Annotated Bibliography

Disclosing Unanticipated Medical Outcomes

Institute for Healthcare Communication

Institute for Health Care Communication
New Haven, Connecticut 06510-3153
(800) 800-5907
www.healthcarecomm.org

Agency for Healthcare Research and Quality (2016). **The CANDOR toolkit.**

Traditionally, health systems have disclosed adverse events to patients only through a lengthy process that involves providing limited information to patients and families, avoiding admissions of fault, and emphasizing protection of the clinicians involved. This approach may harm safety culture and has been criticized as not being patient-centered. Some pioneering institutions, such as the University of Michigan Health System, began implementing an alternative approach known as "communication and resolution," which emphasizes early disclosure of adverse events and proactive attempts to reach an amicable solution. Early adopters of this method have achieved notable results, including a decline in malpractice lawsuits. The CANDOR toolkit, developed by AHRQ as part of the Medical Liability Reform and Patient Safety Initiative, provides tools for health care organizations to implement a communication-and-resolution program. The toolkit includes videos, slides, and teaching materials, and it has been tested in 14 hospitals in several different states.

Allan A, McKillop D, Dooley J, Allan MM, Preece DA. **Apologies following an adverse event: the importance of focusing on the consumer's needs.** *Patient Educ Couns*, 98:1058-1062.

In this study, participants observed two video-recorded scenarios of a surgeon apologizing for an adverse event. Although apologies that focused on admissions of responsibility, expressions of regret, and offers of restitution were viewed positively, those that also explicitly accounted for the patient's perspective by understanding the impact on the patient and offering to address the harm in a meaningful manner were better received.

American College of Physicians. (2003). **Must you disclose mistakes made by other physicians? Case Study by ACP's Ethics and Human Rights Committee and Professionalism.** http://www.acponline.org/journals/news/nov03/mistakes.htm.

CONTEXT: Addresses the question of whether a physician has an obligation to disclose an error made by another physician if it has harmed the patient.
CONTENT: Case discussion in which a physician becomes aware of an error made by his partner who is now on sabbatical. His partner had failed to follow-up on a chest x-ray that had reported a lung nodule on a patient who had presented with breathing symptoms 18 months prior. The case discussants reaffirm the ethical obligation of a physician to provide his patient with an accurate understanding of what has happened in his care. In this case revealing that the radiologist had detected the lung nodule 18 months previous but it has not acted upon by the partner physician. The case discussant encourages contacting the original physician and inviting him to participate in making the disclosure to the patient but the current physician providing care remains obligated to see that the error is disclosed.
CONCLUSION/RECOMMENDATIONS: The article reaffirms the absolute entitlement of the patient to be told about the error that has a harmful impact and affirms the responsibility of the second physician to reveal his colleague's error.

American Society for Healthcare Risk Management (2001). **Perspective on disclosure of unanticipated outcomes information.** *ASHRM*, phone 312 422-3980. www.ashrm.org.

CONTEXT: This paper was developed by the American Society for Healthcare Risk Management of the American Hospital Association in order to alert its members to the issues that are raised by the revised JCAHO standard requiring discussion of unanticipated adverse outcomes. The paper is available through their website.
CONTENT: The paper provides definitions and describes concerns from the perspective of patients, professionals, and institutions. The paper offers strategies for addressing disclosure of adverse outcomes, documentation, legal safeguards, ethical consultation and support for patients and families.
CONCLUSIONS/RECOMMENDATIONS: Recommends an honest approach to disclosure when investigation clearly identifies causality and encourages full coordination with risk management in working through the situation with the patient and family.

American Society for Healthcare Risk Management (May, 2003). **Disclosure of unanticipated events: the next step in better communication with patients. The first monograph in a series of three parts addressing the communication and disclosure of unanticipated medical outcomes.** *ASHRM*. Copies available at www.ashrm.org

CONTEXT: The first monograph in a series that addresses the impact of the JCAHO standards, and the legal and psychological barriers experienced by individuals and organizations to more open communication with patients about unanticipated adverse outcomes.
CONTENT: Reviews the literature and describes a model organizations can use to promote constructive communication and gives examples of disclosure situations and how they were handled. Specific concerns about discoverability are addressed with a recommendation that the disclosure of the investigation of outcomes should be factual and broad. The monograph notes the consistent finding that communication issues (specifically the failure to be open, honest and empathic/apologetic) after disappointing outcomes is one of the main drivers to initiating malpractice suits.
CONCLUSIONS/RECOMMENDATIONS: Patients want and should be provided an explanation, an apology when appropriate, and to be informed of the steps being taken to prevent the same type of error from recurring. Legal concerns about the discoverability of evidence should not interfere with the responsibility to inform patients about the facts of their care and be given an accurate explanation.

American Society for Healthcare Risk Management (November, 2003). **Disclosure of unanticipated events: creating an effective patient communication policy. The second monograph in a series of three parts addressing the communication and disclosure of unanticipated medical outcomes.** *ASHRM*. Copies available at www.ashrm.org

CONTENT: This monograph describes the elements of building an effective disclosure policy. Elements include defining terms, and including healthcare staff and board in the development of the policy. The monograph places disclosure in the context of more consistent communication and informed consent throughout the treatment process. The monograph encourages a clear policy that focuses on organizational values and how they apply to disclosure situations but discourages rigidly specified policies that could constrain the flexible use of good judgment. It encourages description of events warranting disclosure, the process steps and personnel who should be involved, the content that should be included in the discussions with patients, and the follow-up steps and documentation that is necessary to resolve the situation satisfactorily.
CONCLUSIONS/RECOMMENDATIONS: Organizations are encouraged to create disclosure policies that are consistent with their values, embed disclosure in a broader expectation about good clinician-patient communication and which give sufficient direction to staff while allowing flexibility to achieve the best result for all involved.

American Society for Healthcare Risk Management (February, 2004). **Disclosure: what works now and what can work even better. The third monograph in a series of three parts addressing the communication and disclosure of unanticipated medical outcomes.** *ASHRM*. Copies available at www.ashrm.org

DESCRIPTION OF CONTEXT: The monograph is intended as a communications guide for healthcare staff who will be involved in thinking through and communicating with patients and families about unanticipated adverse outcomes in various clinical settings.
DESCRIPTION OF CONTENT: It describes the new expectations of disclosure, the goals of effective communication, provides hopeful data about the potential for open disclosure to reduce rather than increase liability costs and finally describes the specific steps in a skill based model for disclosure.
CONCLUSIONS/RECOMMENDATIONS: An open and honest approach is recommended at the outset of a disappointing outcome. Encouraging evidence is cited that honest disclosure will serve to decrease rather than increase the organization's overall liability costs.

Baker GR et al. (2004). **The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada.** *CMAJ*, 170;(11):1678-1686.

OBJECTIVES: To estimate the incidence of preventable adverse events among patients in Canadian acute-care hospitals.
DESIGN: Retrospective review of charts of discharged patients where an unintended outcome was perceived to have occurred.
Subjects: Four hospitals of varying sizes were selected from each of five provinces for review of randomly selected charts of discharges occurring during fiscal year 2000 (with the exclusion of psychiatric and obstetrical cases).
MEASURES: In stage 1, cases were screened for the possibility of one or more adverse events. In stage 2 physicians reviewed the charts selected by the screening criteria to determine the presence of unintended injuries or complications caused by medical care and the likelihood of their preventability. The methodology chosen was adapted from that used in previous studies in United States and Australia to determine prevalence of adverse events brought on by medical management and its preventability.
RESULTS: The overall rate of adverse events in Canadian hospital patients was estimated to be 7.5%, 36.9% of which were calculated to the highly preventable. The rate of preventable adverse events across all hospitals was 2.8% and the rate of deaths from preventable adverse events was .66 %. The adverse event rate in the Canadian study (7.5%, 2.8% of which were determined to be preventable) is difficult to directly compare with those studies in United States, Australia and New Zealand as somewhat different constraints were in place for case inclusion in each of those studies. The U.S. rate of adverse events of 3.7 % in New York study and 2.9% in the Utah/Colorado study applied only to adverse events that occurred and were discovered during the index hospital and the study focused on the more restricted criteria of likely negligence where the Canadian study included adverse events detected after as well as during the index admission and preventability rather than outright negligence was the criteria for inclusion.
CONCLUSIONS: Since the 1999 IOM report in the U.S., Canadians have been anxiously awaiting their own "report card" of the rates of potentially preventable adverse events. In each of the countries studied, the adverse event rates and their likely translation into amounts of injury and deaths per year have indicated that there's great room for improvement. Focus on identifying and disciplining clinicians who were closest to the incidence will not be sufficient to produce the greatest gains in improving patient safety. As a result there will be opportunity for international cooperation and understanding and experimenting with systems changes to improve patient safety.

Banja, J.D. (2005). **Medical errors and medical narcissism.** Jones and Bartlett. Sudbury, MD.

CONTEXT: Author explores observed phenomenon of failure to disclose medical errors despite acknowledged ethical responsibility to do so.
CONTENT: Author asserts that rationalization and avoidance are the psychological defenses used by which healthcare providers to reduce their distress and preserve their self esteem in the face of medical errors. He describes the types of self deception used including euphemistic language, distorting the consequences of disclosure (it will do more harm than good) as well as using lack of clarity about the definition of errors, uncertainty about the probability that the error caused harm and difficulty in allocating responsibility as reasons to justify failure to disclose. Banja places disclosure in the context of patient centered care and patient's rights and notes that understanding and accepting this framework is essential to ethical disclosure. He argues that "medical narcissism" blocks disclosure in part because it distances the clinician from the patient, emphasizes clinician control, leads to an over-focus on disease and treatment and inattention to the person. Medical narcissism reflects an inability to empathize with the patient and instead a strong need to control patient thoughts, feelings and decisions. Banja argues that clinical training for physicians fosters this kind of medical narcissism marked by a failure to connect as people and a remoteness and distance which protects the physician from feeling overwhelmed by patient needs and fears of inadequacy while also making it more likely that the physician will see the medical error situation as one in which they need to be self protective rather than one in which they need to ask for forgiveness.

RECOMMENDATIONS : Clinicians need to adopt a patient centered approach to care which reaffirms patients' rights and clinicians' ethical obligations in light of adverse medical outcomes. Training is needed to include increased clinician self–awareness about tendency to rationalization and avoidance, increased empathic capability and specific communication skills that are modeled and encouraged by institutions and malpractice carriers. Organizations need to clearly define error and how it should be handled. Tort reform is needed to reduce the threat of oversimplified blame and punishment that promotes distance between the interests of clinicians and patients who have been harmed by medical, systems and equipment failures.

Banja JD. (2005). **Does medical error disclosure violate the medical malpractice insurance cooperation clause?** *Advances in Patient Safety*, Vol 3, Fall 2005. From Research to Implementation vol 1-4. AHRQ Publication nos 050021 pages 371-381. Rockville, MD. Access at http://www.ahrq.gov/qual/advances/

CONTEXT: Med mal insurance policies typically contain a "cooperation" clause requiring the insured to cooperate with the insurer's efforts to defend a claim. There has been concern expressed that full disclosure, apology and admitting liability would violate this clause and allow the med mal carrier to refuse to defend and compensate on the claim.
CONTENT: Author reviews legal precedents wherein insurers successfully invoked this clause but shows that there were other factors than the insured's truthful and good faith disclosure of what happened to the claimant that were involved. The author goes on to argue that any cooperation clause's possible prohibition of an admission of liability in instances of medical error disclosure would likely be unenforceable. There are other legal precedents (e.g., US Supreme Court 1898) that prohibit insurers from having policies that undermine "public morals" which in this case could be interpreted to mean that prohibiting honest disclosure would undermine the ethical behavior of the physician involved and undermine the public good as a result.
CONCLUSION/RECOMMENDATION: There is no evidence that an insurance carrier has been able to refuse to defend and pay on a med mal claim for the sole reason that their insured honestly admitted liability in good faith. The fear that this would happen has had an unnecessarily chilling effect on disclosure and the threat needs to be exposed as likely baseless.

Beckman, HB, Markakis KM, et al. (1994). **The doctor-patient relationships and malpractice: Lessons from plaintiff depositions.** *Arch Intern Med*,154(June):1365-1370.

OBJECTIVE: To explore plaintiff depositions to gain insight into issues that prompt malpractice claims.
DESIGN: Retrospective qualitative analysis of a convenience sample of 45 depositions randomly selected from a sample of 67 made available from settled claims between 1985 and 1987.
SETTING: Large metropolitan medical center.
SUBJECTS: Patients who had sought the services of an attorney and provided depositions to the court in medical malpractice cases.
MEASURES: Information extracted included responses to the following questions: "Why are you suing?" and "Did a health professional suggest maloccurrence?"
RESULTS: Relationship problems were identified in 71% of depositions. Four themes emerged: 32% deserting the patient; 29% devaluing patient and/or family views; 26% delivering information poorly; and 13% failing to understand the patient and/or family perspective. 54% of plaintiffs reported that other health professionals suggested maloccurrence. Of these cases, 71% named the post outcome-consulting specialist as the one who suggested maloccurrence.
CONCLUSIONS: The decision to litigate is most often associated with perceived lack of caring and/or collaboration in healthcare delivery. Particular attention needs to be paid to post adverse-event consultant-patient interactions.

Bell SK, Smulowitz PB, Woodward AC, et al. (2012). **Disclosure, apology and offer programs: stakeholders' views of the barriers and strategies for broad implementation.** Milbank Q. 90:682-705.

Some hospital systems have employed a disclosure, apology, and offer strategy for medical errors, with the University of Michigan being the best described. This model includes full disclosure of adverse events, appropriate investigations, implementation of systems to avoid recurrences, and rapid apology and financial compensation when care is deemed unreasonable. Researchers for this study interviewed key stakeholders and found strong support for more widespread implementation of this model, despite a lack of generalizable data. Benefits for both the liability system and patient safety were discussed, along with substantial challenges to implementation. However, none of the barriers described were felt to be insurmountable.

Bell SK, White AA, Yi JC, Yi-Frazier JP, Gallagher TH. (2015). **Transparency when things go wrong: physician attitudes about reporting medical errors to patients, peers and institutions.** *J Patient Saf*, [Epub ahead of print].

Prompt error disclosure to patients and families is the standard of care, despite varying implementation. Reporting errors to the institution and discussing incidents with peers are also recommended safety practices. In this survey study, physicians reported similar attitudes about disclosing to patients, the organization, and peers, suggesting that those who favor transparency do so across the board. Female physicians were more likely to favor transparency compared to male physicians, and academic physicians were more likely to favor transparency than those in private practice. Younger physicians were also more likely to support disclosure, suggesting that attitudes towards error reporting may improve over time.

Berlinger N. (2005). **After the harm.** Johns Hopkins University Press. Baltimore, MD

CONTEXT: Author is an ethicist and director of religions studies. She approaches the problem of disclosure and resolution of medical errors primarily from the perspective of Christian social ethics.
CONTENT: Book covers the sequence from error to forgiveness by considering disclosure, apology and repentance (compensation). Author utilizes narrative ethics in which the stories of physicians, patients and families are examined to understand the dynamics that motivate and affect each party. She focuses on Dietrich Bonhoeffer's "view from below" examining processes from the experience of the victim who must ultimately forgive. From the physician view she takes the position of what affects "truth telling", from full disclosure to concealment. She examines the "hidden curriculum" that communicates attitudes and behaviors to physicians-in-training about how to manage these situations, that has primarily favored self-protectiveness rather than treating the victim's needs for information, compassion and resolution as paramount. While honest examination is encouraged in settings such as morbidity and mortality conferences, little effort is made to explain and ask forgiveness from the patients themselves and often theses settings have protections against disclosure. She offers examples of health systems and malpractice carriers who have adopted full discourse and ethically guided resolution.
CONCLUSION/RECOMMENDATIONS: An ethical perspective can inform healthcare providers in how best to navigate the difficult process from error recognition to forgiveness involving disclosure, apology and fair restitution.

Blendon RJ et al. (2002). **Views of practicing physicians and the public on medical errors.** *NEJM*, 347(24):1933-1940.

OBJECTIVE: To determine the preferences and concerns of lay people and medical professionals re: medical errors.
DESIGN: Survey responses to clinical vignettes.
SUBJECTS: 831 practicing physicians returned surveys and 1207 members of the public participated in telephone interviews.
MEASURES: Participants were asked about their own or family members' experiences with errors as

well as causes and possible solutions to the problem of preventable medical errors. They were also provided a clinical vignette in which an error with injury had occurred and were asked what the consequences should be.
RESULTS: 42 % of the public and 35% of the physicians reported that an error had occurred in their own or a family member's care. Serious health consequences including death, long-term disability and severe pain had been the result of roughly 20% of the errors. In one-third of the situations respondents reported that an apology and explanation had been provided. Both groups assigned the largest proportion of responsibility to the healthcare providers involved rather than to systems or latent/underlying vulnerabilities that would have predisposed individuals to make these errors. Only 5% of physicians and 6% of the public reported that medical errors were one of the most serious problems to be addressed. 65% of the physicians listed one of the following factors as likely contributors to errors; overwork, stress or fatigue on the part of health professionals, failure to work together or communicate as a team, and understaffing of nurses in hospitals. Patients were more punitive than physicians in the recommended responses to medical error, but both supported the use of sanctions against individuals responsible for serious errors. 21 % of physicians and 62 % of the public thought that voluntary reporting systems would be an effective way to identify and reduce error.
CONCLUSIONS: Despite a great deal of publicity at this point (2002) about the problem of medical errors and the fact that a significant number of physicians and the public had experienced medical errors for themselves or family members, neither group views error reduction as a primary priority of health-care system at this point. Both the general public and practicing physicians assigned the bulk of responsibility to individuals rather than system based vulnerabilities, in contrast with current views promoted in safety literature.

Bonacum, Doug et al., (2004) **Communicating About Episodes of Harm to Patients,** IN: Leonard, Michael, et al., Achieving Safe and Reliable Healthcare, Chicago: Health Administration Press, Chapter Six, p.93–112.

CONTEXT: Author is VP for Safety at Kaiser Health Plan and chief sponsor of the program it developed with the Institute for Healthcare Communication on the Communication of Unanticipated Adverse Outcomes.
CONTENT: The author describes the rationale and approach taken by Kaiser in this program which encourages a clear policy and procedures around how to communicate with patients in these situations, that is widely disseminated to clinicians and staff in writing and through training and in which clinicians and administrators are supported to investigate and explain adverse outcomes to patients and families within the context of a "just culture" that does not punish errors but works to create safer systems of care.

Boothman RC. (2006). **Medical justice: making the system work better for patients and doctors.** Testimony before the United States Senate Committee on Health, Education, Labor and Pensions, June 22, 2006. Available from the University of Michigan Health System website.

CONTEXT: Chief Risk Officer for the University of Michigan Health System describes the approach he initiated in 2001 as the newly arrived chief risk officer with 22 years of experience as a med mal defense attorney.
CONTENT: Author states his belief that the chief cause for most patient litigation is "a failure to be accountable when warranted and a reluctance to communicate". He then describes their program of early self-review of adverse outcomes and determination of likely breach of standard of care as cause of patient harm. Their program then involves early disclosure and financial resolution in situations where breach caused harm and vigorous defense of any claims made in situations where the internal review had indicated that the care had been reasonable. The result is a reduction in liability expenses, pending cases, and much more rapid resolution for patients and for the health system and its clinicians. He describes excellent acceptance by the physicians as well as by the attorney's in southern Michigan who now have a much clearer understanding of the merit of claims they might bring and how the University will respond. In situations where the patient and their

attorney file a notice of intent to sue and the University's own review had not revealed a breach of standard they will use the mandatory 6 moths notice to invite the plaintiff to a meeting in which they are transparent about their internal review and ask the plaintiff to reveal the expert review on which they are basing their claim and try to resolve the discrepant viewpoints.
CONCLUSION/RECOMMENDATIONS: The author argues for the dissemination of the U of Mich approach as the most fair and sensible way to address the fair and efficient resolution of adverse outcomes.

Boothman RC. (2006). **University of Michigan Patient Safety Toolkit.** This set of web available publications describes the UM program for early identification and resolution of adverse medical outcomes. Access at: http://www.med.umich.edu/patientsafetytoolkit/overview.htm

Brennan TA, Leape LL, Laird NM, et al. (1991). **Incidence of adverse events and negligence in hospitalized patients.** Results of the Harvard Medical Practice Study I. *NEJM*,324(6):370-376.

OBJECTIVE: To estimate the incidence of adverse events, defined as injuries resulting from medical management, and to further estimate how many resulted from negligent or substandard care.
DESIGN: Retrospective analysis of records of hospital discharges.
SUBJECTS: Review of 30,121 randomly selected discharges from 51 randomly suggested hospital discharges in New York State in 1984.
MEASURES: Records were initially screened by trained nurses and medical records analysts. If screened as positive for injury caused by medical management it was then further independently reviewed by 2 physicians who were trained to identity adverse events caused by negligence. They estimated the degree of disability caused by the injury and whether there was evidence of negligence. And, estimated the number of injuries in the population according to the age and sex of the patient and the specialties of the physicians.
RESULTS: The estimated statewide rate of adverse events was 3.7% and the rate of events due to negligence 1.0%. There was relatively low reliability (agreement) on negligence, which may have biased the results towards an underestimation of negligence in the population of injuries. Specialties had similar rates of negligence although different rates of adverse events. The study could not estimate the number of days of life lost by negligence and a number of the deaths due to medical error may have occurred in patients for whom longer-term survival prospects were already poor.
CONCLUSION: The authors conclude that there is a 1% rate of injury due to negligence in New York Hospitals, a rate high enough to warrant serious attention.

Calman NS. (2001). **No one needs to know: A physician recalls taking part in his first cover-up.** *Health Affairs*, 20(2);243-249.

CONTEXT: Family physician and professor of family medicine tells the story of the first time as a resident he was asked to cover-up the true causes of infection and death in a patient treated by more senior physicians.
CONTENT: He concludes that there are 4 chief barriers to disclosure of errors that cause harm. First is the tacit agreement among physicians that mistakes are an inevitable aspect of practicing medicine and one learns to only discuss errors made by employees or subordinates. Second is the specter of malpractice suits with associated public humiliation and financial consequences. The third barrier is the physician's felt need to move past mistakes to prevent being paralyzed by self-doubt. The fourth barrier is the firewall that has been built between quality assurance activates and public scrutiny which blocks any mechanism for fairly compensating injured patients, rewarding the small minority while leaving most damages unaddressed.
CONCLUSIONS/RECOMMENDATIONS: The author urges the development of a different approach on the part of law and medicine to the reporting and reduction of medical errors and the adequate compensation of those who have been harmed.

Chamberlain CJ, Koniaris LG, Wu AW, Pawlik TM. (2012). **Disclosure of "non-harmful" medical errors and other events: duty to disclose.** *Arch Surg,* 147:282-286.

A critical element in managing medical errors, the duty to disclose, is endorsed as a key safety practice by the National Quality Forum. This commentary focuses on the disclosure of near misses or non-harmful errors, which are situations when providers typically feel less inclined to disclose. The authors offer a working definition of patient harm before providing a compelling discussion that advocates for greater reporting of nonharmful events to patients and to formal reporting systems. Recommendations for how to disclose errors are also shared along with rationale for why an open disclosure approach can lead to improved patient care.

Charles, SC. (1993). **The doctor-patient relationship and medical malpractice litigation.** Bulletin of the Menninger Clinic. Spring;57(2):195-207.

CONTEXT: The author discussed reactions in doctor and patient that may lead to problems in the relationship, the outcome of which may be malpractice litigation.
CONTENT: Charles identified critical events that generate anxiety in patients and may lead to malpractice litigation. These include: the doctor's reaction to a bad outcome and tendency toward self-condemnation which may create misunderstanding and miscommunication with patients at a critical time; the doctor's ability to communicate an appropriate amount of optimism to a patient who is dealing with a poor prognosis; the doctor's ability to balance between the extremes of patient autonomy and physician "paternalism" and move toward a collaborative model of doctor-patient relationship; and the doctor's negative reaction to "hateful" or other difficult patients which may influence the quality of care delivered to the patient.
CONCLUSIONS/RECOMMENDATIONS: In this era of increased litigation and shifting perceptions and demands on the doctor-patient relationship, physicians need to be especially cognizant of how they are interacting with the patient, especially in stressful situations. Physicians should be alert to critical events that generate anxiety in both doctor and patient and thus disrupt the equilibrium which may lead to litigation.

Cole AP, Block L, Wu AW. **On higher ground: ethical reasoning.** *BMJ Qual Saf,* 2013;22:580-585.

Clinicians frequently do not fully disclose errors to patients; lack of training in disclosure practices and fear of malpractice lawsuits are often cited as reasons why clinicians avoid disclosure. This study investigated the role of physicians' personal morality in attitudes toward error disclosure. Internal medicine residents were asked to complete a validated test of ethical reasoning and then to describe how they would disclose an adverse drug event experienced by one of their patients. Although hampered by a low response rate, the study did find that residents with higher ethical reasoning scores were more likely to fully disclose the error, apologize for the error, and acknowledge personal responsibility. In addition to training on disclosure methods, this study implies that ethical training may improve the quality of error disclosure.

Duclos CW, Eichler M, Taylor L et al.(2005). **Patient perspectives of patient-provider communication after adverse events.** *Intl Jour of Qual in Health*, 17(6) 479-186.

OBJECTIVE: Explore patient perspectives of communication with provider after an actual adverse event.
DESIGN/SUBJECTS: 16 patients who had experienced an adverse event agreed to be interviewed in focus groups. These were all patients whose situations were addressed through the "3R's" program of early recognition and no fault compensation that is utilized by the Colorado Physicians Insurance Company.
SUBJECTS/MEASURES: Responses to semi structured discussion questions in 4 focus groups.
RESULTS: Communication with provider after the event determined whether relationship was preserved and whether the patient viewed the error as an "honest mistake" or "negligence". Patents reported physical, emotional and financial trauma as a result of the adverse event. Actual or feared financial consequences of the adverse events in terms of actual costs or disability was a powerful

determinant of the patient's behavior. Most patient's anger was more about the way they were treated after the event than driven by the event itself.
CONCLUSIONS: Communication between patient and provider following the adverse event was crucial in shaping the patient remembered experience of the event and degree of trauma that remained.

Edel EM. (2010). **Increasing patient safety and surgical team communication by using a count/time out board.** *AORN,* 92: 420-424.

Communication and collaboration in patient care settings is vital for promoting the best possible patient outcomes. The counting of sponges, sharps, and instruments, and the surgical time out before the start of any surgical procedure are opportunities for the surgical team to address patient safety risks. Personnel in the surgical services department at St Luke's Episcopal Hospital, Houston, Texas, implemented the use of a hanging, magnetic, dry-erase board that includes the elements of a time out (e.g., patient name and identifiers, procedure, site, allergies) and provides a means to document countable items. The board promotes team awareness of this time out and count information at all times during a procedure. Specific magnets on the count board identify items intentionally packed inside the patient to remind the team of the location of these items when the count is reconciled at the end of the procedure. In addition, a process of obtaining an radiograph of items similar to any missing items assists radiologists in identifying the location of retained surgical items. As a result of implementing both changes, our ability to locate missing items has significantly increased.

Elwy AR, Bokhour BG, Maguire EM, et al. (2014). **Improving healthcare systems disclosures of large-scale events: a Department of Veterans Affairs leadership, policymaker, research and stakeholder partnership.** *J Gen Intern Med*,29(suppl 4):895-903.

This interview study examined how the Veterans Affairs medical centers disclosed large-scale adverse events to stakeholders. These incidents impacted multiple patients and included system failures as well as errors by individuals. Interviews with frontline staff, local leadership, and affected patients and family members examined strengths and weakness of the current disclosure process and elicited input for improvement. All stakeholders reinforced the need for tailored, interactive, multi-modal communication rather than standard mailed letters. While staff expressed the concern that adverse event disclosure led to loss of trust, patients and families stated that despite their initial distress they supported disclosure and follow-up care associated with large-scale adverse events. These findings are consistent with prior studies of error disclosure, but demonstrate a gap in frontline staff understanding of the rationale for disclosure.

Elwy AR, Itani KMF, Bokhour BG, et al. (2016). **Surgeons disclosures of clinical adverse events.** *JAMA Surg*, 2016 Jul 20; [Epub ahead of print].

Even though disclosure of medical errors reduces litigation and patient distress, many providers remain uncomfortable with disclosing and apologizing for errors. In this survey of 67 surgeons across 3 medical centers, most reported prompt disclosure of adverse events. Surgeons who had difficult disclosure conversations experienced more anxiety. These results highlight the continued importance of supporting providers who experience emotional distress after medical errors.

Frenkel DN and CB Liebman. (2004). **Words that heal.** *Ann Intern Med*, 140(6);482-483.

CONTEXT: The authors addressed issues of effective communication following medical error with injury, the role of apology in the process of repairing the damaged relationship, and a likely need to be proactive in offering some form of compensation for the tangible injuries and inconveniences the patient experiences.
CONTENT: The authors emphasize the importance of the complete and effective apology in resolving disputes. They describe research in civil litigation indicating partial apology maybe worse than none at all as it lacks the moral dimension required and therefore can appear insincere and evasive. They also differentiate the tangible from the intangible aspects of injury. Healthcare organizations that are

inclined to accept responsibility, and make full and complete apologies, and offer reasonable compensation proactively appear to be most successful in resolving these disputes with injured customers. The authors comment upon the need for further research re: how best to respond in situations where responsibility for the adverse outcome cannot be clearly established. They acknowledge the concern of attorneys and risk managers that apology in these situations could be interpreted as an acceptance of culpability. Addressing these more ambiguous situations effectively is likely to involve including the patient more fully in the process of understanding the investigation that takes place and how the conclusions were reached.
CONCLUSIONS/RECOMMENDATIONS: The authors expressed concern that physicians and related health-care professionals are too often deficient in the kind of communication skills and attitudes that are likely to restore trust in these situations.

Gallagher TH, Mello MM, Levinson W, et al. (2013). **Talking with patients about other clinicians errors.** *N Engl J Med,* 369:1752-1757.

Physicians are notably loath to fully disclose their own errors, but some progress is being made in this area due to institutional policies supporting error disclosure. This article is intended to foster discussion of an especially thorny issue: how clinicians should approach error disclosure when the error was committed by a colleague. As little prior literature exists regarding this dilemma, the authors emphasize a patient-centered approach that begins with a respectful peer-to-peer conversation and does not shirk the need to fully disclose the error. The importance of institutional support, particularly in establishing a just culture that promotes error disclosure, is also emphasized.

Gallagher TH, Studdert D and Levinson L. (2007). **Disclosing harmful errors to patients**. *N Engl J Med*, 356(26). 2713-2719.

CONTEXT: Studies are reporting high prevalence of errors and concern that there has been a professional ethos of discretion or even cover-up. Pressure from many directions is creating an environment ripe for change.
CONTENT: Authors describe recent sources of guidance and disclosure requirements from JCAHO (2001), National Quality Forum (2006) and state legislatures. Where JCAHO in the US has not compelled admission of error, the NQF (2006) Safe Practice Guideline requires admission of error or system failure if known. The authors go on to describe prominent disclosure programs that have been on-going in the US from hospitals as well as liability carriers.
CONCLUSION/RECOMMENDATIONS: They finish by discussion of future developments with the expectation that full disclosure will be normal in 10 more years. The suggest that some tort reform will need to accompany this change if disclosure is not to bring potentially large increases in system liability costs. This could be true if the existing pool of injured people, who may be unaware of the cause of their injury decided to seek compensation despite skillful disclosure. There are a number of organizations that are reporting lower liability costs with open disclosure but this is far from guaranteed to be the universal experience when there is widespread full disclosure.

Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, and Levinson W. (2003). **Patients' and physicians' attitudes regarding the disclosure of medical errors.** *JAMA*, 289(8);1001-1007.

OBJECTIVES: To determine patients' and physicians' attitudes about error disclosure.
DESIGN: Qualitative analysis of focus group content and responses to case studies.
SUBJECTS: Thirteen focus groups were organized. There were 6 groups of adult patients, 3 groups of combined physicians and patients and 4 groups of academic and community physicians. A total of 52 patients and 46 physicians participated between April and June 2002.
MEASURES/INTERVENTION: Participants were asked to discuss the definition of medical errors and then were asked to consider hypothetical situations involving an error that caused patient injury. One case involved an ICU admission for an insulin dosing error made by staff misreading doctor's handwriting. The second case involved a patient who became hyperkalemic as a result of a physician

not reviewing a lab on the second day of inpatient treatment. The error resulted in the patient experiencing arrhythmias for which treatment was initiated before the hyperkalemia was noted. RESULTS: Patients wanted disclosure of all harmful errors and an apology. They desired information about how the error happened, how the injury/consequences to the patient could be mitigated and how similar errors could be prevented in the future. Physicians agreed that adverse outcomes should be reported but suggested much more care be taken in wording the disclosure to avoid stating that an error had occurred and were concerned that apology would create legal liability. CONCLUSIONS: There was a mismatch between the desire of patients for full disclosure with an apology when an error has caused harm, and the physicians' concern that nothing be said that increased the chance of legal liability. Neither patients nor physicians appear to be getting the kind of emotional support that they need these situations.

Gallagher TH, Garbutt GM, Waterman AD, et al. (2006). **Choosing your words carefully: how physicians would disclose harmful medical errors to patients.** *Arch Intern Med*, 166:1585-1589.

CONTEXT: To describe how physicians would disclose errors to patients
DESIGN: A survey was answered by 2637 physicians and surgeons in the US and Canada. Participants received one of 4 scenarios depicting serious errors that differed by specialty (surgical or medical) and by how obvious the error would be to the patient if not disclosed. Five questions measured what respondents would disclose using scripted statements.
RESULTS: 56% chose statements that mentioned the adverse event but not the error. 42% would explicitly state that an error occurred. How likely the patient was to discover the error on their own affected willingness to acknowledge that an error was made (51% with explicit apparent error and 32% with less apparent error). While surgeons were slightly more likely to disclose that an adverse event had occurred, medical specialists were much more likely to explicitly mention error (58% to surgeons 19%). Canadians physicians (who have lower risk of suit than US physicians) were more likely to acknowledge an error.
CONCLUSIONS/RECOMMENDATIONS: Authors acknowledge that surveys of patients consistently reveal their desire for full disclosure in these situations and this is the position taken by ethicist (AMA code of ethics) and patient advocacy organizations. On the other hand, risk managers and malpractice carriers have traditionally advised limited disclosure and avoidance of disclosing that an error caused the harm. In this study only 42% of physicians explicitly mentioned that an error had occurred, even though they believed that to be the case. The authors encourage the development of more clear standards of behavior and training in order to better meet the stated preference of patients for full disclosure.

Gallagher TH, Waterman AD, Garbutt JM, et al. (2006). **US and Canadian physicians' attitudes and experiences regarding disclosing errors to patients.** *Arch Intern Med,* 166:1605-1611.

CONTEXT: Canadian physicians are only 20% as likely to be sued as US physicians. The authors studied the impact of these different environments on willingness to disclose errors to patients.
DESIGN: 2637 surgeons and medical specialists in the US and Canada completed surveys about their attitudes to disclosure of errors.
RESULTS: Disclosure attitudes and experiences were similar across the 2 countries although Canadian physicians were slightly more likely to disclose. 64% of all physicians reported that errors were a serious problem but only 50% agreed that they were usually the result of system failures (although this is a popular conclusion of error science researchers). 98% endorsed disclosing serious errors to patients and 78% would disclose minor errors with 66% agreeing that error disclosure reduces malpractice risk.
CONCLUSIONS/RECOMMENDATIONS: The authors conclude that significantly different malpractice risk environments did not result in substantially different willingness to disclose errors. They hypothesize that other qualities of medical training and practice contribute to reluctance to disclose despite very high levels of venereal agreement that disclosure should take place. They encourage the medical profession to address barriers to transparency in light of well established ethical obligation to disclose.

Gandhi TK and Lee TH. (2010). **Patient Safety beyond the Hospital**. *NEJM, 363*(11);1001

There are differences in the types of errors (treatment errors predominate in inpatient settings, whereas diagnostic errors do in outpatient settings), the provider-patient relationship (e.g., adherence is more critical in outpatient settings), organizational structure (ambulatory practices tend to lack the infrastructure and expertise to address quality and safety improvement), and regulatory and legislative requirements (e.g., there are staffing ratios and accreditation requirements for hospitals that do not exist for private practices).3 In addition, the signal-to-noise ratio is much lower in outpatient settings: in ambulatory care, a physician may see 100 patients with chest pain before seeing one with an actual myocardial infarction

Hamm G, Kraman SS. (2001). **New standards, new dilemmas - reflections on managing medical mistakes.** *Bioethics Forum*, 17(2);19-25.

CONTEXT: The authors have been responsible for the development and implementation of the full disclosure policy at the Lexington, KY Veterans Medical Center. In this article they describe how their disclosure process has evolved and how it could be duplicated in other medical centers.
CONTENT: When a patient is harmed by an act of negligence or error, medical center management, with the hospital attorney, attempts to avoid the use of litigation through making a full accounting of the facts to the injured party. The disclosure includes apologizing, accepting and stating full responsibility, which is acknowledged to include legal liability, and offering fair compensation. The hospital initiates such discussion even when the patient and family appear unaware of the cause of the injury. The authors describe the favorable record of liability payments and staying out of court that they have achieved in comparison with other VA hospitals. Full disclosure creates a new set of problems that require attention. Attention should be given to supporting providers, acknowledging system contributions to errors, and offering a forum for disclosure that does not overwhelm the responsible providers emotionally. Additionally, there needs to be processes in place for fairly and expeditiously determining when the standard of care had been broached (by bringing in outside peer reviewers), developing consensus among all those involved about what has happened and the ethical and business consensus about what should be done about it. The authors caution that liability should not be accepted until a reasonable medical certainty has been established. Patients and families may need preliminary information that advises them that patient care is being reviewed and they will be given full information when it is available. At the Lexington VA disclosure is seen as an ethical obligation of the institution. As such, the disclosure meeting is lead by the Chief of Staff with medical center counsel present. The responsible clinician(s) are invited but not required to attend. In contrast to Wu and others, they are wary of making the responsible clinician the lead in the disclosure in recognition that these are fragile conversations in which any defensiveness or difficulties in the communication between provider and family could undermine the entire effort. They do not encourage disclosure of near misses. They do appreciate that reports to the National Provider Data Bank may be required and support a consensus model in which the responsible clinicians are accepting their responsibility for the injury and so accepting of the reporting requirements that may arise.
CONCLUSIONS/RECOMMENDATIONS: The article describes a process for recognizing and fully disclosing about injuries caused by medical errors. Openness, a willing to offer compensation and the efficient provision of a process that providers and patients believe is fair and accurate are all part of making this system work and assuring that any liability payments are reasonable and deserved.

Hammami MM, Attalah S, Al Qadire M. (2010). **Which medical error to disclose to patients and by whom? Public preference and perceptions of norm and current practice.** *BMC Med Ethics, 18*;11:17.

BACKGROUND, METHOD AND RESULTS: There is a question of internationally and culturally there is a preference for disclosure of medical errors (ME). In this article, patients in Saudi Arabia were asked for their preferences re disclosure of ME and by whom. Disclosure of near miss medical error (ME) and who should disclose ME to patients continue to be controversial. Further, available

recommendations on disclosure of ME have emerged largely in Western culture; their suitability to Islamic/Arabic culture is not known. Research surveyed 902 individuals attending the outpatient's clinics of a tertiary care hospital in Saudi Arabia. Personal preference and perceptions of norm and current practice regarding which ME to be disclosed (5 options: don't disclose; disclose if associated with major, moderate, or minor harm; disclose near miss) and by whom (6 options: any employee, any physician, at-fault-physician, manager of at-fault-physician, medical director, or chief executive director) were explored. Mean (SD) age of respondents was 33.9 (10) year, 47% were males, 90% Saudis, 37% patients, 49% employed, and 61% with college or higher education. The percentage (95% confidence interval) of respondents who preferred to be informed of harmful ME, of near miss ME, or by at-fault physician were 60.0% (56.8 to 63.2), 35.5% (32.4 to 38.6), and 59.7% (56.5 to 63.0), respectively. Respectively, 68.2% (65.2 to 71.2) and 17.3% (14.7 to 19.8) believed that as currently practiced, harmful ME and near miss ME are disclosed, and 34.0% (30.7 to 37.4) that ME are disclosed by at-fault-physician. Distributions of perception of norm and preference were similar but significantly different from the distribution of perception of current practice ($P < 0.001$). In a forward stepwise regression analysis, older age, female gender, and being healthy predicted preference of disclosure of near miss ME, while younger age and male gender predicted preference of no-disclosure of ME. Female gender also predicted preferring disclosure by the at-fault-physician. CONCLUSIONS: Saudi Arabian patients had a less strong preference for disclosure of medical errors than western patients who typically have expressed a preference ofr disclosure in the 90%+ range compared to overall 60% range in this study with younger men less likely than other groups to prefer disclosure. Also noted were as follows.1) there is a considerable diversity in preferences and perceptions of norm and current practice among respondents regarding which ME to be disclosed and by whom, 2) Distributions of preference and perception of norm were similar but significantly different from the distribution of perception of current practice, 3) most respondents preferred to be informed of ME and by at-fault physician, and 4) one third of respondents preferred to be informed of near-miss ME, with a higher percentage among females, older, and healthy individuals.

Hannawa AF, Shigemoto Y, Little TD. (2016). **Medical errors: disclosure styles, interpersonal forgiveness and outcomes.** *Soc Sci Med*, 156:29-38.

Error disclosure is receiving increased attention as a strategy to improve communication and patient safety. Using video-recorded vignettes with professional actors, this study found patients were more likely to forgive a medical error when the physician showed high nonverbal involvement during disclosure.

Harvard Affiliated Hospitals. (2007). **When things go wrong: responding to adverse events.** MA Coalition for the Prevention of Medical Errors.
http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Literature/WhenThingsGoWrongRespondingtoAdverseEvents.htm

CONTEXT: This is the latest consensus paper of the Harvard-affiliated hospitals on how best to respond when there is an adverse medical outcome.
CONTENT: The paper represents the collaborative effort of a group of clinicians, risk managers, and patients participating from several Harvard teaching hospitals and the Risk Management Foundation. Lucian Leape, MD, Adjunct Professor of Health Policy in the Department of Health Policy and Management at the Harvard School of Public Health, was a leading contributor to the consensus document. The paper recommends a full disclosure when adverse events or medical errors occur, including an apology to the patient.

Harvard Medical Institutions: Risk Management Forum. (2003). **Disclosure of Medical Error.** May 2003, Volume 23, Number 2.

CONTEXT: This issue is devoted to the disclosure of medical errors.
CONTENT: Eight pieces discuss the full range of dimensions including recognition of errors, impact on litigation, and disclosure strategies including the need for skills training. An ethicist, John Banja

writes about self-serving rationalizations that blind providers and risk managers to the ethical responsibility to disclose to patients in these instances. Peggy Popp writes about a mock jury comparison of reactions to a closed case in which there was full disclosure with apology versus incomplete disclosure after medical error caused injury to the patient. The mock jury where there was full disclosure "awarded" much less compensation to the family.
CONCLUSIONS/RECOMMENDATIONS: The series of articles strongly supports open and honest disclosure of injuries caused by error and stresses the importance of sincere apology and recognition that staff need training and support to handle these situations skillfully.

Healthcare Risk Control. **Disclosure of Unanticipated Outcomes.** Plymouth Meeting (PA):ECRI; (January, 2002) . For more information about purchasing the report, contact ECRI's Circulation Department via telephone at (610) 825-6000, ext. 5888; via email at circulation@ecri.org; or via Web services at www.ecri.org.

CONTEXT: This advisory article does a comprehensive job addressing the issues involved in disclosure of unanticipated adverse outcomes.
CONTENT: Topics include summarizing the JCAHO standard that applies, describing risk management attitudes towards disclosure, offering a disclosure checklist for organizations developing policies and procedures in this area, and defining the elements of effective disclosure including the who, when, where, what, why and how of disclosure.
CONCLUSIONS/RECOMMENDATIONS: This white paper recommended that risk managers and organizations accept the implications of the JCAHO standard on disclosure and decide how to meet their obligations constructively rather than view the JCAHO standard as a dangerous intrusion.

Hickson GB, Clayton EW, et al. (1994). **Obstetricians' prior malpractice experience and patients' satisfaction with care.** *JAMA*, 272(20);1583-1587.

OBJECTIVE: To examine the relationship between prior physician malpractice and patients' satisfaction with care.
DESIGN: Survey questionnaire with structured and open-ended questions.
SETTING: Florida obstetricians and their patients.
SUBJECTS: 963 mothers of all stillborn, infant deaths, and random sampling of viable infants drawn from 1987 Florida Vital Statistics were sorted into four groups based on malpractice claims experience of the obstetrician between 1983 and 1986. Physicians who practiced obstetrics for at least 3 years in Florida were classified into four categories according to malpractice history. The four categories included: no claims, high frequency and low pay suits, high frequency and high pay suits, and others (at least one claim).
MEASURES: Responses to closed- and open-ended questions about mothers' perceptions of care they received.
RESULTS: Patients seeing physicians with high frequency and low pay suits were significantly more likely to complain that they felt rushed, never received explanations for tests, and were ignored. Additionally, these patients offered twice as many complaints about their physicians than those seeing physicians who had never been sued. Physician-patient communications problems were the most frequently cited complaints.
CONCLUSIONS: Physicians who have been sued frequently are more often the objects of complaints about the interpersonal care they provide even by their patients who do not sue.

Hickson GB, Clayton EW, et al. (1992). **Factors that prompted families to file malpractice claims following perinatal injuries.** *JAMA*, 67(10);1359-1363.

OBJECTIVE: To identify self-reported reasons that prompt families to file malpractice claims following perinatal injuries.
DESIGN: Survey - Telephone interviews using a questionnaire.
SETTING: Florida obstetricians and their patients.
SUBJECTS: Mothers of infants who experienced permanent injuries or death and had closed

malpractice cases in Florida between 1986 and August 1989. Thirty-five percent of families responded totaling 127 families.
MEASURES: Reasons for filing, families' description of medical event, advice from acquaintances, and quality of physician communication.
RESULTS: Reasons for filing included: 33% advised by knowledgeable acquaintance, 24% recognized a cover-up, 24% needed money, 23% recognized child would have no future; 20% needed information; 19% decided to seek revenge or protect others from harm. Over 33% of families were told by health care professionals that the care provided had caused the child's injuries. Physician-patient communication problems included: 13% physician wouldn't listen, 32% physician wouldn't talk openly, 48% physician attempted to mislead them, and 70 % physician did not warn about long-term neurodevelopmental problems.
CONCLUSIONS: Patients who sue are not a homogeneous group. Communication is an important factor in medical care that cannot be overlooked. Many suits were brought because other health care professionals informed parents of inferior care. Failure to be open with patients was a major motivator for their seeking legal counsel.

Hurst JA. (2011). **Disclosure where do you fit in?** *Nursing*, retrieved from http://www.nso.com/nursing-resources/artcile/290.jsp

Nurses know the value of reporting errors but feel conflicted about disclosing a mistake, according to a recent study in the *Journal of Patient Safety*. Researchers asked nurses about their medical-surgical decision making and learned that nurses have different perceptions of error reporting. Time pressures and whether or not the patient was harmed factored into some nurses' decision making. The nurses also indicated that after reporting an error, they rarely heard about the outcome of reported mistakes. Fear of disciplinary actions and loss of their jobs were other concerns that nurses identified. Authors conclude that doing the right thing: Disclosing an error may not be easy, but ethically it's the right thing to do. Decision to own up to an error is an individual's personal decision, but not divulging an error can put the patient's safety and well-being, as well as other patients' safety and well-being, at risk.

Johnstone MJ and Kanitsaki J. (2006). **The ethics and practical importance of defining, distinguishing and disclosing nursing errors: a discussion paper**. *International Journal of nursing studies*, 43:367-376.

Nurses globally are required and expected to report nursing errors. As is clearly demonstrated in the international literature, fulfilling this requirement is not, however, without risks. In this discussion paper, the notion of 'nursing error', the practical and moral importance of defining, distinguishing and disclosing nursing errors and how a distinct definition of 'nursing error' fits with the new 'system approach' to human-error management in health care are critiqued. Drawing on international literature and two key case exemplars from the USA and Australia, arguments are advanced to support the view that although it is 'right' for nurses to report nursing errors, it will be very difficult for them to do so unless a non-punitive approach to nursing-error management is adopted.

JCAHO. (2015). **Crafting an effective apology: what clinicians need to know.** Joint Commission Perspectives on Patient Safety, Vol 5, Issue 4.

CONTEXT: JCAHO issued its original requirement for informing patients about adverse outcomes in 2001. At that time they left it unclear whether they believed acknowledging causation, error and apology were required parts of their accrediting standard. In this brief publication they start out with the clear statement, "Disclosing mistakes and offering apologies are ethical responsibilities supported by various professional and regulatory organizations, including the Joint Commission and the American Medical Association."
CONTENT: The article then goes on to lay out 7 tips for how to craft and provide an effective apology including planning ahead, practicing as needed beforehand, providing the right information which

includes "an honest and straightforward explanation of the unexpected outcome, an acknowledgement of their suffering and assurance that the adverse event will not happen again."

Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, Rogers MA. (2010). **Liability claims and costs before and after implementation of a medical error disclosure program.** *Ann Intern Med, 17*;153(4):213-21.

BACKGROUND: Since 2001, the University of Michigan Health System (UMHS) has fully disclosed and offered compensation to patients for medical errors.
OBJECTIVE: To compare liability claims and costs before and after implementation of the UMHS disclosure-with-offer program.
DESIGN: Retrospective before–after analysis from 1995 to 2007.
SETTING: Public academic medical center and health system.
PATIENTS: Inpatients and outpatients involved in claims made to UMHS.
RESULTS: After full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100 000 patient encounters (rate ratio [RR], 0.64 [95% CI, 0.44 to 0.95]). The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100 000 patient encounters (RR, 0.35 [CI, 0.22 to 0.58]). Median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Average monthly cost rates decreased for total liability (RR, 0.41 [CI, 0.26 to 0.66]), patient compensation (RR, 0.41 [CI, 0.26 to 0.67]), and non–compensation-related legal costs (RR, 0.39 [CI, 0.22 to 0.67]). Limitations: The study design cannot establish causality. Malpractice claims generally declined in Michigan during the latter part of the study period. The findings might not apply to other health systems, given that UMHS has a closed staff model covered by a captive insurance company and often assumes legal responsibility.
CONCLUSION: The UMHS implemented a program of full disclosure of medical errors with offers of compensation without increasing its total claims and liability costs.

Kachalia A, Shojania KG, Hofer TP, Piotrowski M and Saint S. (2003). **Does full disclosure of medical errors affect malpractice liability: the jury is still out.** *Joint Commission Journal on Quality and Safety*, Vol 29 (10) 503-511).

CONTEXT: This article reviews the literature on the question of how disclosure affects malpractice liability costs.
CONTENT: 5,200 citations were examined resulting in one published study directly relating malpractice liability costs when an open disclosure procedure was in place. That is the Lexington, VA experience described by Kraman et al (1999) reported in this bibliography. Kraman's data show the at VA hospital falling to and remaining in the lowest quartile of total liability costs compared with VA peers who were not doing open disclosure of medical errors. The authors summarize the theoretical advantages and disadvantages of full disclosure of medical errors.
CONCLUSIONS/RECOMMENDATIONS: The authors conclude that there is insufficient evidence to reliably predict the effect of full disclosure of medical errors on total liability costs. They expect that more data will be emerging over the next few years as prominent health systems have made their commitment to open disclosure and will be reporting on their liability experience. As the Kraman article indicates however, full discourse must be accompanied by a willingness to help the family recover from the injury by offering financial and other assistance if liability costs are to be contained through reduced litigation costs and more reasonable financial settlements.

Kirch DG, Boysen PG. (2010). **Changing the culture in medical education to teach patient safety.** *Health Aff (Millwood), 29*(9):1600-4.

In 1999 a seminal Institute of Medicine report estimated that preventable medical errors accounted for 44,000-98,000 patient deaths annually in U.S. hospitals. In response to this problem, the nation's medical schools, teaching hospitals, and health systems recognized that achieving greater patient safety requires more than a brief course in an already crowded medical school curriculum. It requires a fundamental culture change across all phases of medical education. This includes

graduate medical education, which is already teaching the next generation of physicians to approach patient safety in a new way. In this paper the authors explore five factors critical to transforming the culture for patient safety and reflect on one real-world example at the University of North Carolina School of Medicine.

Kolaitis IN, Schinasi DA, Ross LF. **Should medical errors be disclosed to pediatric patients? Pediatricians attitudes towards error disclosure.** *Acad Pediatr*, 16:482-488.

The practice of disclosing errors to patients is considered the standard of care, but many physicians remain uncomfortable with error disclosure. This survey study sought to assess pediatricians' perceptions of error disclosure to patients and their parents. Nearly all respondents reported the importance of disclosure to parents, but only about half supported disclosure to children. Physicians believed that patients aged 12 years or older are developmentally appropriate for disclosure discussions. Respondents endorsed collaboration with parents in choosing to disclose errors to children and believed parents should be present during error disclosure. The broad general support for disclosure in this study suggests that prior work in this area is successfully changing physician culture. Corresponding studies of pediatric patients and parents are needed in order to establish guidelines for error disclosure practices in pediatrics.

Kraman SS, G. Hamm. (1999). **Risk management: Extreme honesty may be the best policy.** *Ann Int Med*, 131(12):963-967.

CONTEXT: Authors argue for a humanistic risk management policy including early injury review, close relationship between hospital and patient, proactive full disclosure to patients who have been injured because of accidents and medical negligence and fair compensation for injuries. They report on their experience at the Lexington, KY VA where they have been pursuing open disclosure since 1987.
CONTENT: Compared with other VA's they have slightly above average number of claims and below average payment per claim, falling in the bottom quartile for total liability costs. They attribute this to the willingness of patients and families to negotiate a fair settlement and the lowered costs of managing claims. With the litigation expenses drastically lowered more of the settlement funds go to the injured party. They compare their experience to the private sector and consider those unique factors in the VA system that may facilitate resolving claims. The Lexington VA is often cited as one of the leaders in the open disclosure movement. Their process starts when the risk management committee identifies a patient injury that may have involved accident or negligence. They then conduct an investigation and if malpractice or substantial error is found that resulted in the loss of patient's function, earning capacity or life, the office of the chief of staff contacts the patient and family and invites them into the medical center for the disclosure. There is an emphasis on regret by the institution and personnel involved, and any corrective action that was taken to prevent similar events from occurring in the future. The committee may make an offer of restitution including offering further care or financial settlement or assistance in filing for disability assistance within the VA system.
CONCLUSION /RECOMMENDATIONS: The authors make it clear that disclosure is a pro-active process of investigation and discussion. It includes recognition that an injured patient and family merit offers of restitution rather than the more typical deny and defend approach that leaves the patient bringing malpractice action through an attorney as the only way to redress their sense of injury and entitlement to compensation.

Lamb RM, Studdert DM, Bohmer R, Berwick DM, Brennan TA. (2003). **Hospital disclosure practices: results of a national survey.** *Health Affairs*, 22(2):73-83.

OBJECTIVES: To investigate how hospitals are dealing with the 2001 JCAHO standard on the disclosure of unanticipated adverse outcomes.
DESIGN: Survey.
SUBJECTS: A survey was sent to a random sample of 500 hospitals from the American Hospital

Association database.
MEASURES: The survey had three sections. One: asking respondents to describe their policies and procedures related to disclosure. Two: inquiring about specifics of hospital's willingness to disclose harm in situations of varying severity and whether the hospital routinely offers compensation or support to the injured patient. Third: participants were asked to respond to four clinical scenarios that mixed elements of injury severity and preventability.
RESULTS: There were 245 usable responses for a completion rate of 51%. At this point in 2002, one third of the hospitals had approved disclosure policies and another half had policies in development. 54% reported that disclosure was routine with 44% reporting disclosure took place some of the time. Sixty-five percent of hospitals reported disclosure in the event of serious injury or death. Disclosure included some of the following elements: an explanation, the fact that investigation would take place, an apology, and an acknowledgment of harm. Only 17% of hospitals indicated that their disclosures routinely include all these elements and few hospitals included an offer to compensate injured patients as a regular part of their disclosure practice. The fear of malpractice litigation was the most frequently cited obstacle to implementing disclosure policies, followed by staff opposition. Hospitals are more likely to disclose non-preventable harms than to disclose preventable harm of any severity.
CONCLUSIONS: The authors conclude that the fear of malpractice suits and the risk of adverse publicity contribute sharply to hospitals' reluctance to disclose adverse outcomes. Despite the majority of the respondents reporting that adverse outcomes causing patient injury are routinely disclosed, the authors noted that the respondents reported considerably fewer disclosures than would be expected on the basis of epidemiological estimates or general rates of iatrogenic injury predicted by the New York and Utah/Colorado studies of medical injuries.

Lambert BL, Centomani NM, Smith KM, et al. (2016). **The "Seven Pillars" response to patient safety incidents: effects on medical liability processes and outcomes.** *Health Serv Res*, [Epub ahead of print].

Research has demonstrated that disclosing errors to patients results in fewer malpractice claims, but such discussions do not always take place. This observational study described the effect of implementing the AHRQ Communication and Optimal Resolution (CANDOR) toolkit, an intervention bundle intended to support error disclosure, at a single health system. The investigators found that incident reports increased, suggesting that more safety problems were identified and reported. Also, the number of malpractice claims, along with their resultant costs, decreased significantly. Using an interrupted time series design, they established that these outcomes persisted more than 7 years after the program was introduced. The authors suggest that such programs can result in significant cost savings to health systems.

Levinson W, Yeung J, Ginsburg S. (2016). **Professionalism: disclosure of medical error.** *JAMA*, 316:764-765.

Disclosing medical errors to patients is essential for maintaining a therapeutic relationship and preventing further harm. This commentary describes a case in which a physician inadvertently used nonsterile instruments to perform procedures on two patients and presents options for what the physician might do next. Recommended best practices for error disclosure include being honest about what happened, explicitly stating that an error occurred, and explaining to the patient any relevant specific information that might be helpful in terms of necessary follow-up. The authors suggest that all errors be formally reviewed to prevent future harm and that health care systems should create an environment that facilitates error reporting.

Kolaitis IN, Schinasi DA, Ross LF. (2016). **Should medical errors be disclosed to pediatric patients? Pediatricians' attitudes toward error disclosure.** *Acad Pediatr*, 16:482-488.

The practice of disclosing errors to patients is considered the standard of care, but many physicians remain uncomfortable with error disclosure. This survey study sought to assess pediatricians'

perceptions of error disclosure to patients and their parents. Nearly all respondents reported the importance of disclosure to parents, but only about half supported disclosure to children. Physicians believed that patients aged 12 years or older are developmentally appropriate for disclosure discussions. Respondents endorsed collaboration with parents in choosing to disclose errors to children and believed parents should be present during error disclosure. The broad general support for disclosure in this study suggests that prior work in this area is successfully changing physician culture. Corresponding studies of pediatric patients and parents are needed in order to establish guidelines for error disclosure practices in pediatrics.

Lazare A. (2004). **On apology.** New York, NY: Oxford University Press.

CONTEXT: Author is respected psychiatrist and chancellor of U Mass School of medicine. He described a long tradition of effective apology as essential to the resolution of wrongs and harms.
CONTENT: Lazare describes the 4 steps of an effective apology i.e., acknowledgement of wrong, description of how wrong occurred, expression of remorse and commitment to prevent recurrence and finally offers of reparation. He uses example from political gaffes, interpersonal disputes and hurts, international incidents and medically induced harm to show how effective and ineffective apologies differ.
CONCLUSION/RECOMMENDATION: Lazare reaffirms the value of a full apology for repairing damaged relationships in light of injury and disappointment.

Lazare A. (2006). **Apology in medical practice: an emerging clinical skill.** *JAMA*, 296(11), 1401-1404.

CONTEXT: Author acknowledges emerging interest in full disclosure of medical errors. He described how effective apology is an essential part of making disclosure constructive.
CONTENT: Author describes an apology as an acknowledgement of responsibility for an offense coupled with an expression of remorse. He described the 4 parts of effective apology, which includes acknowledgement of the offending behavior and validation that the behavior was unacceptable. Next is an explanation of the offense (not to excuse but to help the victim understand the situation). Third is an expression of shame, remorse and promise to prevent recurrence and fourth is reparation. He described how apologies may have their healing impact, including restoration of the victim's damaged self esteem, restoration of power to the victim by humbling of the offended, clear validation that offense and fault occurred, reassurance that there are shared values and therefore trust can be restored about the future of the relationship, and finally reparation to compensate for damages victim experienced through no fault of their own.

Leape LL. (1994). **Error in medicine.** *JAMA*, 272:1851-1857

CONTEXT: The author argues that the error rate in medicine is much higher than that permitted in other safety sensitive industries.
CONTENT: He cites the expectation of infallibility that leaves errors buried and unacknowledged and so does not plan ahead for their reduction in a systematic way. He reports that human errors are inevitable, that punishment only reduces its frank reporting and so prevents efforts to understand, and reduce the potential harm to patients. Human factor research and cognitive psychology offer insights into how and why errors occur. He differentiates slips, small errors in automatic routines made more likely by multitasking and distraction, from mistakes resulting from misapplication of rules and miscalculation or inability to accurately weigh and sort among multiple factor patterns and their implication. He describes the "latent" errors in systems; those aspects of the way work is structured that predisposes individuals to make "active" errors in situations. Examples could be design factors of the equipment, work schedules, communication patterns that inhibit flow of information or are too autocratic to allow input from others. Possible solutions are described for each source of error. Forcing functions could require that necessary steps be completed before an activity (e.g., a prescription being filled) can occur. Reducing distractions and scheduling appropriately and using standardization and checklists or "expert computer systems" could all help

with the weakest aspects of human cognition namely short term memory, planning, and problem solving when multiple factors must be integrated. He compares the aviation and the medical models in terms of the openness to error reporting and the proactive stance of the industry to take evidence of "acute errors" and find and correct the underlying latent errors that make them more likely to occur. Thus corrective action is taken for the industry rather than merely for the individuals involved.
CONCLUSIONS/RECOMMENDATIONS: The author supports the view that, while errors may be expected, we can reduce the harm they cause to patients by building checks and redundancies into our work design. He argues strongly that blaming individuals for errors will not lead to meaningful improvement in patient safety.

Leape, L. (2006). **Full disclosure and apology – an idea whose time has come**. *The Physician Executive*, 16-18.

CONTEXT: Author is one of the most respected researchers on medical errors.
CONTENT: Author lays out the case for full disclosure, apology and reinstitution in the clearest terms. He outlines the ethical as well as the therapeutic reasons for disclosure, noting the trauma experienced by both patients and providers, who are part of harm caused by error and who have not experienced apology and chance for forgiveness. Leape states that appropriate restitution is an essential part of resolution. He gives examples to show that it can be affordable for the healthcare system if a sensitive and timely offer allows compensation to address out of pocket costs and disability in a timely manner.
CONCLUSION/RECOMMENDATIONS: This is a clear and succinct statement of the ethical and therapeutic imperative for full disclosure, apology and timely restitution. Leadership must set expectation, provide support and training and provide early settlements for injured patients in order to make this work.

Lester G W and Smith SG. (1993). **Listening and talking to patients: A remedy for malpractice suits?** *West J Med*,183(3):268-272.

OBJECTIVE: To evaluate the validity of the hypotheses that malpractice suits are influenced by quality of communication between physician and patient and the perception that the physician is at fault for a bad outcome.
DESIGN: Randomized control trial.
SUBJECTS: 160 adults from adult classes at two local community colleges and a volunteer network in Houston, Texas.
INTERVENTIONS: Subjects were assigned to two groups to view a video of a physician-patient interaction. One group saw an interaction with "positive communication behavior" while the other group saw an interaction with "negative communication behaviors". The patient had the same complaint in each video and the diagnosis was the same with identical treatments. Subjects read one of four outcome reports: 1) good outcome, 2) physician not at fault but bad outcome, 3) uncertain if physician at fault but bad outcome, and 4) physician at fault and bad outcome.
MEASURES: After viewing the video and reading one of the four outcomes, subjects completed a questionnaire asking about how professional, caring, friendly, trustworthy, and competent the physician was, severity of outcome, likelihood they would consider the physician negligent, and likelihood they would initiate litigation against the physician as a result.
RESULTS: The use of negative communication behaviors by the physician increased litigious intentions of these study subjects. An increased perception of physician fault for bad results also increased litigious intentions. Uncertainty as to reason for bad outcome also raised litigious feelings.
CONCLUSIONS: Results support the hypothesis that improving the way physicians communicate and better explanation of uncertainty in medicine when bad outcome occurs, without clear fault, can affect the risk of malpractice suits.

Liang, BA and Coulson KM. (2002). **Legal issues in performing patient safety work**. *Nursing Economics,* 20(3).

CONTEXT: The authors review laws and potential legal risks that providers and institutions face in doing patient safety improvement work.
CONTENT: While very supportive of the ethical and professional responsibility to improve patient safety, the authors focus on ways in which potential plaintiffs can get access to information that institutions may now believe is protected from discovery. The authors describe the boundaries of "legal discovery' and "legal privilege". They point out that laws vary among the states in the degree of protection from discovery afforded and federal courts allow even less protection. Usually only information specifically generated by a QA/PR committee is protected from discovery, but protection does not extend to information from an original information source. The general subpoena and testimony process allows ready access to non-members of the QA/PR, and to documents created in the normal course of business including personnel, administrative and other hospital records potentially including incident reports. Attorney-client privilege is also potentially weaker than one would expect. Error and safety information that must be reported to 3rd parties (e.g., Dept of Health, JCAHO) has gone beyond attorney client privilege and may be discoverable directly or through the Freedom of Information Act. The defendants may wish to utilize "protected information" in their defense. Disclosure of any of the error analysis by any of these parties would break the privilege. Using patient safety information for any purpose other than in the preparation of a defense (e.g., as in service improvement initiatives) undoes the attorney-client privilege as well. The authors discuss the risk that malpractice carriers may object to information being disclosed that impedes their ability to defend a claim, a standard clause in most medical liability insurance policies. This is particularly a risk where full disclosure of adverse outcomes is being encouraged and requires close cooperation between provider/institution and carrier to best preserve the legitimate right to defend a claim while also seeing that the ethical, legal and administrative requirements to inform patients of adverse outcomes is met.
CONCLUSION/RECOMMENDATIONS: The authors conclude that there is less protection for quality assurance activities and information than many organizations believe.

Liebman CB and Hyman CS. (2005). **A mediation skills model to manage disclosure of errors and adverse events to patients.** *Health Affairs, 23*(4);22-32.

In 2002 Pennsylvania became the first state to impose on hospitals a statutory duty to notify patients in writing of a serious event. If the disclosure conversations are carefully planned, properly executed, and responsive to patients' needs, this new requirement creates possible benefits for both patient safety and litigation risk management. This paper describes a model for accomplishing these goals that encourages health care providers to communicate more effectively with patients following an adverse event or medical error, learn from mistakes, respond to the concerns of patients and families after an adverse event, and arrive at a fair and cost-effective resolution of valid claims.

Martinez W, Hickson GB, Miller BM, et al. **Role-modeling and medical error disclosure: a national survey of trainees.** *Acad Med*, 2014;89:482-489.

Although physicians generally support disclosing adverse events, they often choose their words carefully when discussing errors with patients. Since few training programs include formal curricula in error disclosure, most residents and medical students learn these skills through direct observation of senior clinicians. This survey of trainees evaluated the effects of negative and positive role models on their attitudes and behaviors regarding error disclosure. Most trainees had observed a harmful medical error, and the majority reported exposure to positive role models. Poor role models were associated with negative trainee attitudes about disclosure and an increased likelihood of trying to evade responsibility for harmful errors. More than one-third of trainees reported nontransparent behavior in response to a harmful medical error they had made. Addressing the importance of role models in shaping clinicians' future behaviors will be important to advancing full disclosure efforts.

Marx D. (2001). **Patient safety and the "just culture": a primer for healthcare executives.** http://www.mers-tm.net/support/marx_primer.pdf

CONTEXT: Safer healthcare requires a willingness on the part of staff to identify problems so they can be understood and solved. This is unlikely to happen if staff feel threatened with discipline for errors that were made with good intentions and perhaps made more likely by the latent vulnerabilities built into their systems and procedures such as staffing, design and equipment.
CONTENT: This paper describes a way of thinking about error that differentiates situations in which accountability is appropriate but discipline is inappropriate in light of the good intentions of the staff involved. It addresses mitigating circumstances that influenced/made certain kinds of errors and procedural work-arounds more likely. Marx goes on to lay out a rationale and a matrix for determining when discipline is necessary and how to create a system where staff are willing to identify and report errors and unsafe conditions in need of improvement. He divides these situations into 4 categories: human error (unintentional), negligence, (should have been aware that behavior fell below expected standard and could cause harm) intentional rule violations (often accepted work-arounds in the workplace yet knowing violations of rules/required practices, and reckless conduct (conscious disregard). These behavioral categories are presented here because they are the principal labels we use socially, and legally, to describe blameworthy conduct. Marx describes how these categories can help to determine when discipline appropriate and when discipline will merely drive reporting underground and make unsafe practices less easy to detect and correct.

Mazor KM, et al. (2004). **The health plan members' views about disclosure of medical errors.** *Ann Intern Med*, 140 (6):409-418.

OBJECTIVES: To determine how the kind of error, the severity of the clinical outcome, and the extent of disclosure affect patients' responses to both the error and its disclosure.
DESIGN: Survey response to clinical vignettes.
SUBJECTS: 1500 adult members of a New England based health plan were mailed one of eight versions of a questionnaire.
INTERVENTION: None.
MEASURES: Vignettes described: 1) a medical error (failure to check for medication allergy or inadequate monitoring of a medication); 2) a clinical outcome that was either life-threatening or less serious; and 3) patient-physician conversation that included either full disclosure (accepting responsibility and apologizing) or limited or non-disclosure (expressions of regret without fully accepting responsibility or offering a clear apology). Dependent measurements included: the likelihood of changing physicians, seeking legal action, ratings of patient satisfaction, changes in the amount of trust in the physician, emotional reaction to the clinical vignettes and the subsequent doctor- patient dialogue, and respondents' overall views on medical error and the disclosure of medical errors.
RESULTS: Open disclosure by the physician reduced the likelihood of changing physicians, increased patient satisfaction and trust and produced more positive emotional responses. In only one scenario however, did the full disclosure reduce the likelihood of seeking legal advice. 98.8% preferred to be informed about errors, and 83% favored financial compensation if harm occurred that was directly related to an error.
CONCLUSION: While patients are likely to respond more positively to doctors who were willing to openly disclose medical errors, their desire to seek legal advice may not be reduced despite full disclosure. One likely explanation described in the article relates to the absence of any offer of financial compensation or other assistance in recovering from injury that the physician is acknowledging was caused by error. It appears likely that the more significantly patient is injured by a medical error the more entitled they feel to offers of compensation and assistance in the recovery process and full disclosure alone without these offers will not be sufficient to prevent legal action.

Mazor K, Roblin DW, Greene SM, Fouayzi H, Gallagher TH. (2016). **Primary care physicians' willingness to disclose oncology errors involving multiple providers to patients.** *BMJ Qual Saf* 2016, 25:787-795.

Despite widespread calls for full disclosure of medical errors, physicians often choose their words carefully rather than explicitly detail how errors may have occurred. This study used two hypothetical vignettes to explore primary care providers' willingness to disclose errors involving multiple providers. The first vignette included a diagnosis of breast cancer that may have been delayed due to miscommunication with a covering physician. The second vignette described a breakdown in care coordination between providers responding to a patient's telephone call concerns, resulting in an adverse outcome. The majority of respondents said they would provide only a partial disclosure in either situation. More than three-quarters of physicians in the breast cancer case said they would offer either no information or would make vague references to miscommunication.

Mazor KM, et al. (2006). **Disclosure of medical errors: what factors influence how patients respond?** *J Gen Intern Med*, 21(7):704-710.

OBJECTIVES: To determine whether full disclosure, an existing positive physician-patient relationship, an offer to waive associated costs, and the severity of the clinical outcome influences the patients' responses to medical errors.
SUBJECTS: 407 health plan members.
DESIGN: Subjects were randomly assigned to experimental condition in which they viewed video depictions of 2 medical errors (overlooking an allergy to penicillin-type antibiotic and failing monitor an anti-epileptic medication adequately) and full and partial disclosure. Conditions varied in type of medical error, level of disclosure, reference to prior positive physician-patient relationship, an offer to waive costs , and severity of outcome (life-threatening vs. less severe). 16 versions if the video scenarios were utilized to create the different conditions. Each subject viewed only one version.
RESULTS: Non-disclosure increased the likelihood of changing physicians and reduced satisfaction and trust in both error conditions. Nondisclosure increased the likelihood of seeking legal advice and was associated with a more negative emotional response in the missed allergy error condition, but did not have a statistically significant impact on seeking legal advice or emotional response in the monitoring error condition. Neither the existence of a positive relationship nor an offer to waive costs had a statistically significant impact. Overall, full disclosure had either positive or no impact on patient and family members. There was no evidence that it increased the risk of negative consequences for the physician. In contrast to previous literature (Kraman and Hamm Lexington VA reports), the offer to waive fees did not improve the subject's reaction to the situation.
RECOMMENDATIONS: Study provides evidence that full disclosure is likely to have positive effect or no effect on how patients respond to medical errors. Severity of clinical impact affects likelihood of changing physicians and seeking legal advice. Impact of existing positive physician patient-relationship or waiving fees associated with the cost remains inconclusive in this study. Both these lasts results are counter to previous research and need further exploration. It may be that waiving fees is insufficient when harm has occurred, raising the idea of financial consequences but not adequately addressing patients entitlement to more compensation of some kind for other consequences of the harm they have experienced.

McLennan SR, Diebold M, Rich LE, Elger BS. (2016). **Nurses' perspectives regarding the disclosure of errors to patients: a qualitative study.** *Int J Nurs Stud*, 54:16-22.

In this qualitative interview study, most nurses believed that errors should be disclosed to patients, but few of them reported actually disclosing errors. Barriers to error disclosure included insufficient training, lack of organizational support, and personal fears. These findings are consistent with prior studies of physicians and underscore the difficulty in making error disclosure the standard of care.

Mehtsun WT et al. (2012). **Surgical never events in the United States.** Surgery. Published online December 28, 2012. http://www.surgjournal.com/article/S0039-6060(12)00623-X/fulltext

BACKGROUND: Surgical never events are being used increasingly as quality metrics in health care in the United States. However, little is known about their costs to the health care system, the outcomes of patients, or the characteristics of the providers involved. We designed a study to describe the number and magnitude of paid malpractice claims for surgical never events, as well as associated patient and provider characteristics.
METHODS: We used the National Practitioner Data Bank, a federal repository of medical malpractice claims, to identify malpractice settlements and judgments of surgical never events, including retained foreign bodies, wrong-site, wrong-patient, and wrong-procedure surgery. Payment amounts, patient outcomes, and provider characteristics were evaluated.
RESULTS: We identified a total of 9,744 paid malpractice settlement and judgments for surgical never events occurring between 1990 and 2010. Malpractice payments for surgical never events totaled $1.3 billion. Mortality occurred in 6.6% of patients, permanent injury in 32.9%, and temporary injury in 59.2%. Based on literature rates of surgical adverse events resulting in paid malpractice claims, we estimated that 4,082 surgical never event claims occur each year in the United States. Increased payments were associated with severe patient outcomes and claims involving a physician with multiple malpractice reports. Of physicians named in a surgical never event claim, 12.4% were later named in at least 1 future surgical never event claim.
CONCLUSION: Surgical never events are costly to the health care system and are associated with serious harm to patients. Patient and provider characteristics may help to guide prevention strategies.

Miller N. (2016). **Pathologists, patients and diagnostic errors-part1 and part 2.** *The Pathologist*, (20):18-29; (21):18-33.

In light of the growing focus on diagnostic errors, this magazine series reports on unique challenges that pathologists face when they discover potential errors. The first article in the series discusses how pathologists may experience barriers to disclosure including feeling shame in disclosing their own error, discomfort with raising concerns about a colleague who has misdiagnosed a patient, and lack of direct relationships with patients. The second article expands the discussion to focus on how industry support of open transparency can enable pathologists to participate in reporting and disclosure activities.

Morath J and Hart T. (2016). **Partnering with families: disclosure and trust.** White paper available from Children's Hospitals and Clinics of Minneapolis. 2525 Chicago Ave. S. Minneapolis, MN 55404.

CONTEXT: Authors are the chief operating officer and medical director of Children's Hospital and Clinics of Minneapolis. This organization has been a leader in patient safety, just culture, open disclosure, apology and rapid resolution of adverse outcomes in its facilities. The authors describe the approach, the rationale and their experience to date.
CONTENT: When adverse outcome occurs(which they prefer to call accident), the organization reports the results of its investigation, the steps taken to prevent a recurrence for any other patient and, when error is involved, removes any charges immediately from the patient's account. They also promise to assist the family in obtaining compensation if actual damages warrant. Staff involved who promptly report the accident and were not involved in intentional acts of malfeasance are promised that they will not be subject to retaliation and will receive the organization's support in all matters related to the accident.
CONCLUSION/RECOMMENDATIONS: The authors conclude that disclosure is a integral part of a commitment to patient safety that includes fairness to staff involved and assistance families who have been affected by medical accidents involving error.

Moskop JC, Geiderman JM, Hobgood CD, Larkin GL. (2006). **Emergency physicians and disclosure of medical errors.** *Ann Emerg Med*, 48(5):523-531.

Error in medicine is a subject of continuing interest among physicians, patients, policymakers, and the general public. This article examines the issue of disclosure of medical errors in the context of emergency medicine. It reviews the concept of medical error; proposes the professional duty of truthfulness as a justification for error disclosure; examines barriers to error disclosure posed by health care systems, patients, physicians, and the law; suggests system changes to address the issue of medical error; offers practical guidelines to promote the practice of error disclosure; and discusses the issue of disclosure of errors made by another physician

Murtagh L, Gallagher TH, Andrew P, Mello MM. (2012). **Disclosure and resolution programs that include generous compensation offers may prompt a complex patient response.** *Health Affairs*, Vol 31 No. 12:2681-2689.

CONTEXT: Under "disclosure-and-resolution" programs, health systems disclose adverse events to affected patients and their families; apologize; and, where appropriate, offer compensation. Early adopters of this approach have reported reduced liability costs, but the extent to which these results stem from effective disclosure and apology practices, versus compensation offers, is unknown.
METHOD: Using survey vignettes, they examined the effects of different compensation offers on individuals' responses to disclosures of medical errors compared to explanation and apology alone.
RESULTS: Their results show that although two-thirds of these individuals desired compensation offers, increasing the offer amount did not improve key outcomes. Full-compensation offers did not decrease the likelihood of seeking legal advice and increased the likelihood that people perceived the disclosure and apology as motivated by providers' desire to avoid litigation. Hospitals, physicians, and malpractice insurers should consider this complex interplay as they implement similar initiatives. They may benefit from separating disclosure conversations and compensation offers and from excluding physicians from compensation discussions.

Nazione S and Pace K. (2015). **An experimental study of medical error explanations: do apology, empathy, corrective actions, and compensation alter intentions and attitudes*?*** *J Health Commun*, 20:1422-1432.

This simulation study of the disclosure process following a medical error demonstrates the importance of perceived empathy in patient feelings of anger, desire for compensation, and behavioral intentions toward the physician. This study also confirms the role of error severity in the decision to seek compensation, consistent with prior studies of medical malpractice.

O'Connell D and Reifsteck SW. (2004). **Disclosing unexpected outcomes and medical error.** *J Med Pract Management*, 317-323.

CONTEXT: The article outlines a suggested educational approach for organizations and clinicians interested in developing their skills in interacting constructively in situations where there has been an unexpected adverse outcome, including those situations where investigation has indicated that a medical or systems error was responsible for the injury.
CONTENTS: Clinicians and organizations are encouraged to proactively address questions such as, "What do their patients and families expect from them in these situations?" and "What do their medical groups, malpractice carrier, health-care institutions and the legal system consider in determining an appropriate response?" The authors describe the range of reasons why patients and families may be disappointed with the outcome of care and how they can be understood and addressed. They describe what can be done before, during and after a potentially disappointing outcome to increase the chances that the situation can be resolved sensitively, ethically, and equitably in the eyes of all parties. The authors encourage clinicians and organizations to rethink the appropriate role of legally protected venues (i.e., quality assurance and peer review committees) so they are not misused to conceal from the patient facts that relate directly to their injury. The public is now much more sophisticated about the extent to which individual medical and systems errors

and equipment failures cause injury and has a much wider array of information sources from which to launch their own investigation should they feel that health-care providers are withholding crucial information from them. There is a large and active plaintiff's bar that is aggressively marketing to individuals who feel they have been wronged by the health-care system. The article frames patients' motivation to seek legal advice in the context of their perceived needs to protect their personal financial security, to assure fairness and equity, and to counter the blows to their self-esteem that can come both from medical injury and insensitive response to the injury that health-care system.
CONCLUSIONS/RECOMMENDATIONS: The authors recommend an open and honest approach to disclosure of adverse outcomes. To address this, the authors encourage discussion in which patients and families' questions are elicited and answered and where disputes about facts and interpretations are referred to mutually agreed upon the third parties for review. Where an injury is clearly caused by individual or systems errors a proactive offer of assistance (including compensation) before the upset patient has turned to a plaintiff's attorney may enable the situation to be resolved satisfactorily in the patient-family-provider–organization relationship.

O'Connell D, MK White, FW Platt. (2003) **Disclosing unanticipated outcomes and medical errors.** *JCOM,* 10 (1): 25-29.

CONTEXT: The article describes the rationale for increased openness with patients and families when there has been an unanticipated adverse outcome and offers strategies for approaching these situations in the most constructive manner for all involved.
CONTENT: The authors address the 2001 JCAHO standard requiring disclosure of unanticipated outcomes and point out that it builds on existing statements of ethical obligation by the AMA and ACP with regard to physicians' responsibility to forthrightly advise their patients and their representatives about errors that have caused injury. They acknowledge that the malpractice liability situation has been a significant deterrent to full disclosure in these situations. They further conclude that physicians and institutions need guidance in how to effectively fulfill their obligations to patients in a manner that offers hope of also reducing the likelihood that malpractice litigation will result. It is not uncommon for patients and families to experience unanticipated disappointing outcomes and have trouble differentiating those caused by medical errors and those that occur even when care has met the standard. They recommend that clinicians and institutions work with patient expectations before, during and after potentially disappointing outcomes occur in order to develop and preserve a constructive relationship that can best support honest disclosure when adverse outcomes result. They offer specific strategies and language for approaching disclosure situations where error has contributed to injury as well as in situations where the adverse outcome was not the result of a deviation from the standard of care.
CONCLUSIONS/RECOMMENDATIONS: The authors encourage healthcare providers to elicit, clarify and correct patient expectations, to share decision making about risks as well as benefits and to whole heartedly attempt to work through disappointments and disputes with patients and families to reduce their perceived need to go outside the clinician-patient relationship to get answers and satisfaction.

O'Connell D and Keller VF. (1999). **Communication: A Risk Management Tool.** *JCOM*, 6*(,1);35-38.*

CONTEXT: This article describes the roles that patient's and family's expect clinicians to fulfill and how failure to fulfill these roles adequately affects their motivation to initiate a malpractice action in the face of a disappointing medical outcome.
CONTENT: Patients and families expect that the physician will assume both technical and human roles in their care. Technical roles include that of "scientist" and "artisan". The "scientist" role involves systematically gathering, analyzing and sorting through scientific information to diagnose and treat their condition most effectively. While patients are rarely experts in the science itself, they do feel able to judge the coherence, thoroughness, logic and consistency with information they have obtained from other sources. The "artisan" role includes the non-verbal skills that the patient can observe or infer when procedures are performed (both complex procedures as well as simple ones like the physical exam). The "human" role includes those of "companion" and "champion". The

"companion" role involves the patient's impression of the physician's ability and willingness to understand their thoughts, feelings and needs about the medical care, and to maintain a consistent availability and attentiveness that they feel matches the urgency of their need. The "champion" role refers to the clinician's willingness to advocate for the patient with staff, colleagues and health plans to get the care that the patient feels is needed.
CONCLUSIONS/RECOMMENDATIONS: The authors emphasize that the clinicians needs the benefit of the doubt from the patients and families that they are competent and committed in each of these areas in order to reduce the motivation to go outside the relationship to get satisfaction when there is a disappointing medical outcome.

Penchansky R and Macnee C. (1994). **Initiation of medical malpractice suits: a conceptualization and test.** *Medical Care*, 32(8):813-31.

OBJECTIVES: To explore the relationship between specific characteristics of patient, doctor, injury and doctor-patient relationship and the initiation of malpractice suits.
DESIGN: Survey of attorneys.
SUBJECTS: Attorneys from three states who are active in medical practice law.
MEASURES: Three medical outcomes were described to the surveyed attorneys who were asked to rate the likelihood of a successful legal settlement or outcome in a malpractice claim; probable size of an award or settlement; and the patient's willingness to pursue a malpractice claim. Four independent variables in the study were: patient characteristics, characteristics of the injury, physician characteristics and doctor-patient relationship.
RESULTS: Injury and doctor-patient relationship variables were perceived to have greater affects on the three outcomes than patient or physician variables. Among the doctor-patient relationship variables, three are perceived to substantially decrease the patient's willingness to sue: (1) the physician had provided care for many years; (2) the physician has managed major medical problems for the patient; and (3) the physician explained diagnosis and treatment and was responsive to questions.
CONCLUSIONS: The emphasis in much of the literature on the importance of the doctor-patient relationship is supported by these attorneys' perceptions.

Quill TE, Arnold RM and Platt F. (2001). **I wish things were different: Expressing wishes in response to loss, futility and unrealistic hopes.** *Ann Intern Med*, 135(7) 551-555.

CONTEXT: Situations that evoke loss, guilt or hopeless are hard for physicians to respond to empathically. Many adverse medical outcomes occur when the care was reasonable but the physician still needs to respond empathically without implying error occurred.
CONTENT: The author express concern that the statement beginning "I'm sorry this happened to you." Can be misinterpreted as pity, and be confused with an apology for wrongdoing. Instead they explore the utility of substituting the phrasing "I wish …" to address the need for an empathic response in these situations. Examples include: "I wish I could promise you that." "I wish there was a way to predict who will have side effects to these medications." "I wish that medicine had better answers." "I wish I had some other kind of news to give you." "I wish this complication had not happened to you." "I too wish we had been able to do more for your mother."
CONCLUSIONS/RECOMMENDATIONS: The authors show the language of "I wish…" can humanize those situations where the patient's desires cannot be met and loss must be worked through without implying something more could have been done to avert the disappointment.

Raemer DB, Locke S, Walzer TB, Gardner R, Baer L, Simon R. (2016). **Rapid learning of adverse event disclosure and apology.** *J Patient Saf*, 12:140-147.

Obstetricians and labor nurses who were given a best practices guideline performed better in a standardized disclosure and apology discussion simulation than colleagues who were provided as much time as they thought was needed to prepare. Similar cognitive aids may help clinicians faced with disclosing adverse events to patients.

Rathert C and Phillips W. (2010). **Medical error disclosure training: evidence for values-based ethical environments.** *Journal of Business Ethics, 97*:491–503.

Disclosure of medical and errors to patients has been increasingly mandated in the U.S. and Canada. Thus, some health systems are developing formal disclosure policies. The present study examines how disclosure training may impact staff and the organization. We argue that organizations that support ''disclose and apologize'' activities, as opposed to ''deny and defend,'' are demonstrating values-based ethics. Specifically, we hypothesized that when health care clinicians are trained and supported in error disclosure, this may signal a values based ethical environment, and staff may be more committed to the organization. We surveyed 325 clinical care providers employed by a large hospital that had recently begun implementing disclosure policies and training. Disclosure training explained significant variance in perceptions of the ethical environment, and the ethical environment mediated the relationship between disclosure training and organizational commitment. Although this study explored disclosure of medical errors, organizational support for error disclosure is a concept that could be relevant for many types of organizations.

Rowlands A and Steeves R. (2010). **Risk factors associated with incorrect surgical counts**. *AORN J, 92*:410-419.

Ensuring that patients remain free of unintended retained foreign bodies is a primary responsibility of perioperative nurses and surgical technologists. However, these incidents continue to occur despite hospital policies and AORN recommended practice guidelines for their prevention. To provide insight into how incorrect surgical counts occur, researchers conducted a qualitative analysis of the tasks and challenges faced by perioperative nurses and surgical technologists in an academic medical center and a community hospital. Using hermeneutic phenomenological methodology, we identified bad behavior, general chaos, and communication difficulties as problems associated with incorrect surgical counts. As point-of-care providers, perioperative RNs are well poised to identify problematic areas and design systems and processes that protect patients. Perioperative RNs should consider using red rules or a code of conduct as tools for improving the manual counting process. These strategies could be developed in the shared governance council or a perioperative staff-led committee to ensure adherence to AORN standards.

Sage WM, Gallagher TH, Armstrong S, et al. (2014). **How policy makers can smooth the way for communication-and-resolution program.** *Health Aff* (Millwood), 33:11-19.

Communication-and-resolution programs continue to face challenges to implementation despite their demonstrated value. This commentary recommends policy adjustments for legal, payment, and peer review protection to address barriers to implementing such programs and optimize their widespread adoption.

Sage WM and Kersh R eds. (2006). **Medical Malpractice and the U.S. Healthcare System.** Cambridge University Press.

CONTEXT: Editors assemble leading figures in law and medicine to write chapter covering the full range of issues.
CONTENT: This very comprehensive view of the leading thinkers and researchers on the medical malpractice system in the US and its effect on the provision of health care, its costs and practices. The contributors described the current performance of the system for accomplishing its goals of deterrence of errors, compensation for victims and retributive justice. They describe proposals for alternative dispute resolution systems, enterprise liability systems and debate current enthusiasm for caps on damages and other attempts to limit increasing costs and disruption that result.

Shannon S, Foglia MB, Gallagher TH. (2009). **Disclosing errors to patients disclosing: perspectives of registered nurses**. *Jt Comm J Qual Patient Safety*, 35:5-12.

BACKGROUND**:** Disclosure of medical errors has been conceptualized as occurring primarily in the physician-patient dyad. Yet, health care is delivered by interprofessional teams, in which nurses share in the culpability for errors, and hence, in responsibility for disclosure. This study explored nurses' perspectives on disclosure of errors to patients and the organizational factors that influence disclosure.
METHODS**:** Between October 2004 and December 2005, 11 focus groups were conducted with 96 registered nurses practicing in one of four health care organizations in the Puget Sound region of Washington State. Focus groups were analyzed using qualitative content analysis.
FINDINGS**:** Nurses reported routinely independently disclosing nursing errors that did not involve serious harm, but felt the attending physician should lead disclosures when patient harm ad occurred or when errors involved the team. Nurses usually were not involved in the error disclosure discussion among the team to plan for the disclosure or in the actual disclosure, leading to ethically compromising situations in nurses' communication with patients and families. Awareness of existing error disclosure policies was low. Nonetheless, these nurses felt that hospital policies that fostered a collaborative process would be helpful. Nurse managers played a key role in creating a culture of transparency and in being a resource for error disclosures.
DISCUSSION**:** Nurses conceived of the disclosure process as a team event occurring in the context of a complex health care system rather than as a physician-patient conversation. Nurses felt excluded from these discussions, resulting in their use of ethically questionable communication strategies. The findings underscore the need for organizations to adopt a team disclosure process. Health care organizations that integrate the entire health care team into the disclosure process will likely improve the quality of error disclosure.

Sharpe VA and Faden AI. (1998). **Medical Harm: Historical, conceptual and ethical dimensions of iatrogenic illness.** Cambridge University Press. Cambridge, UK.

CONTEXT: Authors intend a broad based effort to understand the causes, impacts and ethical dimension in the healthcare provider-patient relationship of adverse effects of diagnostic and treatment efforts.
CONTENT: Authors examine the evolution of healthcare including the structures in which it is provided and changing expectations for practitioners in terms of technical skills, outcomes, and communication and shared decision making with patients. They trace the development of care models from highly paternalistic to increasingly patient centered and explore the ethical implications in terms of ethical principles of fiduciary responsibility, patient autonomy, beneficence, non-malfescience, and justice. Patient centeredness vs. paternalism is traced through evolving standards of informed consent. Responsibility for and understanding of the causes of adverse medical outcomes is traced from the traditional focus on individual agency through to the more recent acknowledgement of the primacy of systems issues in affecting rates and types of patient harms. The authors consider payment mechanisms and incentives that have existed including the vulnerabilities caused by schemes ranging from full fee for service to managed care. They consider adverse effects of over and underutilization as well as the technical quality of the care delivered and the patient experience in receiving care.
CONCLUSION: The authors support a model of fiduciary responsibility that makes the healthcare provider responsible for adopting an ethical stance with patient that reflects patient centeredness as a primary value in all considerations of potential and actual costs and benefits of treatment decisions. They support the development of evidence-based standards to guide proposed care and evaluate delivered care as the backbone for prospective and retrospective analysis and communication about medical care.

Sheridan S, Conrad N, King S, Dingman J, Denham CR. (2008). **Disclosure through our eyes.** *J Patient Saf*, 4:18-26.

This article relates personal experiences of medical errors and offers a powerful message to providers by discussing how disclosure might have influenced family members healing in the aftermath of these preventable incidents. Each individual has made a substantial contribution to the furtherance of effective disclosure and resolution through lecturing and writing nationally about their personal experiences.

Stanford University Health System. (2007). **PEARL Program.** Contact Jeff Drivers, Director, Stanford University Health System Office of Risk Management for brochure describing this program. Risk Management 651 Serra Street, Room 250 Stanford, CA 94305-6207. (650) 723-4554 or 723-4555.

CONTEXT: Information on the PEARL program for early recognition and resolution of patient harm caused by medical errors and systems failures.
CONTENT: Stanford self-insures its employed physicians and requires that adverse outcomes be handled within the PEARL program. Program involves rapid review of adverse outcomes both internally and through external experts, determines which cases should move towards early resolution/compensation negotiations with full disclosure and apology on behalf of the health system. (The program appears similar to that developed by the University of Michigan Health System: http://www.med.umich.edu/patientsafetytoolkit/overview.htm for description of their program and the positive impact it has made on total liability costs and early claims resolution).

Studdert DM, Mello MM, Gawande AA, et al. (2006). **Claims, errors and compensation payments in medical malpractice litigation.** *NEJM,* 354:2024-2033.

CONTEXT: The authors examine the belief that frivolous claims are common and costly in the malpractice tort system.
METHOD: Trained physicians reviewed a random sample of 1452 closed claims to determine whether a medical injury had occurred and if so whether it was due to a medical error.
RESULTS: 37% of claims did not involve errors and only 16% of those resulted in compensation amounting to about 13-16% of the total liability system cost. 73% of claims that involved error did result in payment averaging $520K. More legitimate claims were denied payment than illegitimate claims received payment. 54% of liability system costs went to administrative/legal expenses, not to claimants.
CONCLUSION: Claims that lack evidence of error are common but most are denied compensation. The administrative costs of the liability system are exorbitant.

Studdert DM, Mello MM and Brennan TA. (2004). **Medical malpractice.** *N Engl J Med*, 350(3). 283-292.

CONTEXT: Authors are physicians and attorneys. They describe the malpractice legal system in the U.S.
CONTENT: Authors outline the framework and goals of the system, which hinges upon a defendant who can show he was owed a duty of care, the standard was breached and injury results. The 3 social goals of the system are to deter unsafe practices, to compensate injured persons and to exact corrective justice. The authors described the evidence that each of these 3 goals is poorly or partially accomplished by the current system. Evidence shows that 4% of patients experience an iatrogenic injury in hospital and around 1% were the result of negligence. Only 1 in 8 of these negligent harms however appear to result in claim and only 1 in 15 result in payment. Crises in terms of availability and cost of malpractice coverage have come in 3 waves since 1970 to some extent stimulated by reduced barriers to filing and winning malpractice suits along with increased recognition of medical errors and the business practices and financing of the liability carriers themselves. They describe the current movement towards transparency and contrast this with the clinicians' fear of malpractice lawsuit and continued insurability. A pool of exiting uninformed patients could lead to a pent up demand for claims and suits if transparency became the norm. They go to described liability reforms including institutional rather than individual liability, caps on damages, healthcare courts and

requiring arbitration as well as no-fault systems where the standard for compensation of an injury is "likely avoidability" rather than proven "negligence".
CONCLUSIONS/RECOMMENDATIONS: Authors express concern that the well-established antagonistic stances of the plaintiff's bar and the healthcare industry could further block meaningful reform although that is desirable and necessary to address failing of current tort system in terms of its stated goals.

Studdert DM, Mello MM, Gawande AA, Bennan TA and Wang YC. (2007). **Disclosure of medical injury to patients: an improbable risk management strategy.** *Health Affairs*, 26(1)215-226.

CONTEXT: Authors are prominent researchers in the area of malpractice claims. They are examining the proposition that full disclosure would reduce claims volume and costs as has been suggested.
DESIGN: Authors use a probability based (Monte Carlo) analysis to estimate the likelihood that full disclosure would increases claims and total costs in situation where all injured patients were given full disclosure. They use previous research that estimated number of injured patients, dividing to those caused by negligence/non-negligence and looking at current rates of claims. They further asked experts to estimate the likelihood that patients would initiate a claim in situations where harm was disclosed and negligence/non-negligence was given as cause.
RESULTS: The authors conclude that it is most likely that claims and total costs would increase in a full disclosure situation. This is primarily because currently more than 8/10 injured patients do not make claims and research has indicated that many are not aware of the true cause of their injuries. As a result, making that pool of injured patients fully aware would have a much large impact on increasing the likelihood of claiming than the estimated impact of disclosure would have on reducing the number of claims or the financial demands of the claimants, even if they were mollified to some extent by the honesty of full disclosure.
RECOMMENDATION: The authors acknowledge that disclosure and appropriate compensation of patients injured by negligent care is ethical required. They warn however, that a substantial increase in claims and costs is the most likely result of full discourse, rather than the currently held too optimistic view reported in the literature based on the experience of the Lexington Veterans Health System. The authors did not include more recent experience at the University of Michigan health System, COPIC liability insurance and others that are also reporting substantial reduction in liability costs with full disclosure. As a result this study suggests that liability costs could rise substantially in full disclosure situation although there is no evidence that this has actually happened and some evidence coming in that reduction in liability costs has actually resulted in those health systems where it has been practiced.

University of Michigan Disclosure Policy and Procedures. (2002). Accessed 2007 at www.med.umich.edu/patientsafetytoolkit/discloure.

CONTEXT: University of Michigan Health System has been a leader in the open disclosure and timely resolution of medical errors with its clinicians, patients and their families.
CONTENT: This document lays out their policy, procedures, rationale, and defines important terms and their implications. It describes fallacies about consequences of disclosure. It describes the levels of harm that require disclosure and specific steps to be taken by clinicians and the organization.
CONCLUSION/RECOMMENDATION: This is one of the best and most useful documents for thinking about and carrying through effective disclosure of medical errors that cause harm.

Studies of errors and adverse events in healthcare: the nature and scale of the problem.

Veterans Health Administration. (2012). **Disclosure of Adverse Events to Patients.** VHA Handbook 1004.08. October 2, 2012.

The Lexington Kentucky Veterans Medical Center, took the lead in the open disclosure an early resolution of adverse medical outcomes in 1987. The entire Veterans Health Administration institutionalized much of their process international policy for the disclosure of adverse events. This document is an excellent summary of the VHA national policy with clear guidance to clinicians and

administrators on the disclosure resolution of adverse outcomes in a wide range of situations. Filled an open disclosure and early resolution remains the essential basis of this updated policy and procedure. DISCLOSURE OF ADVERSE EVENTS: For the purpose of this Handbook, the phrase "disclosure of adverse events" refers to the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. VA recognizes three types of adverse event disclosure. NOTE: Depending on the nature of the adverse event, the disclosure process may involve all three types of disclosure in a step-wise fashion, or may only involve one or two types of disclosure. See paragraphs 6-9 for additional information on the three types of disclosure, including what must be disclosed, by whom, when, and how.

(1) Clinical Disclosure of Adverse Events. Clinical disclosure of adverse events is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care. NOTE: Clinicians may also be involved in communicating information as part of an institutional disclosure or a large-scale disclosure, but this is not considered a clinical disclosure.

2) Institutional Disclosure of Adverse Events. Institutional disclosure of adverse events (sometimes referred to as "administrative disclosure") is a formal process by which facility leader(s) together with clinicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse (see par. 8). NOTE: Facility leaders may also be involved in communicating information as part of a large-scale disclosure, but this is not considered an institutional disclosure.

(3) Large-scale Disclosure of Adverse Events. Large-scale disclosure of adverse events (sometimes referred to as "notification") is a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue. This process also generally includes public notification and direct communication to key stakeholders (see par. 9).

Vincent C, Young M and Phillips A. (1994). **Why do people sue doctors? A study of patients and relatives taking legal action.** *Lancet*, 343(8913):1609-13.

OBJECTIVE: To examine the reasons patients and their relatives take legal action.
DESIGN: Qualitative analyses of survey responses.
SUBJECTS/SETTING: 227 patients and relatives who were taking legal action through five firms of plaintiff medical negligence solicitors. 92 were suing on their own behalf, 72 were relatives, generally of a child and 22 were relatives of patients who died.
MEASURES: Questionnaire about the incident which led to filing the claim, reasons for filing the claim and psychological questions about mood and emotional distress.
RESULTS: Patients and relatives taking legal action were disturbed by the absence of explanations, a lack of honesty and the reluctance to apologize or being treated as neurotic. Where explanations were given, they were seldom thought to be clear or sufficiently informative. In most cases these problems contributed to a decision to take legal action. Four main themes emerged from the analysis of reasons for litigation: (1) standards of care—both patients and relatives wanted to prevent similar incidents in the future; (2) explanation—to know how it happened and why; (3) compensation—for financial losses; and (4) accountability—considering that an individual or organization should be held responsible.
CONCLUSIONS: Much could be done immediately after an incident to meet the needs of patients and prevent litigation. A clear, full, and honest explanation is fundamental. Patients' wishes to prevent future incidents to know that changes have been made should be taken seriously. Where

appropriate, patients could be informed of disciplinary action or re-training of staff to reduce the possibility of recurrence.

Wachter RM. (2010). **Why diagnostic errors don't get any respect--and what can be done about them.** *Health Aff* (Millwood), 29(9):1605-10.

The first decade of the patient safety movement achieved some real gains, focused as it was on adverse events amenable to system-wide solutions, such as infections associated with health care and medication errors. However, diagnostic errors, although common and often serious, have not received comparable attention. They are challenging to measure and less amenable to system-wide solutions. Furthermore, it is difficult to hold hospitals accountable, since diagnostic errors usually result from cognitive mistakes on the part of one or more members of the medical staff. Health information technology, better training, and increasing acknowledgment of the problem hold some promise. As approaches to measuring, preventing, and mitigating harm from diagnostic errors are proven to work, it will be important to integrate these approaches into policy initiatives to improve patient safety.

Waterman AD, Garbutt J, Hazel E, et al. (2007). **The emotional impact of medical errors on practicing physicians in the United States and Canada.** The Joint Commission Journal on Quality and Patient Safety, 32(8):467-476.

CONTENT: Being involved in medical errors can compound the job-related stress many physicians experience. The impact of errors on physicians was examined: A survey completed by 3,171 of the 4,990 eligible physicians in internal medicine, pediatrics, family medicine, and surgery (64% response rate) examined how errors affected five work and life domains. Physicians reported increased anxiety about future errors (61%), loss of confidence (44%), sleeping difficulties (42%), reduced job satisfaction (42%), and harm to their reputation (13%) following errors. Physicians' job-related stress increased when they had been involved with a serious error. However, one third of physicians only involved with near misses also reported increased stress. Physicians were more likely to be distressed after serious errors when they were dissatisfied with error disclosure to patients (odds ratio [OR] = 3.86, confidence interval [CI] = 1.66, 9.00), perceived a greater risk of being sued (OR = .28, CI = 1.50, 3.48), spent greater than 75% time in clinical practice (OR = 2.20, CI = 1.60, 3.01), or were female (OR = 1.91, CI = 1.21, 3.02). Only 10% agreed that health care organizations adequately supported them in coping with error-related stress.
DISCUSSION**:** Many physicians experience significant emotional distress and job-related stress following serious errors and near misses. Organizational resources to support physicians after errors should be improved.

Weber DO. (2006). **Who's sorry now? Special report on patient trust and safety.** *The Physician Executive*.

CONTEXT: The American College of Physician Executives conducted surveys of members and the general public on the question of whether physicians and healthcare organizations should apologize for medical errors.
CONTENT: The author provides numerical data as well as individual comments made by survey participants. More than 25% of general public reported experience in their family with medical error. 90% reported they would be more likely to sue if there was a cover-up although 25% reported considering suing simply to obtain compensation for the harm caused by an error. Only 50% of the 1019 physician executives reported that their organizations are currently encouraging apologies for medical errors. The individual comments reported throughout the piece show the range of feelings of executives re: the role of plaintiff's attorneys in driving claims, the need for tort reform, and their differing acceptance of the ethical and legal requirements for honesty in the face of adverse outcomes vs. their feeling that their physicians and organizations are entitled to be self-protective. Embedded in the article is a case study by Rick Boothman, Director of Risk management for the University of Michigan Health System. He reports on the rationale and success that they have had in

early recognition and resolution of cases where error has caused patient injury coupled with vigorous defense in situations where their own review of care does not find error/negligence. The program has resulted in initial liability cost savings for Uof M and had salutatory benefits on their patient safety program as well.
CONCLUSIONS: More than half of physician executives remain reluctant to encourage apology and full disclosure in the current climate of tort litigation although there has been a substantial movement in this direction I recent years.

Weissman JS, López L, Schneider EC, Epstein AM, Lipsitz S, Weingart SN. (2014). **The association of hospital quality ratings with adverse events.** *Int J Qual Health Care*, 26:129-135.

A recent systematic review found that better patient experiences of care are associated with improved patient safety and quality of care. This survey of more than 2500 adults discharged from 16 hospitals in Massachusetts adds to our understanding of this relationship. Patients who self-reported having experienced an adverse event (AE) while hospitalized rated the overall quality of hospital care lower, but this finding was primarily among patients who did not report that the AE they experienced was explicitly disclosed to them. Among patients who experienced an AE, it appeared that patient satisfaction was highest (and nearly equal to satisfaction of patients with error-free hospitalizations) when the error was disclosed, the patients were engaged in their own care, and discharge was perceived as timely. These findings imply that even when patients experience complications, "service recovery" efforts, such as formal error disclosure programs, can positively affect patients' perceptions of the care quality.

West CP, Huschka MM, Novotny PJ, et al.(2006). **Association of perceived medical errors with resident distress and empathy.** *JAMA*, 296(9); 1071-1078.

OBJECTIVE: Assess the frequency of self-perceived errors by residents and their affect on burnout, quality of life, depression and empathy.
SUBJECTS/MEASURES/DESIGN: 184 residents at the Mayo Clinic completed quarterly surveys of self assessed medical errors and the measures of empathy, burnout, depression and quality of life.
RESULTS: 14.7% of residents reported making a major medical error in the previous quarter. These reports were associated with increased depression, burnout a lower quality of life and decreased feelings of empathy for patients. They were also associated with an increased likelihood of subsequent error.
CONCLUSIONS: Residents frequently perceive themselves as having committed major medical errors and suffer substantial distress as a result. These errors may contribute to the general deadening, burnout and loss of empathy that is reported by many medical residents over the course of their training. Better steps need to be taken to help reduce the number of major errors that reach the patient and to help residents better take steps to resolve these situations emotionally with their patients and within themselves.

Wilson J and McCaffery R. (2005). **Disclosure of Medical Errors to Patients.** *Medsurg Nursing, 14*(5);319-323.

The literature review presented here explores the feelings of patients and healthcare providers regarding the disclosure of medical errors. Findings from these studies illuminate patients' desires for information about medical errors and what they are likely to do with the information once they are informed.

Witman AB, Park DM, Hardin, SB. (1996). **How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting.** *Arch Intern Med*, 156:2565-2569.

OBJECTIVE: To examine patient attitudes about physician errors.
DESIGN: Survey.
SETTING: An academic general internal medicine outpatient clinic.
SUBJECTS: 149 adults responded from among 400 chosen randomly from patients seen in 1993 by

16 general internists at Loma Linda University School of Medicine.
MEASURES: The survey assessed patients attitudes to 3 levels of possible physician mistakes (minor, moderate and severe) and 2 physician responses: disclosure or non-disclosure.
RESULTS: 98% of patients wanted some acknowledgement of even minor mistakes. 14% desired referral to another physician after minor hypothetical mistake and 65% following severe mistake. For both moderate and severe hypothetical error patients were more likely to consider litigation if the physician did not disclose the error. In moderate severity of injury scenarios 12% would sue if informed by physician vs. 20% would sue if physician failed to disclose.
CONCLUSIONS: Patients want physicians to disclose even minor mistakes and doing so may reduce the risk of being sued.

Wolf ZR and Hughes RG. (2008). **Error reporting and disclosure.** Chapter 35. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Hughes RG, Editor. Rockville (MD): Agency for Healthcare Research and Quality. http://www.ahrq.gov/qual/nurseshdbk/docs/WolfZ_ERED.pdf.

An exceptionally thorough chapter with extensive references and table of relevant evidence, which describes reporting of medical errors by nurses and other professionals. The chapter reviews the ethical and legal obligations for disclosure as well as discussing the issues including organizational and personal concerns that create obstacles to disclosure of errors to patients and the underutilization of error reporting systems by nurses and other providers. Good discussion of ethics, reporting systems, current behavior and tie in with patient safety and error reduction.

Wojcieszac D, Banja J, Houck C. (2006). **The Sorry Works Coalition: making the case for full disclosure.** *Jour Qual and Pat Safety*, 32(6): 344-350.

CONTEXT: Sorry Works (http://www.sorryworks.net) is a leading organization promoting full disclosure and early resolution of adverse outcomes involving error.
CONTENT: The author describes the Sorry Works history, rationale and approach and provide evidence for its ethical rightness as well as its effectiveness in reaching reasonable resolutions with patients and families. They use a challenge-response format to address key concerns and objections.

Wu AW, Cavanaugh T, McPhee SJ, Lo B, Micco G. (1997). **To tell the truth: Ethical and practical issues in disclosing medical mistakes to patients.** *J Gen Intern Med*, 12:770-775.

CONTEXT: The authors review the ethical and practical considerations in talking about medical mistakes with patients and their families.
Content: They point out that AMA and ACP ethics manuals have require disclosure of errors to patients when they have significantly affected the care and outcome for the patient. They define a mistake as an act of commission or omission with potentially negative consequences to the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any actual negative consequences. They describe both individual and systems errors while focusing in their article on physician errors that cause significant harm. They described the potential harms and benefits to the patients and the physician. They describe the physician-patient relationship as fiduciary in character, (that is based on trust) and built on the principles of nonmalefescience (first do no harm) beneficence (act in the interests of their patient's health, even if this puts physician's interests at risk), respect for autonomy (frees patients from mistaken beliefs concerning their past, present and future medical conditions, thus enabling them to make informed decisions about future care) and justice (patients are entitled to assistance when they have been harmed by care). They go on to describe practical issues involved in the disclosure of mistakes and barriers to fulfilling this obligation including those situations where the error was made by another treating physician.
CONCLUSIONS/RECOMMENDATIONS: The authors advocate an honest and direct approach to disclosure of adverse outcomes due to medical errors as grounded in longstanding ethical obligations of healthcare providers.

Wu AW. (2000). **Medical error: the second victim.** *BMJ*, 320:726-727.

CONTEXT: Author has researched and written extensively on medical errors and their disclosure.
CONTENT: In this editorial the author describes the healthcare providers as the "second victim" of medical errors who suffers emotionally and often agonizes about what to do. Since error free practice is expected there is no developed norm for talking these situations through, getting support and acceptance of inevitability of error, and assuring that patient is informed and then steps taken to prevent recurrence. Nurses, pharmacists and other clinicians are also vulnerable as both cause and witness to how these situations are handled.
RECOMMENDATION: Physician has ethical obligation to disclose error that causes harm and empathic and apologetic physician is often forgiven by patients. There needs to be a parallel process for discussing with colleagues and creating a pathway for supporting clinicians and coping with mistakes and their consequences.