit disclosure. Second, the profession should begin to develop evidence-based guidelines for disclosure based on existing knowledge. Educational programs in disclosure, including communication skills, should be designed and implemented. Third, based on their professional commitment to safety, physicians should work to make disclosure to patients an integral part of the patient safety movement (not simply a “defensive strategy”). Institutions can take additional steps such as strengthening error disclosure policies and providing disclosure assistance and support to clinicians. Certifying bodies, boards, and medical societies can also take steps to help support the disclosure process.*

Gawande, Atul. *Better: a surgeon’s notes on performance*. Metropolitan/Henry Holt & Co., 2007.

*In this book, Gawande examines the task of improving medical care given the complexity of the health care system; the complexity of medical care itself; and the fallibility of the humans delivering such care. Using detailed examples, Gawande shows both the consequences of medical error and also the possibilities for improving care. In particular, he identifies three factors that contribute to improved performance: diligence, “doing right,” and ingenuity. When medical errors do occur, physicians have the ethical obligation, according to Gawande, to disclose the error to patients. However, Gawande also addresses systems’ problems and the counterincentives of the current malpractice liability system, which he believes should be reformed to operate more fairly in response to medical negligence.*

Herbert PC, Levin AV, Robertson, G. Bioethics for clinicians: 23. Disclosure of medical error. CMAJ 2007;164(4):509-13.

*This chapter provides a brief introduction to the incidence of medical error and the attitudes of patients and physicians about disclosure. It makes strong ethical arguments in favor of disclosing medical errors to patients and families. While acknowledging the concern that disclosure may increase liability, the authors note that under Canadian law, a physician may have a duty to disclose errors to patients. The chapter offers several suggestions for practicing physicians in regard to disclosing medical error.*

Kuzel AJ, Woolf SH, Gilchrist VJ, et al. Patient reports of preventable problems and harms in primary health care. Ann Fam Med 2004;2(4):333-340.

*The authors report on a study involving interviews of patients treated in ambulatory primary care practices. Based on the interviews, the authors construct a taxonomy of patient-reported error. This taxonomy contains five domains: breakdown in access to care; breakdown in communications; breakdown in relationships; technical errors and inefficiency.*

Lazare A. On apology. Oxford: Oxford University Press, 2004.

*This text examines the meaning, nature and uses of public and private apology through the lenses of religion, psychology, political/historical experiences, and everyday life. The author presents and analyzes examples from various arenas, including medicine. This work provides insights into the relational nature of apology; the needs of the person to whom the apology is being made; the characteristics of a “successful” (accepted, healing) apology (vs. a “pseudo” apology); and the barriers to making an apology. While noting that every situation involving an apology is unique, the author also identifies basic characteristics of a sincere apology: the acknowledgment of responsibility; explanation; regret/remorse; intent not to repeat the mistake; and some form of reparation.*

Levinson W, Gallagher TH. Disclosing medical errors to patients: a status report in 2007. CMAJ 2007;177(3):265-7.

*This commentary summarizes the apparent consensus about why errors should be disclosed and what patients want to know after medical error. It cites research showing the continuing gap between patients' desires and actual practice. The short legal summary (focusing on Canadian law) notes the continuing uncertainty about the relationship between disclosure and liability. According to the authors, what is now necessary is institutional support for and provider training in disclosure. They anticipate that in the near future, disclosure of error will become part of routine care.*

Marx, D. Patient safety and the 'just culture': a primer for health care executives (MERS-Transfusion Medicine). Prepared by David Marx, JD, for Columbia University under a grant provided by the National Heart, Lung, and Blood Institute, 2001.

*This primer is designed to help leadership in a health care organization understand the problems inherent in common disciplinary systems and design more effective ones. Its premise is that improvements in patient safety depend on the ability to learn from mistakes, which in turn requires that mistakes be reported. According to the author, a disciplinary system that routinely punishes someone who makes a mistake is unlikely to foster such reporting. The challenge is to design a disciplinary system that is likely to increase patient safety by positively reinforcing safe behavior and encouraging employees to acknowledge and report their mistakes. At the same time, the system needs to be able to deter and/or punish intentional or reckless conduct that creates unacceptable risks to patient safety. The primer includes definitions and illustrations of types of error and examples of actual disciplinary policies.*

Mazor KM, Simon SR, Gurwitz JH. Communicating with patients about medical errors: a review of the literature. *Arch Intern Med* 2004;164(15):1690-97.

*In this review of literature published in 2004, the authors identified 17 articles that reported results of key empirical studies on disclosure of preventable medical errors to patients/families (out of a total of 833 works). Based on their review, the authors posit 3 stages of disclosure: the decision to disclose; the process of disclosure; and the consequences of disclosure. The studies they review on the disclosure decision show that a large majority of patients want to be told about medical error. Physicians, as well, generally support disclosure, particularly when harm occurs. However, in responding to specific scenarios and questions, physicians report a fairly high percentage of cases in which they would not disclose. The authors report many fewer studies on the process of disclosure and even fewer on the consequences, making it hard to generalize on these two topics. This article points out the results, methods, strengths and weakness of the studies available at that time, and suggests studies that might produce useful results in the future.*

Monograph Task Force, American Society for Healthcare Risk Management. Disclosure of unanticipated events: the next step in better communications with patients (first of 3 parts). May 2003. Accessed on June 12, 2008 at [www.ashrm.org/ashrm/resources/monograph.html](http://www.ashrm.org/ashrm/resources/monograph.html).



*This monograph offers a brief historical perspective on disclosure, highlighting the development of Patient Safety Standards by the Joint Commission on the Accreditation of Healthcare Organizations (including standard R1.1.1.2), which require that patients be informed of adverse outcomes of care. While acknowledging that the standards do not provide detailed guidance for disclosure, the monograph stresses that providers should be less concerned about the exact parameters of what “must” be disclosed and more concerned about creating an environment of open communication designed to foster patient safety. The monograph identifies key psychological and legal barriers to disclosure. It also presents several models for managing disclosure, along with examples of specific disclosure situations.*

Rubin SB, Zoloth L, eds. *Margin of error: the ethics of mistakes in the practice of medicine.* Hagerstown, Md.: University Publishing Group, 2000.

*Rubin and Zoloth have edited a rich collection of essays by leaders in the field of medical ethics. Articles in the first section of the collection focus on conceptual aspects of medical error; those in the second section discuss errors in the practice of medicine; and those in the third section explore error in the context of ethics consultation.*

Surbone A, Rowe M, Gallagher TH. Confronting medical errors in oncology and disclosing them to cancer patients. *J Clin Oncol* 2007;25:1463-7.

*The premise of this article is that disclosure of medical error is required – based not only on ethical mandates but also on the needs of the patient safety movement, which relies on a culture of transparency. Nonetheless, many errors are not disclosed, and uncertainties about disclosure remain (such as which events should be disclosed, how they should be disclosed, and how disclosure may affect patient satisfaction and the possibility of litigation). The authors discuss these uncertainties in light of oncology care, which they characterize as involving complex treatments, significant risks, multidisciplinary teams, and the prevalence of clinical trials. In addressing the issue of what to disclose, the authors cite those elements recommended by the Harvard Working Group: what happened, and how and why it happened. They also point to the Harvard Group’s recommendation that clinicians take responsibility and, if an error occurred, offer an apology and information as to what steps will be taken to prevent recurrence. They find further guidance in the National Quality Forum’s safe practice on disclosure. While emphasizing the patient-centered nature of disclosure, the authors recognize the impact of error on clinicians, and the need to work through moral issues of restitution and forgiveness, for which young physicians may need help and training.*

Smith ML, Forster HP. Morally managing medical mistakes. *Cam Quarterly of Healthcare Ethics* 2000;9:36-53.

*The authors explore key questions surrounding medical error: what is an error; why do they occur; what happens to professionals and patients when they do; should they be disclosed; if so, why and to whom. They describe the context in which errors occur, including the medical culture of perfectionism, the tensions within the physician-patient*

*relationship, and the medical malpractice system. They also identify the “costs” to patients/families and professionals of such errors. Applying ethical theory (including rights-based and duty-based theories; virtue ethics; and consequentialism), they conclude that disclosure should become standard practice (with limited exceptions). They note that medicine can learn from other industries that have tackled the problem of human error. Finally, the authors propose action items for improving the handling of medical error, including: training for medical and allied health students; continuing education programs for professionals; emphasis on quality improvement strategies; establishment of institutional policies and guidelines; revision of professional codes of ethics; incorporation of error disclosure into the concept of informed consent; modification of malpractice policies and strategies; and tort reform.*

Sweet MP, Bernat JL. A study of the ethical duty of physicians to disclose errors. *J Clin Ethics* 1997; 8(4): 341-8.

*In one of several articles on medical error published in this volume of JCE, the authors present results of a survey of medical students, house officers and attendings at Dartmouth (106 completed surveys). The survey asked respondents whether, in 3 hypothetical situations, they would report an error to the patient, and what factors would influence their decision. When the error resulted in harm that was limited in time, 95% stated they would admit the error, primarily because of their personal moral belief that physicians should be truthful to their patients and that patients have a right to know about their medical condition. Ninety six percent said they would apologize to the patient. If the error resulted in death, the number fell to 79%, with the same primary reason offered for disclosure. Those who would not volunteer information to the patient cited as the most important reason the pain that the family would feel. Secondary reasons were: fear of liability and loss of respect of colleagues and family. Three respondents indicated they would deceive the family, primarily because disclosure would cause the family more distress. The number reporting they would disclose an error fell even more when the error (which resulted in paraplegia) was committed by a colleague, with 18% indicating they would tell the patient about the error of the referring physician, and 25% indicating they would mention the possibility that misdiagnosis led to the patient’s injury. Reasons for non disclosure included lack of relevant data and expertise. The authors note the high percentages in their study of those who would disclose, and raise the question of whether the percentages would be as high in actual practice.*

Winslade W, McKinney EB. The ethical health lawyer. To tell or not to tell: disclosing medical error. *Nanotechnology* 2006:813-16.

*These authors, countering a simplistic view of the obligations of an attorney to a provider-client who has made a medical error, argue that health care attorneys should advise their clients to tell the truth to patients (and colleagues). Arguments put forth in favor of this position include: the patient’s right to know; the provider’s medical-ethical duty to his/her patient; the provider’s obligation to colleagues affected by the error; the possibility that disclosure will enhance patient safety; and the existence of evidence that honesty enhances a provider’s relationship with the patient. These attorneys would go further and advise the client to accept responsibility, apologize, and extend empathy and*

*support to the patient/family. The authors counter objections to this position, including the argument that attorneys should simply advocate for their clients' interests, by pointing out that failing to advise a provider about his/her professional obligation is not serving the provider's interest. Further, disclosure does not necessarily weaken the defense strategy, but may place the provider in a better position to negotiate a fair resolution. To counsel deception also violates the attorney's professional obligations. While acknowledging the argument that disclosure may encourage litigation, the authors believe that the evidence that disclosure may reduce suits and/or the size of awards is strong. However, even if the data ultimately shows an increase in malpractice costs caused by disclosure, economic considerations may be outweighed by professional obligations. To assist attorneys in interactions with their clients, the authors present a sample dialogue.*

Wojcieszak D, Saxon JW, Finkelstein, MM. SorryWorks! Disclosure, apology, and relationships prevent medical malpractice claims. Bloomington, IN: AuthorHouse, 2007.

*The authors of this book are active in the movement to encourage expressions of empathy in the aftermath of medical error. Their organization is called the Sorry Works! Coalition (see [www.sorryworks.net](http://www.sorryworks.net), accessed on June 18, 2008). This text includes chapters on how to implement a Sorry Works! Program, how and why such a program works, and how to apologize. The authors distinguish between an expression of sorrow and an apology. (One of their goals is to clarify and standardize the meaning of a number of key terms, including: "apology," "error," "adverse event," and "complication.") Communications after an adverse event should almost always include an expression of empathy – "I'm sorry". An acceptance of responsibility and an apology are appropriate in a small proportion of these cases. An actual apology is appropriate and required, according to Wojcieszak et al., when due diligence reveals that an error has occurred.*

Wu AW, Cavanaugh TA, McPhee SJ, Lo B, Micco GP. To tell the truth: ethical and practical issues in disclosing medical mistakes to patients. *J Gen Intern Med* 1997;12(12):770-5.

*In this article, written prior to the IOM report, Wu and his colleagues note that medical errors are "common," but physician disclosure of such errors is not. They conclude that such disclosure is ethically obligatory if the error is made by the physician (and is not a systems error) and causes significant harm that is likely to be remediable, mitigable, or compensable. They base their argument on two ethical theories: consequentialism and deontology. Wu et al. examine both beneficial and non beneficial consequences of disclosure for patient and physician (noting that the consequences to the patient are the more important, and generally call for disclosure). They conclude that the fiduciary nature of the physician-patient relationship and the principles of biomedical ethics (beneficence, non maleficence, autonomy and justice) require that a physician disclose error if disclosure furthers the patient's health and autonomy and enables the patient to be compensated in some way for serious, irreparable harm. The authors offer suggestions on practical issues, such as how to decide whether a mistake should be*

*disclosed; who should disclose; and when. The authors suggest that the conversation with the patient include a statement by the physician that he/she made an error; an explanation of the course of events ( including the nature of the mistake and consequences); information as to corrective action taken; an expression of personal regret; an apology; and mitigation of financial costs, as appropriate. The authors recognize and respond to the pragmatic reasons why physicians might not want to disclose, and encourage the development of guidelines for disclosure, support for physicians, and system changes.*

### **III. Disclosure and Professional Guidelines**

American College of Obstetricians and Gynecologists. Committee Opinion No. 380: Disclosure and discussion of adverse events. *Obstet & Gynecol.* 2007;110(4):957-8.

*The ACOG committee opinion notes that physicians have an ethical obligation to communicate honestly with patients. Studies show that patients want disclosure of adverse events, including acknowledgement of responsibility, facts about the event and what is being done to prevent recurrence, and expressions of sympathy. While there are barriers to such communications, ACOG supports disclosure and discussion of unanticipated adverse events with patients, which should include expressions of sympathy and, in some cases, an apology. The opinion suggests that physicians may want to seek advice from risk managers and their insurance carrier, and obtain information about state laws to assist them in disclosure discussions. It also notes that health institutions should have written policies addressing timing, content, communication and documentation of disclosure; and should consider the need for training and disclosure coaching and staff support.*

American College of Physicians-American Society of Internal Medicine. Ethics Manual. 5th ed. Accessed on June 13, 2008 at [http://www.acponline.org/running\\_practice/ethics/manual/ethicman5th.htm#phys](http://www.acponline.org/running_practice/ethics/manual/ethicman5th.htm#phys)

*This ethics manual includes the statement that “[P]hysicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.”*

American Medical Association. Current Opinions of the Council on Ethical and Judicial Affairs: E-8.12. Accessed June 13, 2008 at [www.ama-assn.org/ama/pub/category/4325.html](http://www.ama-assn.org/ama/pub/category/4325.html)

*According to this standard, physicians are ethically required to deal honestly and openly with patients. In situations in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment, the physician must inform the patient of all facts necessary to ensure understanding of what occurred. Concerns about legal liability resulting from a truthful disclosure should not affect the physician's honest communication with the patient.*

#### **IV. Disclosure, Risk Management and Liability**

Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint, S. Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Joint Comm J Qual Saf* 2003; 29(11):503-11.

*The authors of this article performed an extensive review of published medical and legal literature to determine whether the data supports or refutes the arguments regarding the effect of disclosure on malpractice risk and liability. They found one published study directly examining the incidence and amount of claims after implementation of a policy of disclosure (at the VA Medical Center in Lexington, Kentucky). While this study revealed that malpractice liability decreased, the authors conclude that the results are hard to generalize given the unique nature of a federal hospital system. The authors found a number of studies examining why patients/families sue, including those that suggest that one factor is perceived lack of honesty on the part of providers. Citing a number of articles, the authors conclude that disclosure is supported by ethical, safety, and justice concerns. However, despite extensive literature on disclosure, there is little data showing the effect of disclosure on malpractice risk. According to the authors, because fear of liability has been identified as an important barrier to disclosure, further study is necessary to determine whether or not disclosure increases malpractice risk; if it does, new approaches are necessary to counter such risks.*

Monograph Task Force, American Society for Healthcare Risk Management. Perspective on disclosure of unanticipated outcomes information (2001). Accessed on June 16, 2008 at <http://www.ashrm.org/ashrm/resources/monograph.html>

*This is one of ASHRM's earlier papers on this topic, prepared in anticipation of the implementation of the JCAHO Patient Safety Standard requiring that patients and/or families be informed about outcomes of care, including unanticipated outcomes. The paper addresses a number of factors to be considered in developing policies and/or procedures for managing such disclosures. These include legal concerns, such as whether disclosure could be construed as an admission of liability; ethical concerns, such as whether disclosure might in some cases be adverse to a patient's interests; the possible effects of disclosure on the caregiver, such as corrective action or internal or external reporting; managing multiple reviews (internal and external) with consistency; identifying the appropriate person(s) to be involved in discussions with the patient/family; and appropriate documentation. The paper includes recommendations for supporting the patient and family and involved caregivers. It contains a check-list of possible elements in a policy or procedure, and examples of unanticipated outcome policies.*

Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang C. Disclosure of medical injury to patients: an improbable risk management strategy. *Health Aff (Millwood)* 2007; 26(1):215-26.

*The authors of this article hypothesize that disclosure of medical error will not reduce malpractice claims as has been suggested in other works; instead, any reduction achieved through a policy of disclosure will be countered or negated by the increase prompted by such disclosure. They test this hypothesis by performing Monte Carlo simulations on a model based on existing epidemiological data regarding medical injuries and malpractice claims, plus expert opinion regarding likely patient response to disclosure. Analyzing the results, the authors conclude that while disclosure is the right thing to do, it is highly likely to result in an increase in amount and cost of litigation, rather than a decrease. While additional empirical data is necessary to further test the hypothesis, the results of the study challenge the assumption that disclosure can be justified by reduction in malpractice claims and costs.*

## **V. Disclosure and Views of Patients and Providers**

Blendon RJ, DesRoches CM, Brodie, M et al. Views of practicing physicians and the public on medical errors. *N Engl J Med* 2002; 347(24):1933-40.

*This article, appearing a few years after the 1999 IOM study, reports the results of parallel national surveys of practicing physicians (831) and members of the public (1207) about the incidence, causes, and appropriate responses to medical error. While 35% of physicians and 42% of the public reported personal experience with error, neither group estimated that the incidence of error was as high as that estimated in the IOM study. Neither group identified medical error as one of the most important problems in health care. Important areas of divergence between the groups included the belief that suspension of professional license would be effective in reducing medical error (3% of physicians vs. 50% of the public); and belief that reporting to a state agency would be effective (23% of physicians vs. 71% of the public). Very generally, the public appeared to emphasize individual responsibility of practitioners and the use of consequences such as fines, suspensions and law suits to reduce error. A majority of physicians also saw individuals as more likely to be responsible for medical errors than institutions but did not share the public's view of appropriate consequences.*

Burroughs TE, Waterman AD, Gallagher TH et al. Patients' concerns about medical errors during hospitalization. *J Qual Patient Safety* 2007;33(1):5-14.

*Based on focus groups and interviews, the authors designed a survey to elicit information about how patients define medical error; how concerned they are about medical error; and how such concerns are related to patient satisfaction. The survey was given by telephone to 1,656 patients from Midwestern acute care hospitals. Results showed that patients define medical errors somewhat differently from the way clinicians do. While including events such as medication errors, misdiagnoses and errors in judgment and execution by clinicians – patients add poor communication as well as falls resulting in injury. While a large percentage of patients stated that they believed their “medical safety” was “good” (or better), 39% reported experiencing one of seven concerns: medication errors, mistakes by nurses, errors with medical equipment, being misdiagnosed, mistakes by physicians, having the wrong test or procedure, and being mistaken for another patient. Variables associated with greater concern included*

*ethnicity (African American); age (30-59); being a parent of a pediatric patient; greater severity of illness; longer length of stay; admission through the ER; and being treated in a pediatric, academic or metropolitan hospital. Patients' perceptions of medical safety correlated significantly with their satisfaction with care; willingness to return to the hospital; and likelihood of recommending the hospital. The authors point out how this information might be used in developing patient-centered safety programs.*

Duclos, CW, Eichler M, Taylor L, et al. Patient perspectives of patient-provider communication after adverse events. *Int J for Qual Health Care* 2005;17(6):479-86.

*This qualitative study examines the effect of patient-provider communications in situations involving actual adverse medical events, and thus provides insights into the reactions of a group of injured patients. A goal of the study was to determine whether the reactions of such patients would be similar to those reported in studies of hypothetical events; such studies had indicated that patients want disclosure of information, including what happened and how it can be prevented from happening again, and an apology.) Subjects were recruited from a pool of patients identified by COPIC, Inc., a physician malpractice insurer in Colorado, as part of an early intervention program. In each case, the adverse event had required extensive medical follow-up. Focus groups conducted with these patients and several family members revealed several themes. One was trauma. All participants reported physical trauma. Many reported emotional trauma as well, although those who reported good communications with their providers reported less. An unexpected finding was that many patients/families experienced financial trauma, as they were without sufficient resources to handle the period of follow-up care. Patients also revealed that they were worried about what had happened and what would happen next. They were frustrated and became angry if they had to fight to get information. (Most patients were angrier about how they were treated than about the event itself.) The likelihood of a patient remaining with his/her provider was influenced by the communication process; all patients who indicated the process had not gone well reported no continuing relationship with the provider. Patients who reported good communication also were more likely to perceive the event as a "mistake" rather than incompetence. Two new themes that were identified were the importance to the patient of quick, confident action taken by providers, and patients' sensitivity to the tone of the conversation (whether the providers seemed to be acting in fear of a lawsuit, or attempting to "cover up").*

Fein SP, Hilborne LH, Spiritus EM, et al. The many faces of error disclosure: a common set of elements and a definition. *J Gen Intern Med* 2007;22(6):755-61.

*Fein and colleagues conducted focus groups for physicians, residents, nurses and administrators at academic medical centers, each of which had a policy to disclose medical error to patients. Participants were encouraged to express their views about disclosure of error generally and to respond to a specific hypothetical. Most participants said they would report a medical error to a patient. However, some of the disclosures described by the participants (either in connection with actual cases or in response to the hypothetical) did not meet the authors' definition of "full disclosure." (The 6 elements of "full disclosure" were garnered from the qualitative analysis.)*

*Disclosures were often “partial,” a category that the authors further divided into 3 subcategories: (1) “connect the dots” (failing to link the error and the effect), (2) “mislead” (implying that error was part of the natural condition or expected complication of treatment) or (3) “defer” (suggesting other possibilities when the error is known). Responses considered “partial disclosure” or nondisclosure accounted for the majority of all the disclosures in the study. Based on the study, the authors propose a definition of “disclosure” that will assist clinicians in achieving full disclosure.*

Garbutt, J, Brownstein DR, Klein EJ, et al. Reporting and disclosing medical errors: pediatricians’ attitudes and behaviors. *Arch Pediatr Adolesc Med* 2007;161:179-85.

*This study, which the authors believe to be the first focusing on pediatricians, surveyed academic and community pediatricians (including residents) affiliated with two pediatric hospitals. A high percentage of pediatricians supported disclosure of serious and minor errors to institutions, but fewer were satisfied with institutional reporting systems. Almost all respondents supported disclosure to families, but many identified factors that might make them less likely to do so, including the likelihood that families would not understand or otherwise be unaware of the error. (In this study, fear of malpractice did not appear to affect reporting behaviors; in fact, a majority of physicians felt that disclosure was likely to reduce the malpractice risk.) While participants generally supported reporting of “near misses,” they were less likely to disclose them. Most participating pediatricians felt that disclosing error is difficult. The authors suggest development of guidelines and training programs to assist in this process.*

Gallagher TH, Garbutt JM, Waterman AD, et al. Choosing your words carefully: how physicians would disclose harmful medical errors to patients. *Arch Intern Med* 2006; 166(15):1585-1593.

*The authors surveyed 2637 U.S. and Canadian physicians about whether and how they would disclose information after one of four hypothetical errors. As part of the survey, physicians responded to actual disclosure statements. The results varied among physicians, but reinforced the result of prior studies to the effect that there is a “gap” between what patients seem to want and what physicians provide after medical error. For example, despite past studies indicating that patients desire accountability, apology and information (including what will be done to prevent future error), physicians in the study tended not to use the word “error;” not to frame a specific apology; and not to provide information about actions that would be taken to prevent a similar error. Overall, physicians were more apt to disclose an error if it were obvious, and not to disclose if it seemed that patients would not otherwise know about it. Based on their work, the authors counsel the development of disclosure standards and training.*

Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients’ and physicians’ attitudes regarding the disclosure of medical errors. *JAMA* 2003; 289(8):1001-7.

*The authors report on a study designed to gather information about patient and physician preferences regarding disclosure of medical error. A total of thirteen focus groups*



*(comprised of patients or physicians or both) were presented with hypothetical situations involving medical error. A qualitative analysis of the transcripts of the sessions revealed a number of important differences in the attitudes of patients and physicians, including the following: (1) patients conceived of medical errors more broadly than physicians; (2) patients wanted to be told about any error that caused them harm, whereas physicians, while generally agreeing, described situations in which they would not disclose; (3) patients wanted full disclosure (including what happened, how their health would be affected, why it happened, what would be done to fix it and prevent future errors) and an apology, but some physicians were more cautious about what they would disclose (many noting the fear of litigation and the need to avoid language suggesting liability). In regard to “near misses,” patient preferences regarding disclosure were mixed, while physicians generally opposed disclosure. Both patients and physicians reported that errors would cause them emotional distress. The article discusses the dichotomy between patients’ desires for full disclosure and physicians’ greater reluctance to disclose, and includes recommendations for how to respond to medical error, including minimal disclosure requirements and better institutional support for the emotional needs of practitioner.*

Gallagher TH, Waterman AD, Garbutt JM et al. U.S. and Canadian physicians’ attitudes and experiences regarding disclosing errors to patients. *Arch Intern Med* 2006; 166(15):1605-11.

*This study examines physicians’ attitudes about patient safety and disclosure of error in the U.S. and Canada, looking in particular at whether attitudes are affected by the different malpractice environments. Nearly all physicians responding to the survey agreed that serious errors should be disclosed to patients (98%), with 78% supporting disclosure of minor errors and 35% near misses (more common among Canadian physicians). The authors note that physicians’ estimates of the probability of being sued (significantly higher in the U.S.) did not appear to affect significantly their beliefs about disclosure. The authors report that overall, there is substantial similarity in attitudes among physicians in both countries, leading them to suggest that attitudes toward disclosure may be grounded more in medical culture than in the malpractice environment. The study also examines other factors potentially influencing attitudes, including the fact of being in private practice, beliefs about whether disclosure reduces the risk of being sued, and beliefs about the causes (individual or system) of medical error.*

Gibson R, Singh JP. *Wall of silence: the untold story of the medical mistakes that kill and injure millions of Americans.* Washington D.C.: LifeLine Press, 2003.

*Appearing several years after the publication of the IOM report on medical error, this book presents a series of dramatic stories, collected from patients and families, illustrating the consequences of medical error. In most cases, patients or families report not receiving full information about what happened or an acknowledgement of responsibility or an expression of sorrow. While written for the layperson, and focusing on personal stories (including that of the authors), the book also includes a brief summary of the IOM report; a discussion of the so-called “wall of silence” (the*

*professional practice of not disclosing error to outsiders); and brief discussions of the definition of “medical error,” reasons for such errors, grassroots resources for those patients/families who experience medical error, and suggestions for working toward reducing future errors.*

Gilbert SM. *Wrongful death: a memoir*. New York: W.W. Norton, 1997.

*Gilbert, a poet and academician, wrote this open and painful memoir in response to her husband’s unexpected death in surgery. She describes the trauma she and her family suffered, exacerbated by the silence of the caregivers and the hospital in which he died. She describes her unsuccessful efforts to learn what happened and her decision to bring a law suit (settled before trial). In an introduction to a new edition, the author reports on the numerous letters she received detailing similar experiences with medical error and lack of disclosure.*

Hilfiker D. *Healing the wounds: a physician looks at his works*. Pantheon Press, 1985.

*Dr. Hilfiker work is a classic account of the pressures of practicing medicine -- with its inherent uncertainties, the inevitability of mistake, and the inadequacy of training and support for physicians facing such pressures. His open acknowledgement of his own errors, and the emotional consequences, encouraged a more open discussion among clinicians of their own, similar experiences.*

Hobgood C, Tamayo-Sarver JH, Elms A, Weiner B. Parental preferences for error disclosure, reporting, and legal action after medical error in the care of their children. *Pediatrics* 2005;116(6):1276-86.

*This study was designed to gain information about parental preferences for disclosure of medical error involving their children. As with studies using adults, disclosure was strongly favored. In this study, fully 99% of the parents expressed a desire for disclosure. However, the authors point out that the severity of the error had a more modest effect on desire for disclosure than had been reported regarding adults. The authors report that desire for disclosure did not vary based on the parents’ race, gender, age or insurance status. Given physicians’ concerns about possible adverse effects of disclosure (e.g. reporting to disciplinary bodies or legal action), the study asked parents whether they thought the responsible party should be reported for purposes of punishment; whether, after being informed of the event by the physician, the parent would seek legal action; and whether, in the event the parent learned of the error from a source other than the physician, the parent would seek legal action. Thirty nine percent of parents wanted the error reported to a disciplinary body, with the desire for reporting influenced by the severity of the error. Thirty-six percent of parents were less likely to seek legal action if informed of the error by the physician rather than another source. However, if parents thought the error was severe, they were less likely to be deterred from legal action by the physician’s disclosure.*

Hobgood C, Peck CR, Gilbert B, Chappell K, Zou B. Medical errors – what and when: what do patients want to know? *Acad Emerg Med.* 2002;9(11):1156-61.

*Shortly after the IOM report, these authors collected preliminary data (258 surveys returned) from a convenience sample of ED patients at a tertiary care center -- in regard to patient preferences for disclosure and reporting of medical error, and the role of medical educators in this field. (Basic demographic data and surrogates for health care utilization were also collected and examined.) Eighty-eight percent of respondents reported they would want to know everything about a mistake. The remaining wished to be informed only if it could affect their health. Most (76%) wanted to know about the error immediately; a smaller number (23%) wanted to wait until the full extent of the error was known. A very high percentage supported reporting of errors to government agencies (92%), state medical boards (97%) and hospital committees concerned with quality (99%). In two categories, demographic information was relevant: respondents reporting less formal education were more likely to support reporting the error; respondents older than 40 years were more likely to prefer waiting for disclosure until the full extent of the error was known.) In response to the question about what role medical educators should play, respondents chose “teaching students honesty and compassion” (approximately 38%) and “teaching students how to tell patients about mistakes” (approximately 25%).*

Kaldjian LC, Jones EW, Rosenthal GE, Tripp-Reimer T, Hillis SL. An empirically derived taxonomy of factors affecting physicians’ willingness to disclose medical error. *J Gen Intern Med* 2006;21(9):942-8.

*Using qualitative and quantitative research methods (including a literature search of 316 articles, focus groups, pile sorting and hierarchical cluster analysis and validation methods), the authors construct a taxonomy of factors that may facilitate or impede disclosure of medical errors by physicians. The final taxonomy contains four domains of facilitating factors: (1) responsibility to patients, (2) responsibility to self, (3) responsibility to profession, and (4) responsibility to community. Within each domain, they identify specific factors, such as, a desire to respect and deal honestly with patients (domain one); a sense of duty, acceptance of limits, personal religious beliefs (domain two); a desire to serve as role model and change professional culture (domain three); and a desire to improve patients’ health and enhance trust (domain four). Four domains are identified as impeding disclosure are: (1) attitudinal barriers (such as perfectionism); (2) uncertainties (including doubts about how and what to disclose; (3) helplessness (lack of confidence in reporting systems and in ability to effect change); and (4) fears and anxieties (focusing on potential negative consequences of error disclosure, including external – loss of reputation – and internal – loss of self esteem.) The authors suggest that this taxonomy can assist in designing studies, creating error-reporting systems, and instituting educational interventions.*

Kaldjian LC, Jones EW, Wu BJ, Forman-Hoffman VL, Levi BH, Rosenthal GE. Disclosing medical errors to patients: attitudes and practices of physicians and trainees. *J Gen Intern Med* 2007;22(7):988-996.

*Based on their prior work and a literature review, the authors designed a survey for faculty physicians, residents and medical students to gather information about beliefs and practices regarding disclosure of medical error. The survey was administered (anonymously) across three regions of the country to 538 respondents. The results appear to confirm differences between attitudes and actual practice: while 90% of respondents reported they would likely disclose a hypothetical error resulting in minor or major harm, only 41% of faculty and residents had disclosed an actual minor error and only 5% had disclosed an actual major error. Nineteen percent of faculty and residents reported not disclosing an actual minor error and 4% reported not disclosing an actual major error. Data was also gathered on the relationship between malpractice concerns and disclosure. Ten percent of physicians reported that on at least 1 occasion they had not disclosed an error to a patient because of concerns about legal liability, and 6% reported at least one case in which they had wanted to disclose but were instructed by an attorney not to. In responding to a vignette, 18% said they believed disclosure would decrease the risk of being sued; 47% believed it would increase the risk; and 35% said there was no way to predict. Variables associated with actual risk disclosure included: feeling an obligation to tell the patient what had happened, and not believing that the decision to disclose should be based on the physician's assessment of the patient's best interest. Variables associated with disclosure in vignettes included these two plus others, including believing in the obligation to make it clear that a mistake occurred; believing disclosure "right" even if it comes at personal cost; believing disclosure strengthens patient's trust; and believing that the physician would want disclosure in a similar circumstance. Faculty were more likely than residents and students to disclose in all cases and less likely to be concerned about malpractice, discipline and other negative consequences. They were also less likely to think that the disclosure decisions should be based on their own view of the patients' interests. Pediatric faculty and residents were more likely than other specialists to disclose. Two-thirds of respondents believed that disclosure would relieve feelings of guilt. Respondents who reported that forgiveness was an important part of their spiritual belief system were more likely to disclose in hypotheticals and less likely to report not disclosing actual errors.*

Mazor, KM, Reed GW, Yood RA, Fischer MA, Baril J, Gurwitz, JH. Disclosure of medical errors: what factors influence how patients respond? *J Gen Intern Med* 2006; 21(7):704–710.

*The authors report the findings of a study involving 407 New England health plan members who responded to video taped presentations of medical error scenarios. Scenarios differed in regard to type of error, clinical outcome, extent of disclosure, offer to waive costs, and evidence of prior positive physician-patient relationship. Participants indicated emotional response, level of trust, satisfaction, likelihood of seeking legal advice and intent to change physician. The authors report that in general, results confirmed prior studies that showed that nondisclosure was associated with more negative emotional responses, reduced trust and satisfaction. In this study, severity of*

*clinical outcome also produced more distress (although only slightly more in one scenario). However, in contrast to other studies/hypotheses, offers to waive costs and the existence of a prior positive relationship did not greatly affect the measures selected. Nondisclosure increased intent to seek legal advice in one scenario but not in the other. In both scenarios, intent to seek legal advice was increased by severity of error and nondisclosure and severity of error increased the likelihood of intent to change physicians. In sum, disclosure was found to affect positively several of the measures selected and not to affect negatively any of them. However, some of the results differed from findings in other studies, and the authors note the need for additional research, particularly on the effect of offers of financial assistance and the factors influencing legal action. .*

Waterman AD, Garbutt J, Hazel E et al. The emotional impact of medical errors on practicing physicians in the United States and Canada. *JT Comm J Qual Safety* 2007; 33(8):467-476.

*This article reports the result of a survey designed to see how physicians' experiences with medical error affect job satisfaction (including levels of professional confidence, professional reputation, anxiety about future errors, ability to sleep, interest in counseling/training). The survey was completed by 1,767 American physicians and 1,414 Canadian physicians. Among the results reported was the fact that 92% of the physicians had been involved with an error or a near miss. Error disclosure was also fairly common; of the physicians surveyed, 89% reported having disclosed a serious error to a patient (although few had received training in how to conduct the conversation.) Approximately half of the physicians reported that involvement in medical error increased their job-related stress. (Factors contributing to increased stress included the severity of the error, the perception of the likelihood of being sued, and feelings of lack of support.) There was widespread dissatisfaction with the support received from health care institutions after an error was made, and interest in further training.*

White AA, Gallagher TH, Krauss MJ, Garbutt J, Waterman AD, et al. The attitudes and experiences of trainees regarding disclosing medical errors to patients. *Acad Med* 2008; 83(3):250-6.

*As context, the authors note that despite the strong preference of patients that they be informed of medical errors, and the general support of physicians for such disclosure, studies show that disclosure is not as common as might be expected. The authors of this study sought to learn more about trainees' attitudes toward and experiences with of medical error. They surveyed medical students, interns and residents (889 responses) from two academic medical institutions. The authors report that most trainees agreed that medical error is a serious problem (although they were divided as to whether the cause was primarily systems-based or individual). Almost all agreed that serious errors should be disclosed to patients. A majority supported disclosure of minor errors and 27% favored disclosure of near misses, although these figures declined with length of*

*training. One third had disclosed a serious error and a majority had disclosed a minor error. Most were satisfied with the process, although most also agreed that disclosing would be difficult (fewer surgical residents reported such concerns). Eight-seven percent noted at least one factor that might make them less inclined to disclose (such as patient anger, fear of being sued, uncertainty about whether the patient wanted to know), although identification of such factors declined by specialty (surgery) and level of training. Only a minority of trainees reported having received education or training in error-disclosure; a large majority wanted such training; and 97% wanted “just in time” coaching at the time of a serious error. The authors conclude that education (early in training) as well as “just in time” training should be provided and they offer some suggestions for curriculum development.*

## **VI. Disclosure of Medical Error and the Law**

Banja JD. Does medical error disclosure violate the medical malpractice cooperation clause? AHRQ, *Advances in Patient Safety* 2005; 3, accessed on June 18, 2008 at [ahrq.gov/qual/advances/](http://ahrq.gov/qual/advances/)

*Banja attempts to address the problem faced by providers who want to comply with ethical obligations to disclose medical error without violating “cooperation clauses” in malpractice insurance, which generally forbid providers from admitting liability. He argues that legal research does not offer compelling evidence that disclosure will lead to denial of coverage. He cites a number of decided cases in which insureds were denied coverage because of failure to comply with the cooperation clause, and argues that there are significant factual differences between these cases and those involving providers disclosing medical error. He also argues that to the extent cooperation clauses prohibit providers from fulfilling ethically mandated responsibilities, they may be unenforceable as against public policy. He points out that the enactment of “apology” laws may cut against arguments by insurance companies that disclosure adversely affects their chances of successfully defending a suit. Finally, he notes that at least one jurisdiction has ruled that a provider’s verbalization of her belief that she made a mistake was not sufficient to establish departure from standard of care, which would require expert testimony. On a larger scale, citing prior studies and the experience of the VA Medical Center in Kentucky, Banja questions whether discouraging open communication about error actually serves the financial interests of insurers.*

Bender FF. ‘I’m sorry’ laws and medical liability. *AMA Journal of Ethics* 2007; 9(4): 300-304.

*Bender reports that, at the time of writing, twenty-nine states had enacted evidentiary rules that make certain expressions of sympathy inadmissible in a court to prove malpractice liability. Bender points out the variations among the statutes -- with Colorado, for example, protecting a broad range of statements and conduct, and other states, such as Texas, excluding only expressions of sympathy and benevolence. Five states had gone further and required hospitals to notify patients of adverse medical*

outcomes. Bender points out the potential benefits of the “I’m sorry” laws in promoting open communication, possibly reducing litigation or costs (for example by leading to prompt settlement instead of extensive litigation) and preserving the patient-physician relationship.

Cohen JR. Toward candor after medical error: the first apology law. *Harvard Health Policy Review* 2004; 5(1):21-4.

Cohen points out that the “apology” law enacted in Colorado in 2003 represents a significant deviation from traditional legal principles and from prior so-called “apology” laws. Under traditional evidentiary law, statements by parties to a case can be admitted as evidence against them. Starting in 1986, several states enacted statutes that excluded from evidence certain expressions of sympathy after adverse medical outcomes. However, the Colorado law goes further and provides that statements or conduct by a health care provider or employee expressing fault (as well as sympathy or compassion) cannot be used against the provider in a malpractice action. While noting that there are pros and cons to all “apology” laws, Cohen focuses on the potential implications of the Colorado statute, such as: (1) encouragement of full disclosure and apology, (2) possible decrease in the incidence of suits (such as those brought in order to get information and those brought out of the patient’s feeling of betrayal and insult), and (3) improved patient safety. Cohen makes the point that an apology does not mean that compensation should not be provided to the patient, especially in cases of serious error. Instead, an apology may determine the nature and tone of procedures for determining compensation.

Dauer EA. A therapeutic jurisprudence perspective on legal responses to medical error. *J Legal Medicine* 2003;24(1):37-50.

Dauer summarizes problems with the way in which the current legal system attempts to deal with medical error, viz., through negligence based litigation. Some of the essential characteristics of this system (including its adversarial nature and focus on fault and public censure) are inconsistent with what is known about effective error reduction. Dauer also points to research that has shown that the current system does not compensate most patients who are harmed by medical error (and compensates some who are not). The tort system also appears to do little to meet patients’ emotional needs, and contributes to high physician stress (which may in turn lead to increased risk of errors, at least in the near term). Dauer suggests that the concept of therapeutic jurisprudence might help in devising a solution for these problems. Therapeutic jurisprudence is based on evidence that the legal process affects the overall well-being of those involved, and that this effect should be “therapeutic.” Dauer uses this standard to review possible legal reforms, such as no-fault liability, enterprise liability, and increased confidentiality of error data. Without describing the model in detail, he proposes that early intervention mediation may be a less radical reform that might be able to address the parties’ needs after medical error (including openness, information, restoration, improved patient safety, and justice).

Taft L. Apology and medical mistake: opportunity or foil? *Annals of Health Law* 2005; 14:55-94.

*Taft, an experienced patient-plaintiff attorney posits that those who are currently urging increased disclosure of medical error go astray when they advise providers to avoid acknowledging error (and potential liability). Although such advisors may use the word "apology" in connection with disclosure, they are generally counseling a "pseudo apology," which is characterized by general expressions of empathy, and is designed in part to serve a defensive function. Taft contrasts such an apology with an "authentic apology," which has the potential to heal both patient and physician. An authentic apology (which he argues is ethically mandated) has as its key components acknowledgment of the legitimacy of a norm that has been violated and fault in violating the norm; genuine remorse and regret; some attempt at restitution; an invitation for the injured party to forgive; and a willingness to accept the consequences of acknowledging fault. His argument is based in part on the concept of patient centered care and in part on ethical theory, which supports the concept of apology as a moral activity involving the relationship between remorse (provider) and forgiveness (patient/family). Apology is a way of restoring the integrity and balance of a relationship that has been harmed. Taft illustrates the difference between empathy and apology using existing disclosure policies (including ASHRM's model). Taft then addresses the legal concern that an authentic apology may be used as an admission of fault in a liability suit. He points out the flaws of one attempt to alleviate this concern, namely, the passage of "I'm sorry" laws. In his view, such laws encourage empathic disclosures or pseudo apologies. The Colorado law, in particular, broadly exempts one class of individuals from being held to their admissions of fault; patients are required to prove in court what their doctor has already told them. One of the reasons that these laws are favored, according to Taft, is a somewhat distorted view of malpractice litigation. Based on his experience as a malpractice lawyer, he concludes that most cases are not accepted by plaintiffs' attorneys because the costs are high and the likelihood of victory small. Further, the chances of a high award may be increased by the presence of an arrogant, unrepentant physician. He argues that cases in which there is negligence should be settled or bifurcated (if allowed) so that the issue of compensation alone can be tried. If new laws are to be enacted, they should promote settlements of legitimate claims without litigation. Taft acknowledges that at this time, authentic apologies could be used in some circumstances against the provider, and that offering such apologies remains an act of moral integrity and courage.*

Waite M. To tell the truth: the ethical and legal implications of disclosure of medical error. *Health Law Journal* 2005;13(33).

*Against the background of increasing interest in patient safety and disclosure of error, Waite addresses what he characterizes as the "unhappy" relationship between clinicians and the law, and makes suggestions to improve this relationship. In the course of his discussion, he reviews ethical and legal bases for the physician's duty to disclose error, with specific reference to Canadian cases. (This obligation does not extend, he concludes to opining that negligence occurred.) Waite also notes the importance of disclosure in*



*increasing the safety of medical care. Despite these reasons to disclose, clinicians continue to be reluctant to do so. To encourage disclosure, Waite recommends a balanced approach that would afford protections for individual physicians (and recognition of the role of systems errors) while ensuring appropriate discipline/education for physicians, and compensation for patients injured through malpractice. Waite believes that greater educational efforts could help reduce physicians' fears of litigation (which occurs less often than they believe) and that defense lawyers and risk managers could further reduce fear of disclosure by supporting appropriate disclosures (without necessarily admitting liability). Waite recognizes that such a disclosure is not easy and counsels case by case responses, with the assistance of trained individuals.*

Wei M. Doctors, apologies, and the law: an analysis and critique of apology laws. *J Health Law* 2006;139(4). Accessed on June 17, 2008 at <http://ssrn.com/abstract=955668>.

*Using existing studies and analyses, Wei identifies and discusses major barriers to open disclosure of medical errors by physicians, including the fear of legal liability and the role of professional norms governing the patient-physician relationship. She then describes in some detail the functions and effects of apology laws as well as of traditional evidentiary rules regarding remedial actions/disclosures. Her conclusion is that the protections afforded by the law do not sufficiently address barriers to disclosure. She notes several other possible strategies that have been proposed to encourage disclosure, including hospital policies and medical education, but concludes that these are also of questionable efficacy in responding to the major reasons behind non-disclosure. She concludes with the comment that while there may be ways to increase the likelihood of disclosure, making such changes in education and practice might also have the effect of undercutting some of the benefits of existing professional norms.*

## **VII. Disclosure and Guidelines, Programs and Recommendations**

COPIC Insurance Company 3Rs Program Newsletters, accessed June 17, 2008 at [www.callcopic.com/home/resources-tools/newsletters/copics-3rsprogram/](http://www.callcopic.com/home/resources-tools/newsletters/copics-3rsprogram/).

*COPIC Insurance Company has developed an early intervention program for its insureds when adverse outcomes occur. Reference to the program, called the 3R's (Recognize, Respond, Resolve), can be found in literature on disclosure of medical error. COPIC posts newsletters and discussions on the 3Rs program and related topics on its website.*

Department of Veterans Affairs. Disclosure of adverse events to patients. VHA Directive 2008-02. Accessed on June 17, 2008 at [www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1637](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637).

*The VA policy requires disclosure to patients or patients' representatives of adverse events even if the harm is not obvious or severe or may become evident only in the future. Such disclosure is based on the VA's core values, including honesty and trust. The policy defines "adverse event" and "disclosure," which it further divides it into three types: (1) "clinical disclosure," which, as part of standard clinical care, is the responsibility of the*

*attending and the clinical team, and includes presenting the facts, expressing concern for the patient, and reassuring them that steps are being taken to prevent recurrence; (2) “institutional disclosure,” which occurs when the adverse event has resulted in death or serious harm or potential liability, and which generally includes notification of organization leaders and counsel, as well as a meeting between the patient (and family) and institutional leaders at which an apology is made and information about the possibility of seeking compensation is provided, if appropriate; and (3) large scale disclosures, involving a large number of patients and requiring collaboration with the Department of Veterans Affairs Central Office. Appendices include further information, such as what events require disclosure, timing of disclosure, how disclosures should be made, and documentation. Individual VA facilities must adopt policies that comply with overall VA policy and these policies must include provision for support systems for staff.*

Harvard Working Group: When things go wrong: responding to adverse events.  
Massachusetts Coalition for the Prevention of Medical Errors, 2006.

*This brochure represents a consensus statement of the Harvard teaching hospitals and the Risk Management Foundation on disclosure of medical error. It contains clear and specific recommendations, supported by available data, expert opinion (including widely-accepted ethical principles), and reasoning. The recommendations are intended to serve as a foundation for the development of specific institutional practices and policies. The brochure begins with an introduction and set of definitions. The first section deals with the patient and family experience, and describes four 4 essential steps in communicating with the patient/family (tell what happened, take responsibility, apologize, and explain what will be done to prevent future harm). It also provides suggestions regarding “who” should disclose, “when,” and “how.” This section provides recommendations for supporting the patient/family, including details such as asking about their feelings and anxieties; providing names and addresses for follow-up questions; and addressing possible needs for financial support. The second section deals with the caregiver experience and recommends that institutions have a flexible program for providing such support. This section also contains suggestions for training and education. The third section addresses management of the event, including elements of a hospital incident policy, analysis of the event, and documentation. In appendices, the brochure offers model language for communicating with patients/family; a case study; and additional elements of caregiver support.*

Joint Commission on Accreditation of Health Care Organizations. Disclosing medical error: a guide to an effective explanation and apology. Oakbrook Terrace, Illinois: Joint Commission Resources, 2007.

*After a brief introduction to the incidence of medical error, this guide succinctly presents information and advice on reporting medical errors and on disclosing medical errors to patients and families. The guide uses case studies to support its recommendations and to provide specific examples of ways to disclose error in a sensitive and compassionate manner. It posits that disclosure will reduce rather than increase costs arising from*

*patient harm, but also presents the counter arguments. The guide cites key references, including web sites.*

Monographs Task Force of the American Society for Healthcare Risk Management. Disclosure of unanticipated events: What works now and what can work even better (3<sup>rd</sup> of three parts), 2004. Accessed on June 17, 2008 at <http://www.ashrm.org/ashrm/resources/monograph.html>.

*In light of new expectations that medical error will be disclosed to patients/families, this monograph focuses on a practical, skills-based model for disclosure. Disclosure skills highlighted are: preparation, verbal initiation of conversation, heart of the discussion, concluding the conversation, and documentation. Some specific language suggestions are included. Other specific recommendations regarding communication are also presented, including cultural sensitivity.*

Shapiro E. Disclosing medical errors: best practices from the leading edge. Supported by the Robert Wood Johnson Foundation in connection with the workshop entitled: “Disclosure: what’s morally right is organizationally right,” at the 18<sup>th</sup> Annual IHI National Forum on Quality Improvement in Health Care, December 10-13, 2006.

*This paper highlights the leading efforts of medical institutions to foster open communication of medical error and to use what they learn from such communication to improve patient safety. Shapiro describes eight such institutions, providing information on the process, the policy, training, outcomes, and lessons learned.*

*Shapiro’s first example is the University of Illinois Medical Center, which began its four year campaign to bring about a policy of full disclosure in 2002. Initially, these efforts were resisted by the hospital’s defense bar, requiring a selection of new attorneys. Key concepts underlying the policy include a commitment to learning from mistakes and to managing the medical malpractice crisis through safer care (rather than tort reform). The Medical Center notes that implementing the new policy required a “culture change,” which included meeting with representatives from the entire organization, from “grass roots” up to the board of trustee. Implementation also required training – not just in the class room but on-the-spot training conducted through the Patient Communication Consult Service. This Service is staffed by trained representatives from various departments in the hospital – who engage in a “train the trainer” process. The Service also maintains a 24 hour hotline. The Medical Center reports positive outcomes to its policy changes, including good patient return rate, improvement in patient safety, and improved attitudes of clinicians who can openly disclose errors in an organized way and offer remedies to patients and families when appropriate.*

*Shapiro next describes the University of Michigan Health System, which initiated its disclosure policy based on a pragmatic view that disclosure and discussion with patients who have threatened to sue would save money. However, the Health System became convinced that a culture of open disclosure fostered clinical improvement as well. Three principles came to guide the University’s approach: to compensate patients and families*

*when an error was made; to fight to defend when care was reasonable; to use mistakes as tools for learning and making change. Adopting the policy was facilitated by a traditionally open culture and leadership and by Michigan law, which requires a 6 month notice period before a malpractice claim can be filed. During this period, the University engages in external and internal review and takes the opportunity to engage in substantive discussions with the patient and family. The biggest barrier to implementation was the perception that disclosure would adversely affect the University's ability to defend itself and practitioners' fear that disclosure would lead to lawsuits. While it is difficult to show a causal relationship, the University reports claims have continued to decline since implementation of the policy.*

*Shapiro notes that for Virginia Mason Medical Center, transparent communication about medical error has been part of its culture for a long time. The organization took the additional step toward improving safety by traveling to Japan to study Toyota's program for error prevention. It then adopted the Patient Safety Alert System, under which everyone is considered a safety inspector and can "stop the line" if they see a patient safety issue. Training is provided through yearly workshops, but when an error or potential error occurs, the physician must consult one of a group of specially trained "situation facilitators". The Medical Center reports that remaining challenges include the difficulty of determining whether certain events constitute errors and the large number of reports to be prioritized and managed. The Patient Safety Alert System has led to increased reporting of potential and actual errors; increased knowledge of and improvement of safety problems; and more prompt communication with patient/family. Virginia Mason also reports slightly fewer malpractice claims.*

*Shapiro notes that, prompted by the 1999 IOM Report, Kaiser Permanente developed a policy statement that reflected its belief in the ethical obligation to have open discussions with patients and families about adverse events. The six-step statement of principle includes: care for the patient; communicate about the adverse outcome; report to appropriate parties; check the medical record; follow up and provide closure; and support the patient care team. Kaiser worked on its policy and procedures for 7 years, implementing training sessions and setting up situation management teams to provide immediate counseling, support, and advice. Kaiser created the role of health care ombudsman/mediator to ensure continued open dialogue with the family. Shapiro notes that Kaiser reports that overcoming physicians' fear is probably the biggest challenge. Sometimes, the outcomes of patient conversations are not pleasant; every disclosure conversation is a risk, but they are conducted because it's the "right" thing to do. Kaiser measures outcomes on a case-by-case basis. Early satisfaction surveys reveal positive reactions.*

*Shapiro notes that Geisinger, a physician-led system, began open communication of adverse outcomes to patients because of a new PA law requiring that a patient who has sustained injury or death because of negligence must be afforded a prompt determination and fair compensation and that efforts must be made to reduce errors by implementing patient safety programs. Geisinger developed a process that would make disclosure routine; it includes prompt communication with patient/family, followed up in writing; an*

*explanation of the circumstance; assurance of an investigation; identification of systems issues; and designation of individuals to engage in on-going communications with family/patient. Geisinger's policy grew into a personal commitment to do the "right" thing. Leadership modeled communication and providers began to discover that the process actually helped them as well as the patient/family. Training included storytelling and videotaped interviews. Geisinger also uses a core team of specially trained people to assist in disclosure conversations. The organization has an on-line self reporting system (that can be used anonymously) and a patient hotline. Patient representatives also have a process for tracking complaints. Fear of legal repercussions was considered the biggest barrier to the policy. Geisinger reports a significant increase in the reporting of events (including near misses); an increase in physician-patient conversations about these events; and fewer malpractice claims.*

*Shapiro reports that the concept of compassionate disclosure has long been ingrained in the Catholic Health Initiative system. Their position on disclosure is based on a belief that patients want and deserve disclosure and that admitting and confronting errors in the only way to improve care. CHI's model policy emphasizes compassion and apology; however, there is flexibility for individual organizations within the system to modify details of the policy. CHI believes it is important to offer guidance, "tools," and support to caregivers involved in disclosure conversations. In regard to legal issues, Shapiro notes that CHI believes that the organization must do what is right, not what it can get away with. Barriers to open disclosure include lawyers and the fear of being sued; negative publicity; fear of financial loss. While recognizing the "down sides" of disclosure, and the imperfections of the legal system, CHI focuses on the upside – to learn and to improve care.*

*Shapiro describes the program instituted by COPIC, a Colorado based, primarily physician led malpractice carrier, whose policy to communicate medical errors began in 2000. They developed an early intervention "3R's" program for certain cases involving unanticipated event. In these cases, they practice quick response and resolution, with offers of compensation as appropriate. Patient/families participating do not waive their rights to sue. Implementation of the program is facilitated by Colorado law, which includes a cap on noneconomic damages and a broad "I'm sorry" law protecting certain physician disclosures from introduction into evidence in court. About half of COPIC's insureds participate in the program. One challenge to physician participation has been reluctance to have candid discussions with patients. COPIC reports that preliminary outcomes are good. Those who participate appear to have fewer claims. According to COPIC, the program is "right" and doesn't seem to have adverse financial effects.*

*As a final example, Shapiro describes the policy of the Brigham and Women's Hospital for routinely disclosing adverse outcomes and medical error. While adopted in connection with the JCAHO standard on disclosure of information, the Hospital believes that the policy represents the "right thing" to do. The Hospital reports support from senior management and close relationships with its risk managers. At the time of writing, there were basic guidelines for disclosure, and help available from risk managers in preparing for the disclosure conversation. The risk management group was in the*

*process of developing training programs. The outcomes of the policy were reported to include no increase in claims and a quicker resolution of those claims made. However, the Hospital reports that success is not measured simply by a reduction in claims; a primary goal is to preserve the patient-physician relationship*

*Shapiro concludes that the experiences of organizations that pursue openness and reject fear of lawsuits do not lead to increased suits, but to greater satisfaction.*

Roberts RG. The art of apology: when and how to seek forgiveness. *Fam Practice Management* 2007;14(7): 44-9

*This article provides straightforward advice to practicing physicians as to when and how to apologize for medical error. Roberts defines medical error and adverse event and notes that when these two intersect, the physician has entered the “apology zone.” He describes the minimum elements of a well-done apology, namely, acknowledgment, explanation, expression of remorse, and reparation. Roberts provides guidance as to who should deliver the apology and how it should be delivered. He acknowledges the painful nature of an apology, in which the physician makes himself or herself vulnerable and looks to the patient for forgiveness. While recognizing that an apology will not immunize the clinician against litigation, Robert contends that it is the right thing to do. Further, error recognition, disclosure and correction are integral parts of improving patient care.*

Woods MS. Healing words: the power of apology in medicine. Oak Park, Illinois: Doctors in Touch, 2004.

*The author proposes that when complications occur in medical treatment, physicians should fully disclose what happened to the patient, apologize, and offer on-going care and support. His position is based primarily on the physician’s professional responsibility to the patient – including the responsibility to treat the patient with respect and to obtain informed consent. He distinguishes an “authentic apology” from a “compelled apology,” and offers specific suggestions for “authentic” communication. The author also recognizes some of the barriers to open acknowledgement of error, including the culture of medicine (with its emphasis on facts, data, and detachment) and malpractice concerns (including the concern that an apology may void coverage in some malpractice policies). While he believes that full and honest disclosure will reduce litigation, his argument is not dependent on such an outcome.*

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