



Disclosure of Adverse Events in Pediatrics

COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT, COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY

Despite increasing attention to issues of patient safety, preventable adverse events (AEs) continue to occur, causing direct and consequential injuries to patients, families, and health care providers. Pediatricians generally agree that there is an ethical obligation to inform patients and families about preventable AEs and medical errors. Nonetheless, barriers, such as fear of liability, interfere with disclosure regarding preventable AEs. Changes to the legal system, improved communications skills, and carefully developed disclosure policies and programs can improve the quality and frequency of appropriate AE disclosure communications.

INTRODUCTION

Patient safety has been characterized as 1 of the 6 domains of health care quality by the Institute of Medicine (IOM),¹ which attributed 44 000 to 98 000 inpatient deaths annually to medical errors (MEs) in the United States.² The American Academy of Pediatrics has called attention to the importance of pediatric patient safety since 2001³ and recommended improved identification and reporting of MEs and adverse events (AEs) to improve the culture of safety in pediatric care.⁴

The IOM defines “patient safety” as the prevention of patient harm and freedom from accidental injury in the health care setting.⁵ An AE occurs when patient harm is caused by medical care.² A ME is an act of commission or omission that unreasonably increases risk of an undesirable patient outcome. AEs may be determined to be preventable (when patient harm is related to a ME) or nonpreventable (when patient harm occurs in the absence of ME). An ME that causes patient harm becomes a preventable AE. An ME that has the potential to cause patient harm but does not do so is referred to as a potential AE or near miss. These concepts and their relationships are illustrated in Fig 1.

The magnitude of harm to patients from AEs can be estimated but has not been quantified reliably. One investigation reported 12.91 AEs per 1000 hospital discharges among patients from birth through 15 years of age,

abstract

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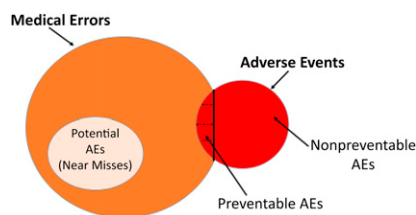


FIGURE 1
AEs and MEs.

with “negligence” identified in 28% of events.⁶ In a study of 3700 pediatric hospitalizations, 1% of patients experienced AEs, and 60% of these were determined to be preventable.⁷ Among Canadian inpatient pediatric AEs, the overall rate was 9.2%, and those related to surgery were most frequent.⁸ Almost half of the AEs in this study were determined to be preventable. A prospective study at 6 pediatric practices found that 3% of patients had preventable adverse drug events.⁹ There have been wide variations in estimates of the incidence of AEs in the pediatric inpatient setting and even more uncertainty about the rates of MEs and AEs in the outpatient setting, where most pediatric care occurs.^{4,10} What is clear is that pediatric AEs are frequent occurrences, with significant patient morbidity and mortality. The economic cost of AEs was estimated at between \$393 and \$958 billion in 2006, at which time these amounts were equal to 18% to 45% of total US health care spending.¹¹ Specific costs for the subset of cases involving children have not been quantified.

AEs not only affect patients and their families but also may have devastating effects on health care providers, who may suffer emotional consequences both from preventable AEs and from subsequent malpractice litigation.¹² Affected clinicians may feel guilt, shame, and isolation, and these feelings may be exacerbated by negative reactions from their colleagues.¹³⁻¹⁶ Anticipated or actual punitive consequences can add additional emotional and financial burdens on providers.¹⁷

The concepts of reporting and disclosure of AEs should be distinguished. “Reporting” refers to the exchange of information among providers and regulators. Reporting systems may be internal to health care organizations or may be required by licensing boards and governmental agencies. These systems may be voluntary or mandatory, and some organizations may use automated AE reporting (eg, bar-code systems and computerized provider order entry). Although in the past, many AE reporting systems focused on punitive consequences, such an approach has been found to deter further reporting. Thus, the current trend has been to reward the reporting of AEs with positive feedback and to use existing reports to develop systematic remedies to promote a safer patient care environment. “Disclosure,” in contrast, is communication directed from health care personnel to the affected patient and/or family about an AE. Disclosure is a description of what is known and does not include speculation about causation or individuals’ motivations or assumptions about judgment or fault.

The IOM noted that most MEs are attributable to flaws in systems rather than individuals and called for a “dramatic improvement in the reliability and safety” of the health care process.² For this improvement to occur, AEs must first be identified and given attention to understand their preventable causes and to allow for systematic safety improvements. Disclosure and open communication with patients and their families after an AE may provide benefit to the patient and to the health care provider, reduce consequential harms, allow for better follow-up, and promote a safety culture. Additionally, patients and caregivers most often desire complete disclosure of AEs and may be less likely to pursue litigation against their health care providers

if complete disclosure is done.¹⁸ Conversely, lack of communication may make patients feel worse and may erode the sense of trust in their caregivers that is key to healing and to optimal health care.¹⁸ The health care provider’s self-perception and self-confidence may deteriorate when health care outcomes are poor.^{15,16} Full and open communication may alleviate the provider’s feelings of anxiety, disgrace, and guilt.¹⁹ However, those feelings may also persist and may even be an obstacle to full disclosure. Pediatric clinicians and institutions should be alert to the involved provider becoming a “second victim” of an ME.¹⁷

ETHICAL CONSIDERATIONS IN DISCLOSURE

In addition to the quality-control and systems-improvement benefits of disclosure, physicians broadly acknowledge that disclosure of AEs is an ethical obligation.²⁰⁻²³ Although there is evidence that they often do not “practice what they preach,”^{13,18,24-27} physicians and medical trainees, in particular, agree that physicians have an ethical obligation to their patients to disclose preventable AEs.^{21,26-28} In an anonymous survey among pediatric residents and attending pediatricians, pediatricians in private practice were less likely to report errors than other attending pediatricians (72% vs 92%; $P < .001$).²⁵ Most agreed that disclosing a serious error would be difficult (overall, 88%; attending pediatricians, 86%; residents, 96%; $P = .005$). More residents than attending pediatricians had received education about how to disclose errors (57% vs 29%; $P < .001$).

BARRIERS TO DISCLOSURE

Despite the compelling benefits and ethical imperatives for AE disclosure, many physicians nevertheless continue to have difficulty completing the task of informing

patients and their families about AEs and MEs.^{13,21,25,29} Several barriers can create obstacles to disclosure, including perceived legal risks and the cautionary advice of legal counsel, concerns that disclosure might harm patients, a lack of confidence in disclosure skills, and a fear of embarrassment.^{14,25,30-32} Language and cultural differences may also interfere with meaningful communication about AEs.¹⁴ Among these barriers, perceived legal risks and legal advice cautioning against disclosure may be the most significant.^{27,32}

LEGAL RISKS ASSOCIATED WITH DISCLOSURE AND APOLOGY

Historically, lawyers advised their physician-clients not to disclose MEs and did so with sound legal justification.³³⁻³⁶ In the US legal system, previous statements by an observer of an event generally are not permitted to be introduced in court as evidence about that event.³⁷ In other words, a courtroom witness can testify about what he knows from his own observation but not about what someone else told him about the event. This “hearsay rule” presumes that bringing a witness into the courtroom to discuss what he actually knows from firsthand experience is more informative and more reliable than having someone else recount what another observer, on some previous occasion, said that she had seen.³⁷ However, the law recognizes the possibility that a witness might be less likely to fully and truthfully describe his observations when that witness has become the defendant in the lawsuit. Moreover, that defendant-witness might recant truthful statements that he might have previously made about the event. Therefore, a well-established exception to the hearsay rule permits previous, self-incriminating statements by defendants to be admitted into evidence, even though those

statements are hearsay.³⁸ This “admission of a party-opponent” exception has been used by plaintiffs in numerous cases to quote a defendant-physician’s earlier admission of fault to help prove that the physician-defendant committed malpractice.³⁶

The concept of “apology” generates similar legal concerns but may be even more problematic because of variations in definition. “Apology” is defined by *Webster’s Dictionary* as “a statement that you are sorry about something” or “an expression of regret for having done or said something wrong.”³⁹ This definition does not include any acknowledgment of fault. Alternatively, “apology” may be defined as “an admission of error or discourtesy accompanied by an expression of regret.” This lack of clarity in what it means “to apologize” can result in plaintiffs asserting in court that a physician-defendant “admitted” to fault, when the physician-defendant had no intention of admitting fault in the course of the apology.⁴⁰

Some lawmakers have attempted to encourage physician disclosure and apology by reducing this legal risk through legislative changes to the hearsay rule exceptions.^{30,33,41} Many state legislatures have attempted to encourage disclosures and apologies by adopting “apology laws,” intended to encourage physician-patient communications about AEs by limiting, or even completely excluding, plaintiffs’ ability to use such communications as evidence against the physician in later litigation.^{30,41} “Sympathy-only” apology laws bar the use of physician expressions of sympathy by plaintiffs at trial to prove negligence but do permit plaintiffs to use physician statements that expressly admitted fault.³⁰ On the other hand, “admission of fault” apology laws prevent plaintiffs from using virtually any previous physician disclosures to the

patient and family, even when the physician admitted responsibility for an ME or other improper care, to prove negligence at trial.^{30,*}

The effects of these apology laws in reducing liability risks remain unclear. Nevertheless, there is some evidence that they may be effective in reducing liability risks. For example, in *Deutsch v INOVA Health Care Services*, the plaintiff alleged that the defendant cardiologist was negligent in failing to personally evaluate a tachycardic patient in the emergency department.⁴² The cardiologist subsequently met with the family in the ICU and reportedly stated, “I am sorry I wasn’t there.”⁴² The Circuit Court of Virginia prohibited the plaintiffs from using this statement at trial, declaring that this “expression of sympathy and benevolence” was precisely the type of communication that the Virginia apology law was enacted to protect.⁴² Similarly, in *Airasian v Shaak*, the Georgia Court of Appeals prohibited the plaintiffs from using as evidence the defendant surgeon’s postoperative statement to the patient’s wife that “this [need for a second, emergency surgery] was my fault.”⁴³

The *Deutsch* and *Airasian* cases demonstrate how apology laws can protect physician disclosures about AEs, thus encouraging other physicians to communicate with patients and potentially preserving physician-patient relationships, improving patient and family satisfaction, and helping to identify systems weaknesses leading to AEs. However, some apology laws, particularly sympathy-only apology laws, may not provide protection and reassurance sufficient to encourage disclosure.^{33,36} Mastroianni et al opined that “sympathy-only” apology laws have a fatal structural weakness in that they do not protect the key

*For information on current state apology laws, please contact the AAP Division of State Government Affairs at 800/433-9016, extension 7799, or at stgov@aap.org.

information that patients want communicated to them after an AE.³³ These authors observed that patients (and families) want full and clear explanations and accountability for adverse outcomes. Mere expressions of sympathy, in the absence of full disclosure and accountability, may be unsatisfactory to patients and may fail to bring about systems improvements that might prevent future adverse outcomes.¹³

There is evidence that disclosure, even in the absence of protective apology laws, may reduce liability risks and litigation costs.^{44,45} Nevertheless, some researchers have suggested a theoretical risk that the sheer volume of patients who could be put on notice of MEs by full disclosure policies might result in a greater volume of lawsuits.⁴⁶

FACILITATING BETTER DISCLOSURE

In the event of a preventable AE, the pediatrician's first responsibility is to attend to the immediate medical needs of the patient. Thereafter, improved physician-patient communication may contribute to enhanced patient satisfaction, better ongoing medical care for the patient, and prevention of future AEs. Moreover, full disclosure about such events is ethically indicated. Therefore, pediatricians should endeavor to provide appropriate disclosure when their patients experience preventable AEs. Pediatricians can help facilitate such disclosures in at least 2 ways: developing and implementing disclosure policies and procedures for their own practices, and supporting public policies that facilitate disclosure.

Unfortunately, preventable AEs are often the result of a cascade of errors rather than a single mistake.⁴⁷ Gaining a clear understanding of whether an ME occurred, how it occurred, and whether and how it affected a patient may be a

difficult and complex process. Hasty confessions have the potential to generate legally admissible admissions of fault, even if the confession later turns out to have been erroneous. To reduce the risks of inaccurate or premature admissions of fault, practices and hospitals may choose to establish disclosure policies that govern how preventable AEs are investigated and how the findings of such investigations are communicated to patients and families.

Pediatricians can prepare for future AEs by developing disclosure policies and procedures. Disclosure plans will help pediatricians determine in advance what types of information that they will communicate with patients and families when AEs occur. Pediatricians can be ready to appropriately express their sympathy about adverse outcomes and to declare their willingness and intention to investigate the cause(s) of the AE, to take measures (when appropriate) to prevent similar events in the future, and to provide ongoing necessary medical care and support to the affected patient and family. Pediatricians can also be prepared to take appropriate steps to protect themselves from unnecessary and inappropriate medical liability, by having a plan in place to notify medical malpractice insurance carriers and to consult with legal counsel.

EDUCATION ON DISCLOSURE OF PREVENTABLE AEs

Education regarding practical disclosure skills and patient safety can be valuable to pediatric trainees and clinicians at all levels of experience. Simulation technology has been successfully used as one technique to assist in this learning.⁴⁸ Several other approaches to resident patient safety curricula have been reported.⁴⁹

CONCLUSIONS

There is little doubt that patients, families, and physicians are better served when full and honest communications can take place after AEs. The American Academy of Pediatrics and its members can help to promote such communications by becoming informed about, and encouraging, state apology laws and other public policies that support disclosure.

RECOMMENDATIONS

1. Pediatric health care providers and institutions should develop and implement their own policies and procedures for identifying and disclosing AEs to patients and families in an honest and empathetic manner as part of a nonpunitive culture of ME reporting.
2. Pediatric institutions and practices should develop policies and procedures to provide emotional support for clinicians involved in AEs.
3. Pediatric medical educators should develop and implement educational programs regarding identification and prevention of MEs and communication about AEs with patients and their families as part of a comprehensive patient safety curriculum.
4. Additional research is needed on the consequences of various approaches to disclosure as well as of the effectiveness of disclosure education.
5. State legislators and other governmental and regulatory bodies are encouraged to continue developing apology laws and other mechanisms to reduce liability risks associated with disclosure.

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ABBREVIATIONS

AE: adverse event
IOM: Institute of Medicine
ME: medical error

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