Disclosure of Adverse Events: A Guide for Clinicians

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ABSTRACT
Introduction: Children’s Hospitals’ Solutions for Patient Safety (SPS) acknowledged a recommendation from the American Academy of Pediatrics to develop education programs on the communication of adverse events with patients and families. SPS set out to create a guide that would outline a standardized disclosure process and provide a training curriculum and tools so that providers would feel better prepared to have effective disclosure conversations. Methods: SPS disclosure work began with the development of a project team made up of 9 network hospitals. The team utilized key driver diagrams and process maps to show the relationship between the project aims, key drivers, and specific interventions. The team developed a training curriculum, guide, and tools for each area of improvement. To ensure these were effective, they were tested using case studies and plan-do-study-act cycles. Results: One of the cohort hospitals piloted the curriculum and tools, training 48 physicians, nurses, executives, and other allied health professionals. Pretest to posttest scores improved from an average of 82.7% to 90.2%. Survey feedback was favorable with 100% of respondents noting that they strongly agree or agree that attending this educational activity increased or improved their competency, performance, and patient outcomes. Conclusions: Initial testing suggests that the developed curriculum is empowering for frontline clinicians. Materials are available in an electronic format on the SPS external website. As member hospitals implement these materials, they will be evaluating learner satisfaction and provider usage. SPS will seek out feedback from these hospitals to further develop the materials and support clinicians. (Pediatr Qual Saf 2019;4:e185; doi: 10.1097/pq9.0000000000000185; Published online June 27, 2019.)

INTRODUCTION
Children’s Hospitals’ Solutions for Patient Safety (SPS) is a network of over 135 children’s hospitals that have come together to eliminate serious patient and employee harm. Partnership with patients and families is a core value of the network, and the group endeavors to integrate patient and family participation in its work to reduce readmissions, eliminate serious safety events, and reduce hospital-acquired conditions (HACs). A unique aspect of the SPS approach is the focus on safety culture within each network institution. SPS emphasizes that cultural transformation must occur for process improvements to be successful and sustainable. This transformation needs to happen at all levels of an institution from the chief executive officer to frontline staff members creating an expectation of personal accountability for safety. By weaving together culture transformation and process improvement approaches and coupling them with strong family partnerships, SPS seeks to achieve the highest quality outcomes for patients, families, and staff.

As the SPS network focused on improving pediatric patient safety through the development of clinical practice bundles and training programs, network leaders recognized the gap in providers’ knowledge and skills around the disclosure of adverse events (AEs) to patients and families. Although most clinicians have limited disclosure training during their formal education, clinical training, practical experience, or even via continuous education, most clinicians agree further training is needed. According to Brown et al, “Even veteran physicians experience substantial stress when communicating with patients when errors occur, and any patient anger and physician shame may compound the stress.” Attitudes toward disclosure have changed because the release of the IOM reports, such that both providers and patients and

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families expect a greater degree of transparency. Also, SPS acknowledged a recommendation from the American Academy of Pediatrics to develop education programs on the communication of AEs with patients and their families. With this information, SPS set out to create a guide that would outline a standardized disclosure process and a training curriculum and tools so that providers would feel better prepared to have effective disclosure conversations.

An AE is the unintended outcome of a medical treatment or procedure that results in an actual or potential negative consequence to the patient. Nearly, all healthcare facilities have systems in place for reporting AEs within administrative structures, but this is not the same as disclosure to the patient and family. Reporting systems are internal structures for tracking and reporting events to regulatory bodies. Reporting systems allow organizations to identify trends and work to prevent future events. Disclosure is communication provided by healthcare professionals to the patient and/or family about an AE. Disclosure is a description of the known facts surrounding the event and does not include speculation or assumptions about the cause.

According to the National Patient Safety Foundation's Lucian Leape Institute, “transparency between clinicians and patients can be defined as extreme honesty with patients and their families from start to finish. The span of honesty includes shared decision making, fully informed consent before treatment, free and open communication during the process of care, and openness with patients and families when things go wrong.” Transparency and patient safety go hand-in-hand and afford many benefits to the patient, family, and the clinician.

Disclosure following an AE has many benefits for both clinicians and patients and families including improved care experiences and the ability to engage in effective and shared decision-making. Additionally, full transparency can allow for the avoidance of adversarial situations between patients and clinicians and prevent inconsistency between messaging and behavior. Finally, after an event, transparency and disclosure can help minimize the disruptive consequences of litigation and may result in reduced legal fees.

Despite the benefits of disclosure, there are just as many, if not more barriers to the disclosure happening after an AE, particularly regarding how one discloses AEs. These include the lack of training, tools, practice, and coaching; limited role modeling of the disclosure; and lack of institutional culture and norms supporting disclosure. Organizational policies may require clinicians to disclose AEs, yet gaps in knowledge and skill among providers may exist. Often, clinicians essentially learn and practice disclosure real-time in front of distressed families. Clinicians sometimes are not sure what is permissible or desirable to say or not to say. Additionally, they often fall short, failing to meet patient expectations.

There are some existing disclosure training programs available. One example is Communication and Optimal Resolution, developed by the Agency for Healthcare Research and Quality. This program offers training materials and tools to guide providers through a disclosure conversation following an AE. The SPS training curriculum will add to the existing educational resources; however, this resource has been designed by pediatric hospitals for pediatric hospitals.

**METHODS**

In early 2016, SPS disclosure work began with the development of a pioneer cohort of 9 interested SPS network hospitals who each had several members of their physician, legal and quality department teams who volunteered to be on the project team. The project team also contained a parent and Family Consultant from Children’s Hospital of Philadelphia. The team developed key driver diagrams to show the relationship between the project aim, key drivers, and specific project interventions. The team developed a global aim for the project of highly skilled frontline ordering clinicians continuously trained in disclosure.

The team then outlined the disclosure process from start to finish in a disclosure process map (Fig. 1). There are many steps within the disclosure process. The project team defined the scope of this project to include the following 3 steps: (1) the Huddle, which is a meeting that occurs to gather relevant facts, to plan for the patient and family conversation, and to quickly rehearse; (2) the Disclosure Conversation, which is the actual conversation where patients and families are informed of the facts that something has happened; and (3) Disclosure Documentation of the disclosure conversation in the medical record. The team further defined the scope of the project to include the disclosure of events that occurred as a result of a deviation from the standard of care that either resulted in minimal patient harm, no detectable harm, or no harm or events defined as HACs by SPS. Project work excluded near-miss events, serious safety events, HACs in the initial phase of SPS definition and development, and hospital readmissions.

The team developed key driver diagrams for each area of improvement: the Huddle (Fig. 2), the Disclosure Conversation (Fig. 3), and Documentation in the Medical Record (Fig. 4). Each key driver had interventions that were the aligned tools and templates. The guide would contain a training curriculum and tools to prepare providers to have effective disclosure conversations. The team of network hospitals worked collaboratively to develop a training curriculum, tools, and templates for each area of improvement. To ensure these were effective, the staff of team member hospitals tested those using case studies and plan-do-study-act (PDSA) cycles. The case studies were developed using real scenarios from the team member hospitals. After each test, which consisted of the project team members simulating the Huddle, Disclosure Conversation, and Documentation using the provided scenario, hospitals would turn in their PDSA worksheets to the project leaders at SPS with suggestions for
improvement. Suggestions were then discussed on conference calls with the entire project team.

Following multiple PDSA cycles and discussions, the team decided to expand the scope of the project and include postdisclosure debriefing. This step in the disclosure process allowed the team to gather their thoughts, identify key learnings, clarify next steps, and prepare for documentation. Additionally, the team identified the value of a Disclosure Worksheet (see Appendix A, Supplemental Digital Content 1, http://links.lww.com/PQ9/A105) which guides practices for synthesizing information surrounding the event into known facts, preparing the disclosure spokesperson for the disclosure conversation, the debriefing process, and documentation in the medical record. This worksheet would serve as a quick reference guide that clinicians could use “in the field.” Last, through the process of completing multiple PDSA cycles and applying the Disclosure Worksheet to case studies of actual AEs, the team noted the benefit of this simulation type practice. Additionally, the literature supports the benefit of applied learning methods such as simulation. Therefore, the simulation was included as a key component of the developed curriculum. It was believed that clinicians that received this training and had a chance actually to practice having a disclosure conversation would feel better prepared and more confident in their ability to have effective disclosure conversations with patients and families.

RESULTS

The team of SPS network hospitals outlined a standardized disclosure process and developed a robust disclosure training curriculum and training guides with aligned tools to support clinicians. All of these materials were intended to prepare frontline clinicians to disclose to patients and families and meet the training need identified in 2016 by the American Academy of Pediatrics. The training curriculum focuses on 4 steps within the disclosure process. It is designed to be 4 hours in length and incorporates multiple teaching methods including lecture, discussion,
videos, and simulation where the participants can practice using the tools. The content of the disclosure curriculum and training guide is shown in Appendix B, Supplemental Digital Content 2, http://links.lww.com/PQ9/A106. The materials serve as a foundational guide for hospitals and can easily be adjusted to align with each organization’s specific disclosure policy and meet state regulatory requirements.

Since completion, the curriculum has been made available online to all SPS network hospitals. Children’s Hospital and Medical Center in Omaha, one of the 9 cohort hospitals that served on the project team, piloted the developed materials, integrating them into their newly developed organizational disclosure program. They trained 48 physicians, nurses, other allied health professionals (radiology staff, pharmacists, patient relations coordinator, etc.) and executives. Physician trainees volunteered while both nurses and other allied health professionals were selected based on their job responsibilities and likelihood to be involved in a future disclosure.

As previously noted, the curriculum and tools were slightly modified to align with the organization’s disclosure policy and state apology law. Training consisted of 1 hour of pre-work, 1.5 hours of didactic training, and 1 hour of simulation training with the use of scenarios and standardized patients serving as the patient’s family. Trainees (n = 47) completed both a pretest and posttest with scores improving from an average of 82.7%–90.2%. The pretest and posttest were identical and contained questions to test the learner’s knowledge of the information shared within the didactic portion of the training. Continuing Nursing Education (CNE)/Continuing Medical Education (CME) survey feedback was extremely favorable with 100% of respondents (n = 16) noting that they strongly agree or agree that attending this educational activity increased or improved their competency (ability to apply the knowledge), performance (what is actually done in practice), and patient outcomes (ability to positively impact health status).

LIMITATIONS
The SPS Disclosure Curriculum was designed to support providers in the disclosure of minimal harm events and excluded serious harm events. Although pretest and

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**Fig. 2.** Huddle key driver diagram. ID, identify; JIT, just in time; LOR, level of reliability.
Fig. 3. Disclosure conversation key driver diagram. LOR, level of reliability.

Fig. 4. Documentation key driver diagram. EMR, LOR. EMR, electronic medical record; LOR, level of reliability.
Disclosure of Adverse Events

posttest scores improved, scores were not evaluated to ensure statistical significance. Additionally, CNE/CME surveys were voluntary and had a low return rate. Although extremely favorable, only 16 of the 48 trainees provided feedback. Last, results were based on a pilot from one SPS hospital so they cannot be generalized and may have been impacted by the pilot organization’s existing safety culture.

DISCUSSION

The importance of effective disclosure of AEs cannot be overstated. How to best disclose an AE is an evolving process, and the SPS Network, which was already working to improve the pediatric patient safety, recognized that standardization of the disclosure process and the development of educational resources on this topic were needed to support a safety culture. The training curriculum, training guide, and tools have been designed to support clinicians, helping them to feel better prepared and more confident in their ability to have effective disclosure conversations with patients and families.

Feedback from training participants at one SPS network hospital that piloted the SPS materials within their newly developed disclosure program was extremely favorable with self-reported increases in competency, performance, and patient outcomes. Preparing frontline clinicians and helping them to feel more confident and competent in their abilities to have disclosure conversations with patients and families will help to establish a safety culture within healthcare organizations further. It is recommended that further research is done on the disclosure of AEs related to the best practice utilization, provider training, pediatric patient presence, and patient and family outcomes.

CONCLUDING SUMMARY

The SPS network has made these disclosure materials readily available in an electronic format on its external, public website (https://www.solutionsforpatientsafety.org/for-hospitals/hospital-resources/). Additionally, materials were reviewed with member hospitals at an in-person learning session and in an online webinar. As member hospitals implement these materials, they will be evaluating learner satisfaction and provider usage. SPS will seek out feedback from these hospitals and their parent and patient advisory boards to further develop the materials and support frontline clinicians.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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