

What to Do with the Unanticipated Outcome

Does Apologizing Make a Difference?

How Does Early Resolution Impact Settlement Outcome?

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Initiatives that advocate full disclosure and apology to patients who suffer unanticipated outcomes during medical care are gaining momentum. These disclosure initiatives complement the patient safety movement's call for open communication following unanticipated outcomes and medical errors. Although consensus is developing that full disclosure is ethically necessary, many healthcare professionals, risk managers, and malpractice insurers worry that disclosure may increase the likelihood of malpractice lawsuits. Advocates of disclosure; however, point to emerging literature that suggests full disclosure of unanticipated outcomes decreases rather than increases the likelihood of lawsuits, and also highlight other important benefits of full disclosure. In this manuscript we discuss the context in which these calls for full disclosure are taking place; patients' and physicians' attitudes regarding the disclosure of unanticipated outcomes; the impact of disclosure on outcomes; and present a detailed case summary of one large malpractice insurer's experience with an innovative program for disclosure and early settlement following unanticipated outcomes.

I. Context

For decades there has been a general recognition that open communication with patients following unanticipated outcomes is ethically appropriate. Recently, however, there has been increased interest in promoting full disclosure of unanticipated outcomes to patients. This renewed focus on disclosure stems in part from the recognition that less than 50 percent of harmful errors are currently being disclosed to patients (R. J. Blendon, *et al.*, *Views of Practicing Physicians and the Public on Medical Errors*, 347(24) *N Engl J Med.* 1933–40 (Dec 12 2002). In 2001 the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) developed standards requiring that health care organizations communicate with patients and their families about all outcomes of care, including those outcomes of care that were unanticipated (Joint Commission on Accreditation of Health Care Organizations. Revisions to Joint Commission Standards in Support of Patient Safety and Medical Health Care Error Reduction July 1, 2001). Other organizations are also promoting transparency following unanticipated outcomes, including "Sorry Works!," a physician-founded group promoting full disclosure and apology. Senators Clinton and Obama recently introduced legislation that would require patients and their families be informed about medical errors, and provide some legal protections for such disclosure. (The National Medical Error Disclosure and Compensation Act. 2005; S. 1784, 109th Congress, 1st session). While the political prospects for this bill are uncertain, its mere introduction emphasizes awareness of this issue at the highest levels of health policymaking.

This interest in promoting full disclosure has mirrored the emergence of the patient safety movement. Previously, errors in health care were thought to be due to "bad apples," healthcare providers who were either incompetent or lazy. Based on lessons learned about errors and safety in other industries such as aviation and nuclear power, the patient safety movement emphasizes that most errors are due not to incompetent providers but rather to breakdowns in the system of care. Furthermore, the safety movement seeks to diminish the culture of "blame and shame" that has surrounded errors in health care. Blaming errors on incompetent providers creates a strong incentive for healthcare workers to keep information about errors to themselves, which inhibits opportunities to learn from errors and prevent recurrences. Instead, the safety movement encourages greater dialogue among healthcare professionals as well as between healthcare professionals and patients when errors happen.

However, the impact of such disclosure on outcomes is uncertain. While some literature suggests that full disclosure has a positive effect on outcomes such as the likelihood of patients filing malpractice claims, skeptics point out that little prospective or controlled data exists on this topic. There is also relatively little known about how healthcare professionals currently approach disclosure of unanticipated outcomes to patients and whether any specific approach to disclosure has a noticeably better impact on outcomes.

One confusing aspect of this area is terminology. *Unanticipated outcomes*, the term used in the JCAHO standard, simply refers to outcomes of care that are different from those expected by the health care professionals and the patient at the start of the health care intervention. In many respects, the unanticipated outcome language harkens back to the informed consent conversation prior to a procedure, where known complications of the intervention are discussed. A related term is *adverse event*. An adverse event is defined as “an injury that was caused by medical management and that resulted in measurable disability.” Both unanticipated outcome and adverse event refer to the outcomes of care, not the process of care. These outcomes of care do not address whether or not an error has taken place. While the ideal definition for medical error is subject to much disagreement, the most commonly used definition is “the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.” Regarding the relationship between unanticipated outcomes/adverse events and medical errors, it is important to realize that the vast majority of adverse events are not associated with a medical error (*i.e.*, are not preventable), and the vast majority of medical errors are not associated with an adverse event (*i.e.*, do not cause harm).

Current standards for disclosure of unanticipated outcomes mostly follow the JCAHO language. The JCAHO standard states that “patients and, when appropriate, their families are informed of outcomes of care, treatment, and services that have been provided, including unanticipated outcomes.” The standard goes on to clarify that those unanticipated outcomes of care that require disclosure are those that “. . . the patient (or family) must be knowledgeable about to participate in current and future decisions affecting the patient’s care, treatment, and services.” In addition, the standard also requires the disclosure of those sentinel events considered reviewable by JCAHO, a list of specific serious unanticipated outcomes including an unanticipated death or major permanent loss of function, surgery on the wrong individual or wrong body part, and/or a retained foreign body following surgery. Several states also require that unanticipated outcomes be disclosed to patients, with Pennsylvania requiring the disclosure take place in writing. Of note, none of these standards address the specific content of disclosure; in particular, they do not address whether or not the patient needs to be told if the unanticipated outcome was due to an error.

In addition to emerging requirements on disclosure of unanticipated outcomes, many states have adopted or are in the process of adopting laws intended to promote apology. These laws mostly provide protection for expressions of regret from being considered an admission of liability. However, most of these state apology laws do not protect admissions of liability made elsewhere in the disclosure statement. Colorado is a notable exception to this, and protects the entire disclosure conversation from being considered an admission of liability (J. R. Cohen, *Apology and Organizations: Exploring an Example from Medical Practice*, 27(5) *Fordham Urban Law Journal* 1447–82 (2000)).

II. Research Overview

A variety of empiric studies in the last 15 years have explored patients’ and physicians’ attitudes about error disclosure, as well as the impact of disclosure on different outcomes.

A. Patients' Preferences for the Disclosure of Unanticipated Outcomes

Several research studies have explored patients' attitudes about the disclosure of unanticipated outcomes. These studies uniformly find that patients desire the disclosure of harmful medical errors (T. H. Gallagher, *et al.*, *Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors*, 289(8) *JAMA* 1001–07 (Feb. 26, 2003); K. M. Mazor *et al.*, *Health Plan Members' Views about Disclosure of Medical Errors*, 140(6) *Ann Intern Med.* 409–18 (Mar 16 2004)). Following harmful errors, patients want an explicit statement that an error occurred; an apology; and information about what the error was, how it will affect their health, why the error happened, and how recurrences will be prevented. Patients desire disclosure of errors that have caused even minor harm. Little is known about patients' preferences for the disclosure of near misses, *i.e.*, those errors that could have caused harm but did not by chance or timely intervention.

B. Physicians' Attitudes about Disclosure of Unanticipated Outcomes

While physicians agree in general that harmful errors should be disclosed, they experience numerous barriers to disclosure. Fear that disclosure could precipitate a lawsuit is clearly a major barrier to disclosure, but it is not the only barrier (Gallagher, 2003). Many physicians worry that disclosure could actually harm the patient, either by disrupting the therapeutic relationship and making the patient unduly anxious or by decreasing patient compliance. In these situations, physicians worry that disclosure may cause more harm than good to the patient. Another major barrier to disclosure is concern that the conversation would be awkward and uncomfortable, a concern compounded by the fact that many physicians have not had formal training in disclosure. These barriers cause physicians to “choose their words carefully” when talking with patients about errors (Gallagher, 2003). This careful choice of words typically involves mentioning that there was an adverse event but not explicitly stating that the adverse event was due to an error. Research is ongoing to learn more about how physicians would approach disclosure, for example, whether there are significant differences in how physicians from different specialties approach error disclosure, as well as how the nature of the error affects disclosure.

While the literature on patients' and physicians' attitudes about disclosure provides compelling evidence on these basic themes, there are significant gaps in the literature. For example, most prior studies of patients' preferences have involved patients who are not in the acute care setting at that moment. It is not known whether patients' preferences for disclosure change when they become acutely ill. In addition, medico legal concerns have made it difficult to observe actual disclosure conversations.

C. Impact of Disclosure on Outcomes

A variety of studies from different fields provide some insight on the likely impact of disclosure on outcomes. Research in social psychology suggests that a full apology (one that expresses regret; explicitly admits that an error has occurred, and accepts responsibility) tends to promote more rapid dispute resolutions and lower financial awards (J. K. Robbennolt, *Apologies and Legal Settlement: An Empirical Examination*, 102 *Mich Law Rev.* 460–516 (December 2003)). Ongoing studies are examining whether the wording of apologies affects patient outcomes such as intent to sue. Conducting these studies is difficult because patients respond both to the content of the apology as well as the empathy with which it was delivered. However, it is clear that an apology is no panacea, and some patients will still seek legal recourse despite ideal apologies (C. Vincent, *et al.*, *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343(8913) *Lancet.* 1609–13 (Jun 25 1994)).

The broader literature on the relationship between disclosure and litigation emphasizes the fact that transparency is likely to have a positive effect on litigation, though this is not uniformly true. Researchers who have interviewed patients who filed malpractice claims report that the patient's perception that the truth was

hidden from them is an important motivation for filing a suit (G. B. Hickson, *et al.*, *Factors that Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267(10) JAMA 1359–63 (Mar 11 1992); Vincent, 1994). Mock jury studies as well as survey studies have also found that full disclosure reduces patients' intentions to sue and promotes lower jury awards (P. Popp, *How Will Disclosure Affect Future Litigation?* ASHRM Journal 5–14 (Winter 2003)). In addition, anecdotal evidence is accumulating from multiple institutions that adopting a policy of open disclosure does not lead to a major increase in legal risk or expenses (S. S. Kraman, G. Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131(12) Ann Intern Med. 963–67 (Dec 21 1999); L. Tanner, "Sorry" Seen as Magic Word to Avoid Suits, Seattle Post-Intelligencer. November 11, 2002). Taken together, these studies suggest that effective disclosure would have an overall favorable impact on outcomes following errors.

However, there are important caveats to evaluating this evidence. Many legal scholars point out that the vast majority of patients injured by negligent care never sue, and that lack of awareness of the error may be an important contributor to this low rate of litigation (T. A. Brennan, *Relation between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, N Engl J Med. 335(26) 1963–67 (Dec 26 1996). Therefore, it is possible that more open disclosure may actually increase the likelihood of being sued.

Unfortunately, this debate is unlikely to be settled anytime in the near future. No randomized clinical trial data is available about the impact of full disclosure on these outcomes. In the absence of this data, it is reasonable to consider error disclosure to be akin to a clinical intervention, one with a balance of risks and benefits. Overall, the likely impact of disclosure on outcomes is favorable, but individual cases exist where disclosure either fails to prevent or precipitates a lawsuit.

Healthcare organizations and insurers are developing innovative disclosure programs based on this belief that disclosure is both the right thing to do and that it will have a favorable overall impact on their loss experience. Evaluating these programs may provide valuable information about how disclosure affects outcomes. The COPIC insurance company's disclosure program is presented as a detailed case study of such an innovative program below.

III. Case Study: COPIC Insurance Company

COPIC Insurance Company is a physician-run medical malpractice carrier that has served Colorado doctors since the early 1980s. It is one of the Physicians' Insurers Association of America (PIAA) companies, which are sometimes referred to as "bedpan mutuals." These companies are predominantly the products of state medical societies' reaction to malpractice crises in the 1970s, 80s, and early 2000s. COPIC has always devoted enormous resources to a proactive risk management program that employs several full-time physicians and stresses loss prevention activities.

The physician leadership of COPIC has, since inception, been dismayed at the inefficiency, frequent injustices, adversarial nature and failure of the traditional tort system to achieve its goals of protecting the public from medical injury due to negligence and raising the level of overall quality of health care. While working to achieve and maintain one of the country's strongest tort reform packages in Colorado, the COPIC board and staff have been open to alternatives to tort, such as mediation and early intervention strategies. The founding CEO of COPIC, Dr. K. Mason Howard, was a participant in the study of adverse events in Colorado and Utah that was part of the basis for the 2000 Institute of Medicine report *To Err Is Human* (L. T. Kohn, *et al.*, *To Err Is Human: Building a Safer Health System*, Washington, D.C.: National Academy Press; 2000).

This report is largely credited with stimulating the modern patient safety movement. Dr. Howard expressed a desire for a more rational scheme for management and compensation of medical injury, perhaps

using a “no-fault” mechanism. The COPIC Board was reluctant to commit the company’s entire resources to such a program because of the uncertainty of its acceptance but did authorize a pilot program to be administered by the risk management department in late 2000.

The program was designed to address a scenario that COPIC has seen often: a patient experiences an unanticipated adverse outcome that fails to meet the expectations he or she had for healthcare. The attending physician may be in denial about the nature of the unanticipated outcome and communicate minimally or not at all with the patient. The physician/patient relationship disintegrates and the patient typically becomes frustrated in his or her unsuccessful attempts to get information; ultimately the frustration turns to anger and often leads to a medical malpractice claim. COPIC wanted to create a program where early intervention could shortcut this all-too-common chain of events.

The program created was named the “3Rs Program” for “Recognize, Respond, and Resolve.” The concept was to recognize an injury by early incident reporting, respond in a timely fashion, and help to resolve communication, disclosure and monetary issues related to patient injury. Arbitrarily, certain parameters for financial aid were created; \$25,000 was available to cover medical expenses not covered by insurance and \$5,000 to pay for “loss of time” at \$100 per day.

It is important to understand the Colorado liability landscape that allowed COPIC to conceive and implement such an innovative program. Colorado has a solid package of tort reform initiatives, including a \$300,000 non-economic damages cap and an overall \$1,000,000 cap that can only be penetrated for economic damages and only with the approval of the trial judge. COPIC had a dominant market share, estimated at 75–80 percent of the non-military, nonacademic physicians in the state. COPIC’s influence at the state level has led to tort reform and the passage of strong apology legislation in 2003. We have worked closely with our Board of Medical Examiners as well as the Colorado Insurance Commissioner. We have called on all of these relationships in the creation and implementation of the 3Rs program. In addition, we had 20 years of experience with early incident reporting. We have a “reporting form” variant of claims-made insurance; coverage attaches when an occurrence is reported. One can imagine that such a “perfect storm” is not very prevalent in the United States.

From the beginning, the 3Rs program has stressed open, honest communication and the development of the skills needed for disclosure. These skills have not been emphasized in traditional medical training and may well have been frankly discouraged by many in the healthcare system, including malpractice carriers. We have offered seminars, workshops, written materials and real-time risk management consultation to help coach physicians in these situations.

The process is triggered when a physician in the 3Rs program reports an occurrence. Our software flags the doctor as a program participant and the 3Rs administrators review those occurrences. They, in turn, discuss the case with the physician; if there is agreement as to the appropriateness of this intervention, the physician is instructed to contact the patient and describe and offer 3Rs benefits to them, as well as to instruct them to call the 3Rs administrator for processing of payments. Considerable coaching is often required at this stage. Our expectation is that the doctor will explain the injury to the patient, express appropriate concern, apologize, help the patient project future needs and expectations, and answer questions from the patient and their family members. The physician should be prepared to discuss possible changes in future practice to reduce the chance that the adverse event would recur. Often, all the factors that led to injury are not known at the time of this conversation. The patient should be told this and that they will be kept informed as information becomes available.

Certain criteria exclude participation in the 3Rs program, including cases where a death occurred, attorney are involved, a formal written demand for compensation for damages has been made, or a Summons

and Complaint has been issued. Generally, the physician may decline to participate in the 3Rs program for any case in which he/she is uncomfortable with participation.

While a potential subrogation issue may arise when we make payments, the Commissioner of Insurance has told the health insurers to back off of these demands. The payments are considered a “first party” offering rather than a third party insurance payment. We do not pay vendors directly; rather, we reimburse the patient upon presentation of paid receipts. Turnaround time is under a week for these payments. The medical payments are not taxable event but a W-9 tax form is required for loss-of-time payments.

Incentives for physicians to participate in the program include a sense of doing “what is right.” We do offer points in our ERS system, a risk management program that translates into a small premium discount. A very powerful incentive to participate is that payments made under the program are not reportable to the either the National Practitioner Data Bank or the Colorado Board of Medical Examiners. The rationale for this exclusion is that we are not responding to a demand and we do not ask for a waiver or release from the patient. Our Medical Board is fully informed and supportive of this activity.

A. The 3Rs Program: Experiences and Lessons Learned

Currently, over 2300 physicians are enrolled in the program. We have reviewed over 4400 incidents from this group over a five-year period, the vast majority in the past three years. Approximately 1900 of these incidents have met criteria for program participation with payments made to just over 500 of these injured parties. The average payment is \$5,557 with a range from a few dollars to the \$30,000 maximum allowed in the program. The total cost of the program to date, including administrative expense, has been approximately three and a half million dollars.

We have attempted to measure results in several ways. Historically, an incident report to COPIC has about a one in seven chance of becoming a claim file (defined as a lawsuit or a precautionary file as determined by our claims department). Of the 500 cases that the 3Rs program made payments in, ten have progressed to claim files, four of which were lawsuits. Of the 1400 cases that met criteria for 3Rs participation but no payment was made through the program, 31 have become claims, seven as lawsuits. There have been two significant settlements; no case has proceeded to a jury trial.

A review of our experience in 2003 by an outside claims adjuster indicated that the cost of these cases managed in the traditional way would have been two to three times the money actually spent on their resolution in the 3Rs program. An actuarial study of the physician population participating in the program indicated historic loss ratio slightly higher than our entire insured base. Since enrollment, the same cohort has a loss ratio measured at 25 percent more favorable than the rest of our insured doctors.

The physicians enrolled reflect our overall physician demographics with regard to specialty, practice location, age, and gender. The cases reported exhibit a bias toward procedural intervention, perhaps because unexpected outcomes become apparent in the near term when interventions are performed. The injuries are a mix of severity, but are often major. For example, bile duct injuries, severed ureters, and perforation of the colon during colonoscopy are frequent events.

Satisfaction surveys are sent to all physician and patient participants when cases are closed. The comments from both are generally positive. Physicians tend to assess their communication skills more favorably than patients do. Focus groups conducted by a researcher at the University of Colorado identified some common parameters of the trauma experienced by injured parties, including the physical, emotional, and financial aspects. The affect of sustaining the physician/patient relationship on patient perceptions of negligence cannot be overemphasized.

Our plan is to continue to expand this program to our insured doctors on a voluntary basis. Currently, we are recruiting procedural specialists most actively. We are encouraged by the operating results of this pilot program. It is not inherently adversarial, it is timely, payments go directly to injured parties without legal expense, and it often preserves or salvages the physician/patient relationship. We obviously need more experience and statistical validation to fully assess the program and plan to continue to measure results. I personally liken what we are doing to a “mini no-fault” program that compensates those medical injuries that are filtered through our insured physicians. This, in reality, is only a small percentage of medical errors and injuries occurring in U.S. healthcare. There clearly is a need for broader system change that implements such alternatives that are outside the traditional model of medical malpractice.

IV. Conclusion

While full disclosure of unanticipated outcomes to patients is both ethically desirable and increasingly required by accreditation standards and state laws, controversy still exists about how disclosure affects important outcomes, such as malpractice claiming behavior and the patient/physician relationship. Although physicians feel they ought to disclose, they experience many barriers to disclosure, including fear of malpractice and lack of training in how to disclose unanticipated outcomes to patients.

Innovative programs such as the 3Rs program developed by COPIC provide a much-needed alternative to the often-adversarial fault-based malpractice system, which may hinder open communication about unanticipated outcomes. While it is important to note that the 3Rs program is administered in a state where such alternatives are supported by legislation, its preliminary results demonstrate that such programs are generally received positively by both patients and physicians and actually result in a net savings when compared with traditional methods of handling unanticipated outcomes. As calls for open disclosure increase, more programs such as the 3Rs program should be developed and evaluated for their effectiveness.