POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

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Disclosure of Adverse Events in Pediatrics: Policy Statement

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abstract

Disclosure of adverse events has become the expectation in medicine and is widely regarded as the appropriate path when medical errors occur. Although data are limited on adverse events in pediatrics, that they occur frequently is uncontested. Types and rates of errors vary depending on the care setting and patient population. Patients with complex medical conditions or from historically marginalized groups or minoritized communities likely suffer disparate health and safety outcomes. Systemic factors, including nonpunitive safety cultures and supportive environments within institutions, are essential to promoting disclosure. State laws protecting apologies from use in legal proceedings can also help to encourage open communication. Some states have adopted laws to advance disclosure, and governmental agencies provide materials encouraging open communication and early resolution after adverse events occur. Many programs emphasize the importance of supporting health care workers involved in adverse events. Shame, fear of professional and legal repercussions, and lack of training remain barriers to disclosure. Education for health care clinicians, support in health care settings, additional research on programs and disparities, and governmental and regulatory initiatives can support disclosure of adverse events.

INTRODUCTION

Over the last 2 decades, there has been increased recognition of the frequency and impact of adverse events in health care, accompanied by a transformation in how disclosure of such events takes place. Patients and their families expect such disclosure in a timely fashion. Additionally, data suggest that prompt and accurate disclosure of adverse events may be associated with decreased legal liability for the health care clinician. This policy statement updates a previous version[1]; discusses the current

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Table 1. Definitions	
Term	**Definition**
Patient safety	Prevention of patient harm and freedom from accidental injury in health care setting
Adverse event	Patient harm caused by medical care
Medical error	Act of commission or omission that unreasonably increases risk of an undesirable patient outcome
Preventable adverse event	Patient harm related to a medical error
Nonpreventable adverse event	Patient harm in absence of medical error
Potential adverse event (near miss)	Medical error with potential to cause patient harm that does not do so
Disclosure	Communication from health care personnel to affected patient and/or family about an adverse event
Reporting	Exchange of information about adverse events among clinicians and regulators
Just culture/safety culture	An organization's shared perceptions, beliefs, values, and attitudes that promote safety and minimize harm

state of disclosure in pediatrics and issues surrounding it, including legal and ethical implications; and provides recommendations for pediatricians.

Patient safety is the prevention of patient harm and freedom from accidental injury in the health care setting.[2] An adverse event (AE) occurs when patient harm is caused by medical care.[3] A medical error (ME) is an act of commission or omission that increases risk of an unintended patient outcome. AEs may be preventable (when patient harm is related to an ME) or nonpreventable (when patient harm occurs in the absence of an 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."[4] These concepts and their relationships are explained in Table 1 and illustrated in Figure 1.

Estimates of total annual mortality in the United States attributable to preventable AEs vary widely, from 22 000[5] to as high as 250 000 deaths.[6] It is estimated that 6% of patients have experienced preventable harm.[7] The American Academy of Pediatrics (AAP) has called attention to the importance of pediatric patient safety since 2001[8] and has recommended improved identification and reporting of MEs and AEs to improve the culture of safety in pediatric care.[9]

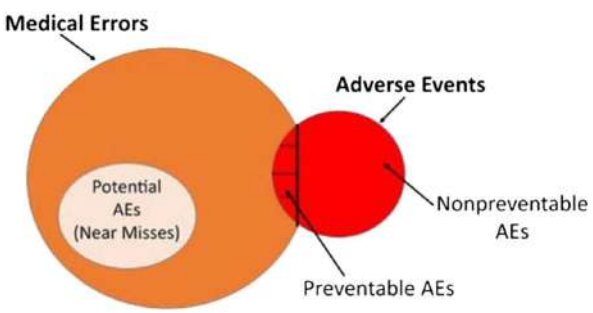

Figure 1.
Graphical Depiction of Adverse Events and Medical Errors

The economic cost of AEs in the United States is substantial, although estimates have varied. In 2006, costs of AEs were estimated between $393 and $958 billion, equal to 18% to 45% of total US health care spending.[10] In 2008, an estimate of the cost of MEs in the United States based on claims data was $17.1 billion.[11] Another study estimated that MEs in the United States cost $985 million in 2008 and over $1 billion in 2009, with median costs per error of $892 in 2008 and $939 in 2009.[12] Specific costs for AEs involving children and adolescents have not been quantified.

ADVERSE EVENTS AND MEDICAL ERRORS IN PEDIATRIC POPULATIONS

While the exact magnitude of harm to pediatric patients from AEs is not well established, pediatric AEs occur frequently, with significant morbidity and mortality. Among Canadian inpatient pediatric AEs, the overall rate was 9.2%, and those related to surgery were most frequent[13]; almost half of these AEs were determined to be preventable. There are wide variations in estimates of the incidence of AEs among pediatric inpatients.[9,14,15] Error rates related to medications in pediatrics have been noted to be 3 times higher than in adult patients.[16]

Types and rates of MEs vary depending on the health care setting and patient population. The majority of research to date has focused on errors in inpatient or emergency department settings. Emergency care settings involve high risks for errors, given the often busy, high-volume environment with frequent interruptions and transitions in care; complex patients who may not be well-known to staff; boarding; and commonly, a lack of standardized dosing, formulary, or information technology systems with pediatric safety features.[17–19] Most pediatric care occurs in ambulatory settings, and studies have reported significant numbers of errors related to medications, vaccines, diagnoses, and coordination and transition of care.[20,21] Medication administration errors account for the majority of preventable adverse drug events in the outpatient pediatric setting.[21–24] Although diagnostic errors occur frequently in

pediatrics, relatively little research has been performed on their incidence and epidemiology.[25,26]

Children with special health care needs and/or medical complexity likely have higher rates of AEs than the general population because of frequent interactions with the health care system, clinicians in multiple settings, and medical needs. They are particularly vulnerable to medical errors during care transitions.[24,27–32] Families are an underused resource for detecting and reporting safety events in these populations and can provide valuable perspectives, including in ambulatory settings.[33–36]

Although research is limited on rates of AEs in historically marginalized or minoritized populations, evidence shows that these communities are more likely to suffer disparate health and safety outcomes.[37,38] Recent data have shown higher rates of AEs in hospitalized Latino children and publicly insured children, including serious AEs.[39,40] Hospitalized children of parents with limited comfort with English were twice as likely to experience AEs from medical care.[41] Language barriers have been associated with increased rates of AEs[42,43]; underreporting of AEs in hospitals relying on voluntary event reports[44]; and less willingness to question health care clinicians, which may contribute to increased safety events.[45]

THE SYSTEMS APPROACH AND SAFETY CULTURE

The Institute of Medicine (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.[3] For this improvement to occur, AEs must first be identified and analyzed 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 benefit the patient and health care clinicians, reduce consequential harms, allow for better follow-up, and promote a safety culture.

Safety culture refers to an environment that facilitates open and honest communication to promote safety and minimize harm[46] and is particularly important when potentially uncomfortable topics such as MEs or preventable harm are being addressed. A growing body of literature, including subspecialty publications in pediatrics, demonstrate that safer culture is associated with safer care. Increasingly, the culture of pediatrics, and health care in general, is to promptly disclose to patients and families after an AE has taken place. Multiple factors are considered when disclosing MEs, including safety culture, clinician and patient level factors, and the type of error itself (see Figure 2).

REPORTING VS DISCLOSURE

The concepts of *reporting* and *disclosure* of AEs should be distinguished. *Reporting* refers to the exchange of information among clinicians and regulators. Reporting systems may be internal to health care organizations or may be

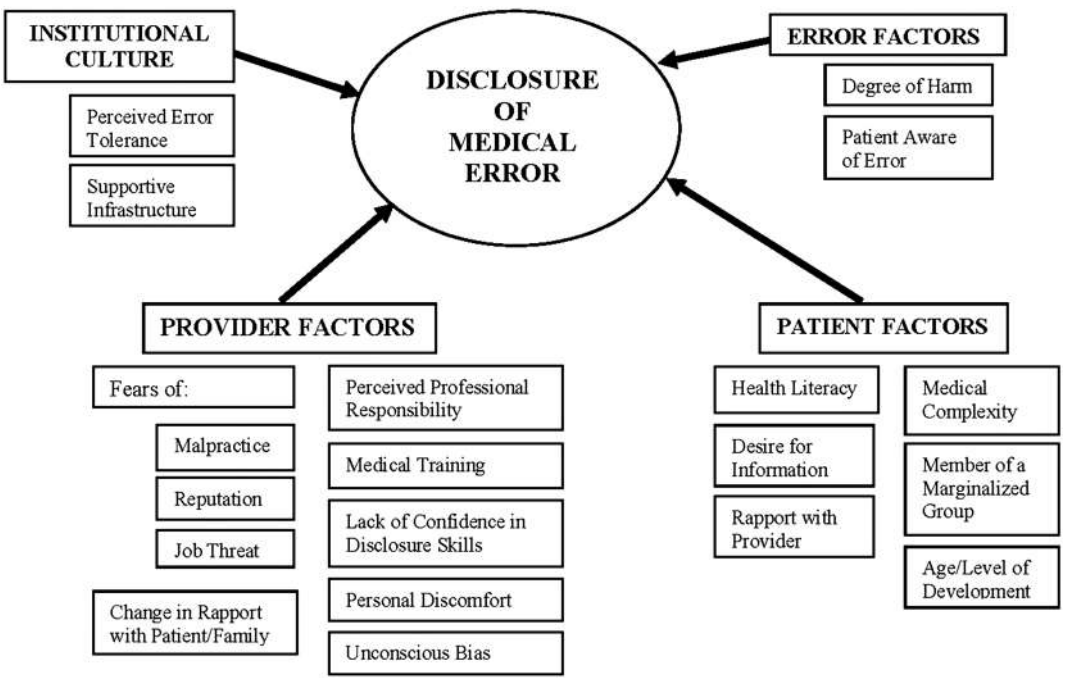

Figure 2.
Influences on the Decision to Disclose a Medical Error (adapted from Fein et al[91] [https://www.ahrq.gov/downloads/pub/advances/vol2/Fein.pdf])

required by licensing boards and governmental regulations. These systems may be voluntary or mandatory, depending on state and institutional policies, and some organizations may use automated AE reporting. Prior reporting systems often focused on punitive consequences, which was found to deter further reporting. More recent trends emphasize the adoption of "just culture," promote reporting of AEs by all clinicians and staff, and utilize reports to develop systematic improvements and a safer patient care environment.[47,48] Additionally, there is emerging evidence that including family reports in safety surveillance systems, which is not typical in many health care institutions, may help to identify more AEs.[34]

DISCLOSURE TO PATIENTS AND FAMILIES

Historically, physicians were not often advised to disclose MEs to patients and their families, but early disclosure and resolution is now routinely encouraged. A variety of programs have been initiated around the United States, including the CANDOR (communication and optimal resolution) approach (https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html).[49] The CANDOR program consists of 2 main components:

1. Prompt and accurate disclosure to families
2. Care for the caregiver (see "Effects on Health Care Clinicians" section)

Clinicians involved are expected to notify their malpractice attorney(s) or institutional legal and risk management contacts as soon as possible. It is important for trainees to immediately notify appropriate supervisors and involve them, whenever possible, in conversations with families. Additional personnel, such as office managers, unit directors, and social workers, can aid in responding and provide support and guidance. Prompt and accurate discussion is encouraged, and whenever possible, a care team should have an organized plan, including predisclosure huddles and checklists, such as those available through the AHRQ, prior to meeting with families. In the immediate aftermath of a serious event, and when there may not be time to involve additional resources, conversations with families are usually limited to statements that something went wrong and that a formal investigation—usually in the form of a "root cause analysis" or "apparent cause analysis"—is forthcoming. At the initial discussion, clinicians can advise families that not all the facts are known and can assure them that additional meetings will be scheduled as more information is available. Apologies, including statements of sympathy with or without expressions of fault, may be included in initial conversations depending on the institutions and clinicians involved as well as the legal landscape around disclosures and protections for apologies and statements of fault in the local jurisdiction.[50,51] A more formal disclosure is usually done after an investigation has been conducted, and at times in conjunction with an early offer for resolution. Attorneys or risk management staff usually direct such discussions. Veracity, meaning that communication should be honest, is one of the guiding principles of bioethics and a moral foundation of disclosure. The principle of truth is deeply rooted in the practice of medicine and is essential for building trust between clinicians and patients or families. Although in the past, patients and their families were often "shielded" from the truth by paternalistic physicians, they should be viewed as partners in shared decision making. Families cannot make informed decisions for their loved ones if they have not been given relevant facts.

ENGAGEMENT OF CHILDREN AND ADOLESCENTS

Children and adolescents, including those with chronic illnesses, have expressed their desire to be involved in disclosures of errors affecting their care,[52] and consideration should be given to involving them in such discussions when appropriate. Disclosure to children should be individualized and should not be determined simply by age and developmental parameters. Koller et al[53] have suggested that the development of policies on disclosure "must begin by examining children's understanding of medical errors and what they expect from their health care clinicians when errors occur."

ADOLESCENT CONFIDENTIALITY

There may be circumstances when AEs occur during the confidential treatment of adolescents, including conditions involving behavioral health, substance use, or sexual activity. Although state laws vary depending on exact age and condition, adolescents are usually legally entitled to seek treatment without needing consent from a parent or guardian for these conditions.[54] In such cases, disclosures are limited to the adolescent alone. Clinicians need to remain cognizant that subsequent care for medical consequences of the AE may fall outside adolescent confidentiality protections, and state laws protecting parental rights may impose further complications. Consultation with legal and/or risk management advisors in the relevant jurisdiction is recommended because of the complexity and variety of these protections.

BEST PRACTICES FOR DISCLOSURE

Disclosure practices may vary depending on setting, type of error, and patient population. Important aspects of disclosure include an explanation of what happened, acknowledgment that something has gone wrong and of responsibility, expression of sincere regret and apology, and commitment to preventing recurrences.[55] These should be conducted with the involvement of appropriate parties in each practice

setting. Participants may include leaders, risk managers, and possibly attorneys. Immediately after an AE occurs, clinicians can follow recommended steps such as involving team members, practice or unit leaders, risk managers, or attorneys; apologizing when appropriate; and communicating with the involved patient and/or family. Resources for responding to AEs are provided in the Toolkit Appendix.

EFFECTS ON HEALTH CARE CLINICIANS

AEs and MEs not only affect patients and their families but also may have devastating effects on health care clinicians, who may suffer emotional consequences both from preventable AEs and from subsequent malpractice litigation.[56–58] Affected clinicians may feel guilt, shame, and isolation, and these feelings may be exacerbated by negative reactions from their colleagues. They may experience depression, anxiety, and/or posttraumatic stress disorder.[59] Anticipated or actual punitive consequences can add further emotional and financial burdens on clinicians. Although the terminology is evolving, the concepts of "second victims" or more recently "care for the caregiver" acknowledge that clinicians often experience significant personal turmoil if an AE occurs and focus on the important need to support health care clinicians involved in these events. Support systems for affected clinicians may reduce distress among health care clinicians.[60–62] The tragedy in 2011 of a pediatric intensive care unit nurse's suicide following a medication error highlights the devastating effects that MEs can have on the health care workers as well.[59]

BARRIERS TO AND PROMOTERS OF DISCLOSURE

Numerous barriers to disclosure have been identified, including shame, fear of litigation and punishment, concern about the impact on professional reputation, decreased patient trust, situational complexity, lack of training or confidence in how to disclose, inconsistent guidelines on disclosure, and the lack of a nonpunitive patient safety culture.[63] Language and cultural barriers may hinder communication about AEs. Even with institutional policies advocating for disclosure, errors may not always be disclosed. In some cases, failure to disclose may impact patients at other institutions. For example, an outbreak of carbapenem-resistant *Enterobacter* infections related to duodenoscope contamination at one institution was associated with later deaths in other hospitals and states.[64]

Factors that promote disclosure include a safe setting for reporting AEs and availability of guidelines and education on how to disclose errors.[65,66] Peer support for disclosure, just-in-time disclosure coaching, refresher trainings, medical school and residency disclosure training and modeling, and organizational and national policies supporting disclosure also influence the likelihood and implementation of disclosure.[55]

LEGAL RISKS AND OUTCOMES

Patients and caregivers most often desire complete disclosure of AEs.[67,68] Yet historically, lawyers advised their physician-clients not to disclose MEs and did so with sound legal justification, because of the risk of statements of apology being used against physicians if an AE should result in a lawsuit.[51,69,70] Physicians were trained that admitting fault would increase the risk of being sued.

However, studies suggest that affected patients and families may be less likely to pursue litigation against their health care clinicians if such disclosure is provided.[71–76] Lack of such 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. Although there is some disagreement in the legal literature on the impact of apologies and admissions of fault,[77–79] the preponderance of the data, as well as the guiding ethical principles, support prompt and accurate disclosure.[80] Patients and families expect information about the error, sincere remorse, and a pledge of improvement.[66]

Numerous states have passed so-called "apology laws," which protect statements of apologies from being used in court against health care clinicians. As of 2022, 39 states and the District of Columbia have such statutes.[81] Most of these states protect only sympathetic statements, such as saying "I'm sorry for your suffering" or "I regret that this happened," while 9 states also protect statements of fault.[50] These apology laws, along with institutional, state, and federal efforts to implement disclosure programs, may help to encourage candid discussions after AEs.[74] More recently, several states have developed "candor laws" that provide a process for investigating and communicating openly about AEs. Under the Colorado Candor Act, for example, discussions and offers of compensation held in the process are privileged and confidential, meaning they cannot be used against clinicians if the injured party later decides to file a lawsuit.[82]

A case in which a nurse was convicted of negligent homicide after a medication error highlights the need for broader legal protections for statements about AEs. In this case in Tennessee, which was decided in 2022, the nurse's words to state investigators were used against her in court. Widespread concern has been expressed that health care workers will be hesitant to disclose errors if their cooperation will be used as part of criminal prosecutions.[83,84] Although this type of legal case is extremely rare, the potential deterring effect on self-reporting could not only undermine the disclosure of AEs but also reverse gains in establishing a culture of safety and other patient safety initiatives.[85]

EDUCATION ON DISCLOSURE OF PREVENTABLE ADVERSE EVENTS

In 2019, disclosure of AEs was included as a common program requirement for resident education and experience,

highlighting the importance of disclosure as a patient safety skill by the Accreditation Council for Graduate Medical Education (ACGME) (https://www.acgme.org/What-We-Do/Accreditation/Common-Program-Requirements). With increased focus on experiential learning, trainees have been involved in real or simulation scenarios, including disclosure of AEs.[86,87] Disclosure practices are also included as one of 13 core professional activities for medical school graduates by the Association of American Medical Colleges, as part of identifying system failures and contributing to a culture of safety and improvement.[88,89] Continued education in patient safety and developing communication skills for effective disclosure is needed at all training and career levels.[55,90]

CONCLUSION

Progress has been made toward routine disclosure of adverse events over the past decades. Further efforts to better understand adverse events in pediatrics, focusing on risks, different health care settings, and inequitable practices that disproportionately impact historically marginalized or minoritized populations, may help to improve trends in disclosure. Support from institutions and legal protections can facilitate a culture of safety, reduce fear of disclosure, and provide enhanced education and support for health care clinicians involved in adverse events.

RECOMMENDATIONS

For Pediatric Health Care Clinicians, Practices, and Institutions

1. Develop and implement policies and procedures for identifying and disclosing AEs to patients and families in an honest and empathetic manner as part of a nonpunitive safety culture.
2. Develop policies and procedures and provide resources to support clinicians and other staff involved in AEs.
3. Encourage a culture of safety, just culture, and reporting by all staff as well as by patients and families.
4. Identify populations and situations with higher risk for AEs, such as patients with chronic illnesses and those from historically marginalized or minoritized communities, and partner with families and care teams to help prevent them.

For Medical Educators

5. 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.

For Researchers

6. Investigate the consequences of various approaches to disclosure as well as of the effectiveness of disclosure education.
7. Further explore and address disparities in AEs and disclosure. More data are needed on trends in AEs and disclosure by race, ethnicity, chronic conditions, and preferred language; impact of AEs and disclosure on historically marginalized or minoritized communities; structural factors related to disclosure; and impact on clinicians underrepresented in medicine.

For Pediatric Advocates

8. Encourage states and the federal government to adopt laws protecting apologies, programs supporting disclosure, and other mechanisms to reduce liability risks associated with disclosure in order to avoid detrimental effects on health care clinicians' reactions to AEs.

For more information about advocating for these issues, contact the AAP state advocacy team at stgov@aap.org.

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The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
AEs: adverse events
AHRQ: Agency for Healthcare Research and Quality
IOM: Institute of Medicine
MEs: medical errors.

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