Patient Safety and Quality Improvement: Terminology

Lucy Pereira-Argenziano, MD,* Fiona H. Levy, MD*

*Department of Pediatrics, NYU School of Medicine, New York, New York.

Education Gap

Medical errors and unintended harm continue to occur, despite preventive strategies. Understanding terminology and key attributes of improving safety can lead to creation of systems to reduce medical errors and preventable harm.

Objectives

After completing the article, the reader should be able to:

1. Understand and apply common terms used during discussions of safety and quality.
2. Describe common types of error and harm in pediatrics.
3. Describe the pediatric response to Institute of Medicine recommendations.
4. Understand attributes of high-reliability organizations and how their principles can be used to improve patient safety.

BACKGROUND

The patient safety movement was galvanized by publication of To Err is Human by the Institute of Medicine (IOM) in 1999. (1) The report estimated that 44,000 to 98,000 people die in US hospitals each year as a result of medical errors. Equally interesting and perhaps as important to the magnitude of preventable injury occurring to patients in the United States is the fact that much of the data used as the basis for these estimates had been published and available in 1991. (2) The economic impact of medical errors has equally alarming implications for both health systems and consumers. Researchers analyzed clinical and billing data from a hospital database containing information from 600 hospitals and ambulatory surgery centers within the United States for visits in which injury occurred as a result of medical error. (3) A cost analysis was performed for each injury visit. Extrapolation of the data to the broader US population estimated the cost of medical errors to the US health-care system to have been $1 billion in 2009. Because the study focused solely on inpatient costs of medical errors and did not account for societal impacts such as time lost from work, this is likely an underestimate of the true cost of medical errors.

With the publication of To Err is Human and resulting attention of both the press and the public, the medical community was held accountable to address

AUTHOR DISCLOSURE

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recommendations for improvement. The stated intent of the IOM recommendations was to achieve a synergy between the external pressures of regulatory, governmental, and purchasing organizations and the internal motivations of clinicians, organizations, and professional societies working to improve the safety of care at the point of delivery. Three of the four key strategic recommendations to achieve safer care can be broadly summarized as: (1)  
1. Develop mandatory and voluntary reporting systems to allow both the identification of and learning from medical errors.  
2. Encourage external oversight organizations, professional groups, and group purchasers of health-care to raise performance standards and set expectations of improved patient safety.  
3. Design and implement safety systems in health-care organizations to ensure safe practices at the delivery level.

TERMINOLOGY

Clarifying terminology is important because there is significant overlap and variation among medical errors, adverse events, and preventability. Probably the best and most widespread definitions come from the IOM.

Medical Error
A medical error has been defined by the IOM as “a failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.” (1) A medical error does not always lead to patient harm because it may not reach the patient and it may not be such a critical aspect in the process of care as to injure the patient (Figure). However, that statement does not mean that clinicians should not track and seek to understand all medical errors. A near miss is a medical error that has the potential to cause patient harm but has not. (4) The knowledge that something kept the error from reaching the patient provides an excellent opportunity to learn about processes of care; understanding how we intentionally or accidentally prevent an error from reaching a patient allows clinicians to improve safety systems. An adverse event is a medical error in management or intervention that leads to patient injury (1)(4) and results in prolonged hospitalization or the presence of a disability at hospital discharge.

Sentinel Event
A sentinel event is a term coined and defined by the Joint Commission as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.” (5) Individual health-care organizations have the responsibility of defining serious physical or psychological injury, but the intent is to capture injuries of permanence and significance, such as loss of limb or function. The phrase “or the risk thereof” can be thought of as a near miss, where the risk and potential consequences of a recurrence may lead to a serious adverse outcome. Of note, a sentinel event may or may not be due to a medical error. Once a sentinel event has been identified, the Joint Commission mandates that an investigation be immediately undertaken to determine the root causes that have led to the event as well as implementation of an action plan and monitoring to minimize future risk that this event will recur. The information is reported to the Joint Commission Sentinel Event Database. Aggregate sentinel event data are reviewed by the Joint Commission for trends of root causes or risk-reduction strategies. Events that demonstrate either frequency or high risk are shared with hospitals and the public via Sentinel Event Alerts. Examples of pediatric-specific Sentinel Event Alerts include: “Preventing pediatric medication errors” and “Revised guidance to prevent kernicterus.” (6) Aggregate data from the Sentinel Event Database are also used to guide development of National Patient Safety Goals (NPSG). (5)

MEDICAL ERRORS IN PEDIATRICS

Medical errors can be categorized as diagnostic, treatment, and preventive. (7) Errors can be further categorized as preventable and nonpreventable.

Diagnostic Errors
Malpractice claims have been used to extrapolate the distribution of pediatric medical errors. According to analysis by the Physician Insurers Association of America, diagnostic errors in the form of missed or incorrect diagnosis account for most pediatric malpractice cases. (8) Pneumonia, meningitis, appendicitis, and testicular torsion were among the diagnoses most frequently associated with diagnostic errors in medical malpractice claims. (9)(10) In an attempt to elucidate pediatricians’ perceptions and experiences with diagnostic errors, Singh et al (11) conducted a multicenter survey. More than 50% of surveyed pediatricians reported making a diagnostic error at least once per month, with misdiagnosis of a “viral illness as a bacterial illness” as the perceived most frequent diagnostic error. Misdiagnosis of otitis media with effusion as acute otitis media is an example of a viral illness diagnosed as a bacterial illness.

Treatment Errors
Medication errors are an example of treatment errors. The National Coordinating Council for Medication Error
Reporting was convened in 1995 with representation from multiple interdisciplinary agencies in an attempt to encourage reporting and prevention of medication errors. (12) The Council developed an Index for Categorizing Medical Errors to provide a standard method for categorizing and tracking errors. The Index classifies medical errors as A through I, according to whether or not they reached the patient, and if they reached the patient, the progressive degree of resultant harm. Medication errors classified in categories E through H are associated with increasing severity of patient harm, with the ultimate outcome of death in category I. A chart review from 12 children’s hospitals throughout the United States found the incidence of medication errors resulting in patient harm (category E or greater) to be 11.1 per 100 patients or 15.7 per 1,000 patient-days. (13) Analysis of the events revealed ordering and monitoring as the stages of medication management that are most prone to preventable error.

Pediatric medication management is especially complex because of calculations necessary for weight-based dosing, off-label use of medications, compounding and dilution needed for medication preparation, and limited ability of young patients to communicate. (14)(15) Within pediatrics, patients in the neonatal intensive care unit are particularly vulnerable due to frequent changes in medication dosing weights and altered pharmacokinetics leading to variation in medication metabolism. (14)(16)

Preventable and Nonpreventable Medical Errors
Medical errors of all types can be further classified as preventable and nonpreventable. Making this distinction allows targeted efforts to eradicate preventable errors and any associated harm, with less focus on nonpreventable errors. Equally important is the determination of whether patient harm is preventable or nonpreventable.

An example of nonpreventable error may be an adverse drug event (ADE), such as a patient without a history of a medication allergy developing an allergic reaction after administration of a medication. Although the patient may be harmed by the event, the event was not preventable because the allergy was previously unknown. In contrast, if a patient has a known medication allergy and the medication is administered, a preventable error has occurred.

Patient harm may also be designated as preventable or nonpreventable. Nabhan et al (20) performed a literature review to determine common themes used to designate a harm event as preventable. According to these authors, “presence of an identifiable modifiable cause, reasonable
adaption to a process will prevent future recurrence and lack of adherence to guidelines implies preventability.”

The concept of the preventability of patient harm has led to a modified and enhanced approach to patient safety in hospitals. In 2008, Nationwide Children’s Hospital set a 5-year goal to eliminate preventable harm within their institution. The journey to elimination of preventable patient harm included a cultural change based upon the principles of high-reliability organizations (HROs). (21) HROs are typically found in the arenas of nuclear power, naval aircraft carriers, and commercial aviation. (22) Many organizations have begun to test and study how these cultural underpinnings of HROs might be brought to the world of healthcare and improve the safety of patient care. HROs are governed by five key principles: three of anticipation and two of containment (Table 1). (23)

To achieve both the preoccupation with failure and the sensitivity to operations, transparency of information about the system in which people work is required. Deviations of performance or errors are transparently shared with members of the HRO. To achieve this, Nationwide Children’s Hospital developed and implemented a Preventable Harm Index (PHI). (21) The PHI is composed of the number of harm events that occur in eight different categories, including hospital-acquired infections, ADEs, preventable non-intensive care unit cardiac arrests, significant post-surgical complications, serious falls, pressure ulcers, and miscellaneous significant harm and serious safety events. (21) In 2008, teams were established to work on reducing each category of patient harm. Through cultural transformation, the work of quality improvement teams, and the measurement and sharing of the PHI, Nationwide Children’s Hospital experienced a significant decrease in preventable harm events and patient mortality. (21) Similar organization-wide initiatives to decrease preventable harm in children also were successful at institutions such as Cincinnati Children’s Hospital (24) and Helen DeVos Children’s Hospital. (25)

Interestingly, the designation of harm as nonpreventable may change over time. Events that are currently determined to be nonpreventable may become preventable if additional knowledge is acquired or new standards of care are established. (26) An example of preventable harm that previously was believed to be the price of being sick and in an intensive care unit and, therefore, nonpreventable is central line-associated blood stream infections (CLABSI). Central line insertion and maintenance bundles emerged from collaborative efforts and sharing of data. (A bundle is a structured approach to improving processes of care and patient outcomes.) As the bundles were tested and the incidence of CLABSI was significantly decreased, (27) use of bundles as well as certain components of the bundle have become the standard of care. The presence of guidelines that have been found to prevent the occurrence of CLABSI has led to the designation of CLABSI as preventable harm.

### MEDICAL ERRORS UNDERSTOOD THROUGH PROCESS ANALYSIS

The occurrence of a medical error is often multifactorial and requires multiple small deviations to occur in sequence, leading to the larger event. The Swiss Cheese Model developed by James Reason can be used to illustrate how a medical error occurs. (22) In the model, every step in a process (the process of care in the case of medical errors) is represented as a slice of Swiss cheese. Each step in the process can prevent or facilitate an error reaching a patient and causing harm. When the process works well, the cheese is intact and blocks errors from reaching patients. When processes of care are flawed (represented by holes in the cheese), they provide avenues for errors to reach the patient and cause harm. When all of the steps are placed together, if some of the holes align through the successive layers, the error reaches the patient. The opportunity to study errors from the perspective of processes and system analysis after real and near-miss events allows for redesigning of systems of care that can prevent the recurrence of adverse or sentinel events in the future.

### TABLE 1. Principles of High-reliability Organizations

<table>
<thead>
<tr>
<th>Principles of Anticipation:</th>
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<tr>
<td><strong>1. Preoccupation with failure</strong></td>
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<td><strong>2. Reluctance to simplify</strong></td>
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<td><strong>3. Sensitivity to operations</strong></td>
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<th>Principles of Containment:</th>
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<tr>
<td><strong>1. Commitment to resilience</strong></td>
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<td><strong>2. Deference to expertise</strong></td>
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Adapted from Weick K, Sutcliffe K. Managing the Unexpected. 2nd edition. San Francisco, CA: Copyright (c) 2007 by John Wiley & Sons, Inc. All rights reserved.
The importance of process analysis can be illustrated by the example of a prescriber making an error when entering a medication order into a computerized physician order entry (CPOE) system. Normally the first barrier to keep this error from reaching the patient might be the CPOE system. In this case, the CPOE system was not designed with safeguards for this medication, so the error passes through the first barrier (it finds the hole in the Swiss cheese). The next barrier could be a pharmacist who needs to verify all orders. On this day, a covering pharmacist who is unfamiliar with pediatrics approves the medication. The error has moved through two intended barriers or safeguards. Finally, the medication is picked up by the nurse, who normally would have checked and rejected the medication. However, on this day the patient care unit is very busy and loud and the nurse is continually interrupted while checking this unusual medication before administering it. Thus, a simple error made by a prescriber passes through all of the safeguards between the error and the patient.

The next step is to understand how the processes broke down and allowed this medication error to happen. What is wrong with the design of CPOE system and what needs to be fixed? What processes are in place to orient new pharmacists to the pediatric pharmacy to prevent error? How is the clinical unit designed to ensure that nurses have the uninterrupted time and space to check all medications thoroughly? Process analysis allows clinicians to determine the real causes of error (latent failures) and focus on how to fix systems rather than punish individuals.

DEVELOP REPORTING SYSTEMS FOR MEDICAL ERRORS

The ability to detect and report medical errors is critical to improving the safety of care. Error reporting via voluntary or mandatory reporting systems allows for review of factors that have contributed to an error (actual or near miss), and the subsequent development of risk-reduction strategies can help prevent the recurrence of a similar event. (28)(29) Understanding and implementing a plan to address barriers to error reporting, including difficulty with error detection, can enhance the use of reporting systems and, therefore, learning potential.

Voluntary Error Reporting

Voluntary incident reporting systems are used in health-care to report the occurrence of errors. Frequently, the errors reported have resulted in little or no patient harm, but they provide critical information necessary to drive performance improvement and improve patient safety. (1) Voluntary reporting systems, although useful, have limitations. In 2004, Tayor et al (30) surveyed 200 physicians and nurses at a large children’s hospital. Fewer than 50% of the respondents indicated that they completed incident reports on 80% or more of the errors they committed. Approximately one third of respondents indicated that they completed an incident report for fewer than 20% of the errors they committed. When evaluating per discipline, nurses were more likely to report their errors than physicians.

To understand barriers to the use of voluntary incident reporting systems, physicians and nurses have been surveyed regarding their practices of and beliefs about error reporting. (31) The barriers encountered by each discipline varied. Physicians most frequently identified “lack of feedback, incident form takes too long to complete, and a belief that an event was too trivial” as barriers. Nurses identified “lack of feedback, a belief that there was no point in reporting near misses, and forgetting to make a report when ward was busy” as the most common barriers to error reporting. Concern about legal implications from the generation of an error report, (32) lack of physician access to electronic incident reporting systems, interruption of patient care to complete incident report, and concern that reporting may result in punitive action have been identified as additional barriers to voluntary incident reporting systems. (33)

Physicians surveyed identified changes to voluntary reporting systems that may increase reporting of medical errors. Recommendations include: “education about which errors should be reported, feedback on a regular basis about errors reported and about individual events, evidence of system changes because of reports of errors, and electronic format for reports.” (30) In addition, the Agency for Healthcare Quality (AHRQ) has recommended key components to increase the effectiveness of an error reporting system. (34) The components include: generation of error reports by a wide range of employees, protecting the confidentiality of the author of the incident report, implementation of a system to review events, performing analysis, implementation of risk-reduction strategies, and timely feedback to staff.

Enhanced Error Detection

The strength of a voluntary reporting system is dependent on the ability to detect medical errors. The Institute for Healthcare Improvement (IHI) developed trigger tools to complement error detection. Triggers are occurrences that may signify the presence of an error if present in a medical record. Examples of triggers include the use of naloxone, a rising creatinine value, hyperglycemia, and unexplained return to surgery. (35) Identification of a trigger prompts further evaluation of the medical record to determine whether a medical error has occurred. Evaluation of trigger tools may be manual or automated. Manual detection
requires that a trained reviewer audit a sample of charts for the presence of a trigger. If a trigger is identified, the chart is reviewed in depth to determine if a medical error has occurred. Currently available pediatric-specific trigger tools through the IHI include the Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children’s Hospitals (36) and Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit. (37) Examples of triggers in the Pediatric Trigger Toolkit include administration of diphenhydramine, rash, and hyperkalemia. (36)

The Children’s Health Corporation of America developed and tested a pediatric-specific trigger tool for ADEs. (13) A manual retrospective chart review was conducted to identify the presence of triggers. Identified triggers, including administration of diphenhydramine, presence of rash, and hyperkalemia, prompted an in-depth review for ADEs. The study determined that the mean ADE rate was 11.1 per 100 patients and 15.7 per 1,000 patient-days. Only 3.7% of the ADEs identified using the trigger tools were also identified by the voluntary reporting system. (13)

Although manual identification of triggers improves error detection, it only samples a small number of charts and is labor intensive. Automated adverse event detection (AAED) uses algorithms to identify triggers in the electronic health record on a continual basis, thereby enabling auditing of all charts. As with manual detection, once a trigger is identified, a chart review is conducted for evaluation of a potential medical error. Lemon and Stockwell (38) published results with use of AAED over a 4-year period. Of the triggers identified, 14% identified adverse events. Only 3% of the adverse events found using the AAED were also identified by the voluntary reporting system.

Mandatory Error Reporting
State law may require reporting of sentinel events and adverse events leading to significant patient harm. The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is an example of a state-led mandatory reporting system. (39) Requirements for reporting to NYPORTS include: deaths not related to anticipated disease progression, medical equipment malfunction or misuse leading to serious patient harm or death, and discharge of a patient incapable of making medical decisions to an unauthorized person. Trending of NYPORTS data allows for identification of opportunities for quality improvement within an institution and throughout the system. Successful institution of preoperative protocols to decrease the incident of wrong-site surgery, wrong-site procedure, and procedure on the wrong patient is an example of an initiative driven by NYPORTS data. (40)

Mandatory error and adverse event reporting is also used by the US Food and Drug Administration (FDA). The FDA is responsible for review of medical equipment to ensure its safety and effectiveness before approval for use. After approval, monitoring for device safety with the use of an event reporting system continues. Mandatory Medical Device Reporting mandates “device user facilities,” which include hospitals and outpatient treatment facilities, to report any serious injuries or deaths that may be attributed to the use of medical equipment. (41)

Medical Error Reporting to Share Lessons Learned
Because the occurrence of medical errors at each institution is relatively small, the knowledge gained through collaboration and sharing of information among institutions can greatly enhance the speed of error prevention. In 2005, Congress approved the Patient Safety and Quality Improvement Act. The Act provides confidentiality protection to members of Patient Safety Organizations (PSOs), allowing for sharing of medical errors and safety events. Currently, 80 PSOs are listed with the AHRQ. Pediatric PSOs include Safe Pediatric Health Care PSO, Child Health Patient Safety Organization, and Wake Up Safe. (42)

Wake Up Safe is a quality improvement initiative of the Society for Pediatric Anesthesia. The initiative contains a registry of serious safety events that have occurred in pediatric anesthesia. The knowledge gained in the analysis of serious safety events is shared with members of the PSO and used to drive learning and safety initiatives. (43)

The AHRQ has established common formats, which serve as a standard for reporting and analyzing patient safety events. PSOs use common formats for submission and reporting of events. Common formats are available for falls, health-care-acquired infections, blood or blood product events, medication or other substance events, perinatal events, surgery or anesthesia events, and venous thromboembolic events. (44)

ENCOURAGE EXTERNAL OVERSIGHT ORGANIZATIONS, PROFESSIONAL GROUPS, AND GROUP PURCHASERS TO RAISE PERFORMANCE STANDARDS AND SET EXPECTATIONS OF IMPROVED PATIENT SAFETY

Standards and expectations for patient safety may be set by accrediting organizations such as the Joint Commission through the development of the NPSPG. More recently, the work of pediatric networks, exemplified by the Children’s Hospitals’ Solutions for Patient Safety (CHSPS), have applied standard bundles for hospital-acquired conditions and complementary work on the culture of safety to improve patient outcomes.
National Patient Safety Goals

In 2002, the Joint Commission established the NPSG program to enhance patient safety across all accredited health-care organizations (Tables 2 and 3). (45) An advisory group that includes nurses, physicians, pharmacists, risk managers, and clinical engineers identifies patient safety concerns throughout the health-care system and potential solutions. Specific patient safety goals are established for ambulatory health-care, behavioral health-care, critical access hospitals, home care, and hospice. Every 2 years these goals are reviewed and revised. Once a goal has become an accepted standard of practice, it and its assigned goal number are removed, so the goals are not numbered sequentially. Accredited health-care organizations are required to establish NPSG as organizational priorities and develop policies and procedures to ensure compliance.

Children’s Hospitals’ Solutions for Patient Safety

In 2009, the children’s hospitals in Ohio joined together to create the Ohio Children’s Hospitals’ Solutions for Patient Safety, a collaborative to improve patient safety. The initial focus was to decrease surgical site infections and ADEs, which subsequently expanded to the goal of eliminating serious harm. The success of the collaborative, which demonstrated a 40% reduction in serious harm events and 55% reduction in serious safety events, prompted the support of the Centers for Medicare and Medicaid Services Innovation Center in 2012, allowing collaboration to spread to hospitals outside of Ohio. (46) Currently the network, renamed as CHSPS, comprises more than 80 children’s hospitals throughout the United States. (47) Current goals of the network include: “40% reduction in hospital-acquired conditions, 20% reduction in readmissions, and a 25% reduction in serious safety events.” (48) The hospital-acquired conditions that form the current focus of CHSPS are: CLABSI, catheter-associated urinary tract infections, ventilator-associated pneumonias, ADEs, injuries from falls, pressure ulcers, surgical site infections, preventable readmissions, venous thromboembolism, and obstetric adverse events. The shared belief in the principle “All Teach, All Learn” allows hospital teams to share lessons learned with one another to promote safety and improved outcomes for all.

IMPLEMENTING SAFETY SYSTEMS IN HEALTH-CARE ORGANIZATIONS TO ENSURE SAFE PRACTICES AT THE DELIVERY LEVEL

Health-care organizations strive to create a safe system and environment for all patients and employees. Despite great efforts and devotion by members of health-care teams, tools to ensure safety of care must be developed and implemented. The military and aviation industries perform incredibly difficult processes under stress yet have implemented processes and protocols to ensure the safety of their employees and others. (22) Some of the tools that have been adapted for use in health-care include: checklists, TeamSTEPPS, and CPOE. Fostering a culture of safety within an organization is an integral component of preventing medical errors and reducing patient harm.

Checklists

A checklist contains a listing of tasks that must be completed to ensure accuracy and safety. Checklists have been used in aviation since the 1950s. The aviation industry realized that checklists play a vital role in ensuring safety by providing a list of tasks that must be completed before engine starts, takeoff, and landing as well as tasks for in-flight procedures and emergencies. The checklist ensures that the same

TABLE 2. 2015 National Patient Safety Goals for Hospitals

| Goal 1: Improve the accuracy of patient identification |
| Goal 2: Improve the effectiveness of communication among caregivers |
| Goal 3: Improve the safety of using medications |
| Goal 6: Reduce the harm associated with clinical alarm systems |
| Goal 7: Reduce the risk of health care associated infections |
| Goal 15: The hospital identifies safety risks inherent in its population |
| UP 01: Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery |


TABLE 3. 2015 National Patient Safety Goals for Ambulatory Care

| Goal 1: Improve the accuracy of patient identification |
| Goal 3: Improve the safety of using medications |
| Goal 7: Reduce the risk of health care associated infections |
| UP 01: Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery |

process is followed consistently each time without reliance on human memory, allows for mutual checking, and enhances communication among crew members. (49)

The role and importance of checklists in ensuring safety has been recognized by the health-care industry. In 2007, The World Health Organization launched the Safe Surgery Saves Lives Campaign in response to an estimated 7 million surgical complications per year worldwide. The initial study included hospital representation from Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, The Philippines; Ifakara, Tanzania; London, United Kingdom; and Seattle, Washington. A surgical checklist was developed for completion at transition points throughout the surgical procedure, including before administration of anesthesia, before skin incision, and at completion of procedure. Through consistent use of the surgical checklist, the rate of major complications and mortality decreased by more than one-third in each of the eight centers. (50)(51)

TeamSTEPPS
Complete, timely, and effective communication is critical to ensuring patient safety. Unfortunately, communication is frequently the root cause of sentinel events. (52) The US Department of Defense and AHRQ have worked collaboratively to develop TeamSTEPPS, a system to enhance communication and teamwork. (53) Some critical times of information exchange include handoff, change in clinical status, and whenever a team member has a safety concern. TeamSTEPPS provides health-care teams with tools and common language to foster timely and effective communication as well as a culture of mutual respect and support. An example of a tool to organize presentation of information that requires immediate response is SBAR: Situation, Background, Assessment, and Recommendation/Response.

Computerized Provider Order Entry
Medication prescription and administration pose a significant risk to the pediatric population. Pediatric patients are at increased risk for harm due to factors such as weight-based dosing, use of off-label medications, large dosing range based on indication for medications, and limited ability of the patient to communicate. Most medication errors occur at the time of prescription. (44) CPOE systems used in conjunction with clinical decisions improve medication safety by eliminating illegibility of orders and transcription errors, providing support for medication selection and adherence to guidelines, and delivering alerts for dosing outside of the accepted range. A meta-analysis conducted to review the effect of CPOE on prescription errors, ADEs, and mortality showed that prescription errors were significantly decreased after the introduction of CPOE, but ADEs and mortality were not. (54) Longhurst et al (55) published results from a quaternary care children’s hospital documenting that the monthly adjusted mortality rate decreased by 20% with the introduction of a commercially available CPOE. With continued evolution of commercially available pediatric-specific CPOE systems and clinical decision support, the contribution of these systems to medication safety should expand.

Culture of Safety
CHSPS maintains that the development of a culture of safety is essential to reducing patient harm. A culture of safety incorporates principles learned from HROs, such as sensitivity to operations, preoccupation with failure, and reluctance to simplify. By following these principles, the organizational expectation becomes that all employees have a personal responsibility to maintain the safety of all patients. (56)

MEDICAL ERROR DISCLOSURE
Despite many efforts, medical errors continue to occur within pediatric practices. Once a medical error has been detected, the medical team must face the difficult task of disclosure to the patient and family. Patients desire disclosure of errors that have caused them harm. They request information, including why it happened, how the error can be corrected, and how the error can be prevented in the future. In addition, patients have stated that disclosure of medical errors by physicians helps build their trust in the clinician. (57) A survey to examine parental preferences for error disclosure and legal action was conducted on a sample of parents who presented to an emergency department with a child. The responses revealed that 36% of parents were less likely to seek legal action if a medical error was disclosed by a physician. (58)

Physician perceptions regarding medical error may differ from that of their patients. Although physicians agree that medical errors resulting in harm should be disclosed to their patients, they hesitate to do so because of fear of litigation. Physicians may find themselves “choosing their words carefully” in an attempt to discuss the adverse event without explicitly mentioning that an error has occurred. The act of apologizing has also been an area of concern due to the perception that an apology creates a legal liability and may be damaging to the physician’s reputation. (59)

The IHI provides recommendations for disclosure of adverse events to ensure that the patient and family remain at the center of communication. (60) Among the recommendations are: clear communication about the event that includes how it happened and what will be done to prevent
this occurrence in the future, appointment of a staff member as the family support person who is available 24/7, assurances that any new information obtained from investigation of the event is shared with the family in a timely manner, and addressing all patient and family concerns as soon as possible.

SECOND VICTIMS

The Hippocratic Oath states, “I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.” The concept that a physician will never do harm and, in essence, never commit a medical error creates professional and societal pressure. Unfortunately, when a medical error resulting in patient harm does occur, the emotional and psychological effects on the clinician can be profound. Anger, fear, guilt, and self-doubt are common. The designation of “second victim” recognizes medical professionals involved in medical errors who experience difficulty in coping with emotions. (61)

Providing appropriate support to second victims is critically important. Many institutions have readily available employee assistance programs, but clinicians may be reluctant to seek resources. (59) Additional programs have been developed specifically to lend support to second victims. Medically Induced Trauma Support Services is an organization established by a patient and a physician involved in a medical error that had caused harm to the patient. The organization provides A Toolkit for Building a Clinician and Staff Support Program as well as support services to clinicians involved in a medical error. (62)

Colleague support for second victims is also important, although it can be challenging. Victims often need support and understanding following an adverse event. Simply asking how he or she feels and listening can be comforting and alleviate concerns and feelings of being shunned. In addition, exchanging personal experiences with errors can be reassuring. (61)

Another program developed to lend support to clinicians in deeply stressful situations is Code Lavender. (63) Code Lavender is a hospital response team that is deployed to care for patients, parents, and clinicians in times of emotional stress and fatigue. The team may consist of nurses, chaplains, social workers, and other clinicians. The tools they use may include imagery, Reiki (Japanese technique for stress reduction and relaxation), meditation, and music therapy.

CONCLUSION

Quality improvement initiatives and implementation of safety systems have resulted in a decrease in patient harm, although harmful events continue to occur. (13)(14)(18)(21)(38)(64) Improved detection and reporting of medical errors allows review of factors that contribute to the error and implementation of risk reduction strategies. (28)(29) The development of pediatric networks and collaboratives enable shared learning and can expedite the rate of change. (24)(27)(46)(50)(51) In addition, the recognition of cultural transformation as a key component of a successful patient safety program has further enhanced the work to prevent patient harm. (21)(29)(26)(28)

Summary

- Case study data continue to demonstrate instances of unintended harm to pediatric patients. (13)(14)(18)(21)(38)(63)
- On the basis of strong evidence, pediatric networks and improvement collaborative mechanisms improve quality and safety of care. (24)(27)(46)(50)(51)
- Increasingly, case studies are demonstrating culture change as a necessary component to improving pediatric patient safety. (21)(25)(26)(28)

References for this article are at http://pedsinreview.aappublications.org/content/36/9/403.full.

To view PowerPoint slides that accompany this article, visit http://pedsinreview.aappublications.org and click on the Data Supplement for this article.
PIR Quiz

1. As you prepare a lecture on patient safety for third-year medical students, you decide to begin by defining the terminology used nationally by governmental agencies as well as by the local hospital administration. The most accurate description of a medical error is that it:
   A. Always injures the patient.
   B. Does not require investigation if patient harm has not occurred.
   C. Is a mistake that always reaches and causes harm to the patient.
   D. Is characterized by the use of a wrong plan to achieve a desired aim.
   E. Offers little to learn if the error was intercepted and prevented from reaching a patient.

2. A fourth-year medical student is completing a quality improvement project as part of his graduation requirements. He is interested in a career in pediatrics and recently completed a sub-internship on the general pediatric ward. He is interested in educating medical students and residents on medical errors among pediatric patients. Which of the following information is most correct in support of his research?
   A. Although incorrectly interpreting viral as bacterial illness is common, pediatricians rarely report this diagnostic error.
   B. In a multicenter survey conducted by Singh et al, nearly 50% of surveyed pediatricians reported making a diagnostic error at least once a year.
   C. In a multicenter study conducted by Singh et al, the most frequent diagnostic error was misinterpretation of complete blood cell count indices.
   D. The most common diagnoses in pediatric medical malpractice claims are intussusceptions and suspected child abuse.
   E. Most pediatric malpractice claims result from missed or incorrect diagnoses.

3. You are conducting rounds on a 4-day-old preterm infant who was born at 26 weeks’ gestation. The infant is maintained on mechanical ventilation and nothing by mouth. You are preparing to write the medication order for a second course of indomethacin for treatment of a patent ductus arteriosus. Which of the following is not a factor that increases the difficulty in pediatric medication management?
   A. Altered pharmacokinetics in preterm infants.
   B. Calculations necessary for weight-based dosing.
   C. Frequent changes in weight that require changes in dosing.
   D. Limited ability of parents to communicate with physicians.
   E. Off-label use of medications.

4. A pediatric nephrologist diagnoses nephrotic syndrome in an 11-year-old boy based on clinical symptoms of gross edema, pleural effusions with dyspnea, proteinuria, and fatigue. He admits the boy to the nephrology ward to begin a course of corticosteroid therapy. The boy has no known drug allergies documented in his medical records. After the initial dose of corticosteroid, he develops an allergic reaction. Which of the following most accurately describes the type of error that occurred?
   A. A diagnostic error made by the pediatric nephrologist.
   B. A nonpreventable medical error.
   C. A preventable medical error.
   D. Not a treatment error because it did not result in patient death.
   E. Not a medical error.

5. During ward rounds last week, one of the general pediatricians wrote orders for vancomycin and cefotaxime to treat orbital cellulitis in a 3-year-old girl. After administration of the antibiotics, clinicians discovered that the child received an overdose of vancomycin. Voluntary error reporting revealed that the medication had been ordered incorrectly by the physician, and the error was overlooked by pharmacy and nursing. Which of the following is a common reason cited by both physicians and nurses as a barrier to voluntary error reporting?
A. Belief that the event was too trivial to make a formal report.
B. Forgetting to file a report.
C. Incident form takes excessive amount of time to complete.
D. Lack of feedback.
E. Not necessary to report near misses.
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Lucy Pereira-Argenziano and Fiona H. Levy
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