Patient and Family Involvement

One System's Journey in Creating a Disclosure and Apology Program

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Patients in acute care hospitals experience a major permanent injury or death 0.2% to 2% of the time as a result of their medical care.[1] The Harvard Medical Practice Study found that 3.7% of patients experienced an adverse event during hospitalization.[2] Patients and families expect prompt and honest disclosure of adverse events.[3–6] Boothman et al. affirmed that disclosure is absolutely integral to patient safety and quality improvement.[7]

A number of health systems inaugurated the movement towards open, prompt, and compassionate disclosure of unanticipated outcomes. Perhaps the first, the Veterans Affairs hospital in Lexington, Kentucky, instituted a policy of full disclosure in 1987.[8] The University of Michigan launched a new system in 2001.[9] The effectiveness of clinician education on how to respond to adverse events is unknown. Sophisticated investigations involving multicenter controlled trials of training interventions are planned, but the results are several years away.[10] Until then, reports of implementation of disclosure and apology programs may foster more efficient adoption. This article describes one health system's decisions and experiences in implementing such a program.

Implementation

Setting

Baystate Health (BH) is an integrated health care system in western Massachusetts that consists of three hospitals (770 beds and 57 bassinettes), a children's hospital at the largest campus, a visiting nurse association, an ambulance company, and a cancer center. Its flagship hospital, Baystate Medical Center (BMC), is a 653-bed academic center and the western campus of Tufts University School of Medicine.

BH's strategic plan promotes a culture of safety through active involvement of leadership (for example, senior leader walk-arounds), medical staff (physician-led peer review and performance improvement), and frontline staff (an online safety reporting system since 2001). BH has provided a quality report on its Web site since 2004.

Article-at-a-Glance

Background: Patients experience adverse events more frequently than the public appreciates. A number of health systems have led the movement toward open, prompt, and compassionate disclosure of adverse events.

Implementation: In 2006 Baystate Health (BH) formed a disclosure advisory committee to design and implement an enhanced program to support prompt and skillful disclosure of adverse events. The proposed model for a disclosure and apology program resembled a consultation service, similar to a hospital ethics consultation service. BH hired an outside trainer to teach coaches/facilitators. Emotional support services were formalized and expanded not only for patients and families but also clinicians.

The Experience so Far: Implementation of a formal disclosure and apology program has placed internal pressure on the organization to more promptly determine causality of adverse events and to respond to patient/family requests for information and/or assistance. Root causes and degree of system culpability are often not clear early after an event and sometimes are debated among the clinical team and the trained coaches/facilitators and risk managers.

Discussion: After a medical error, patients and families expect the organization to make changes to the system to prevent other patients from being harmed by the same mistake. To minimize the chance that patients and families feel that their suffering has been "in vain," health care systems will need to put systems in place to deliver on the promise to reduce the risk of future harm. Some of the challenges in sustaining such a program include the ability to promptly investigate, to accurately determine liability, to communicate empathetically even if unable to meet all patient/family expectations, and to ensure establishment of a just culture.

The majority of unanticipated adverse events come to the attention of risk management through phone calls from clinicians and from submissions to our online patient safety/incident reporting system. BH defines an adverse event as an "untoward, undesirable, and usually unanticipated *outcome*, such as the death of a patient or a loss or injury resulting from a medical intervention."

To advance our culture of safety and to extend our commitment to transparency, creating a robust disclosure and (when indicated) apology program for our patients seemed a key next step.

Formation of Disclosure Advisory Committee and Project Coordination

In 2006, BH recognized an opportunity to improve communication with patients and families following adverse events. BH's professional liability program and board of trustees strongly supported this initiative. Three senior disclosure champions (the chief quality officer [E.M.B.], the chief nursing officer [D.S.M.], and the chief risk officer [P.K.B.]) chartered a project advisory committee and assigned the director of risk management for BH [L.M.T.] and the medical director for quality and patient safety at BMC [R.R.P.] to lead the design and implementation of the project.

A literature review identified a preponderance of articles focused mostly on the ethical imperatives of disclosure and apology[11,12]; clinician and patient family preferences for disclosure conversations[13,14]; the potential impact (including the financial impact) of open, prompt disclosure[15,16]; and practical tips for disclosing.[17–19] Although a few health systems have described disclosure and apology programs, surprisingly little was available from the literature which described the details of how such programs are created. (A few months into the project, the Harvard teaching hospitals released a consensus document[20] on the key elements of a best practice disclosure program.)

Model Development

The proposed model for a disclosure and apology program resembled a consultation service, similar to a hospital ethics consultation service (Figure 1, page 489). The advisory group endorsed a plan to train professionals within the three BH hospitals who would be available for support, coaching, and just-in-time training in the aftermath of a medical error (Sidebar 1, right).

During the refinement of the disclosure and apology model, presentations were made to internal groups (including the board of trustees quality subcommittee) to communicate the following:

- Leadership from the highest level of the organization was committed to providing a proactive, state-of-the-art disclosure and apology system.
- Such a program was consistent with, and a natural outgrowth of, our mission statement and our "operating principles" (collaboration, communication, trust, respect, and integrity).
- Evidence suggested that patients and providers benefit from such programs.

These informational sessions also provided the opportunity to receive feedback and concerns from providers.

Sidebar 1. Disclosure Conversations and Interaction with the Patient and Family

Patients and families are promptly informed of serious adverse events. Those responsible for care of the patient, usually the physician, may consult with risk management or other members of the communication consultation team before meeting with the patient and/or family. In this meeting, the physician discloses the known facts, often focusing on acknowledgment of the event, expressions of regret, and plans for care of the patient.

The patient and/or family are also given assurances that the causes of the event will be investigated and that the information and findings will be shared with them once more information is known. A commitment is made to remain in contact with the patient and/or family and to be available for follow-up questions and requests for information. When it is known or recognized that an error caused the adverse event, an apology is offered, and a commitment is made to find the cause of the error. After the investigation is completed, patients and families are informed of any corrective actions or changes in systems or processes to prevent recurrence.

Training

The advisory group wrestled with the options for training: hiring an outside trainer to come on site, sending a BH team to outside training, or building a training program internally. After phone interviews with outside trainers, conversations with early adopter hospitals, and observation of one consultant's training session at another hospital, BH elected to engage outside experts to train an internal communication consult team. BH made this choice, in part, because of the expectation that outside experts with national experience would be more credible to BH physicians.

The advisory group also deliberated about the optimum number of BH staff to invite to intensive training. To accommodate role-plays and breakout groups, the lead trainer

Disclosure/Apology Pathway

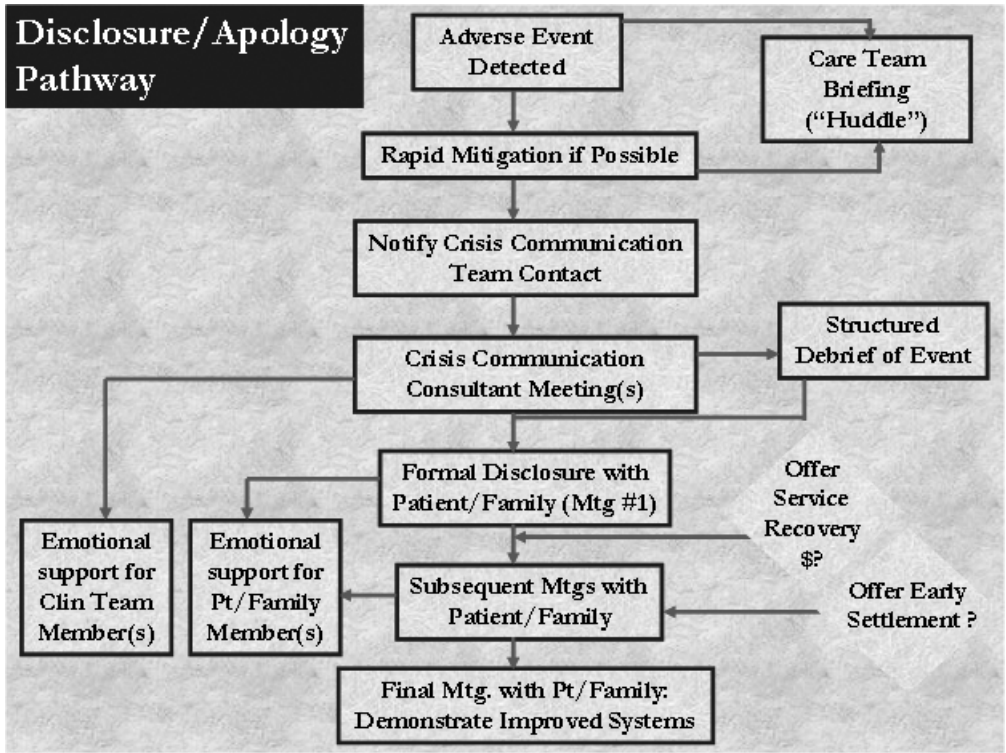

Figure 1. *This conceptual model highlights the likely key steps after a serious adverse event and the key resources available for patients, families, and clinicians. Mtg, meeting; Clin, clinical; Pt, patient.*

proposed five BH trainees per outside trainer. BH determined that for all three hospitals the following groups would be represented at the joint training sessions:

- Physicians and nurses
- Risk management staff (including claims staff)
- Spiritual services
- Social services
- Quality improvement
- Staff serving or having served on the ethics consultation team
- Patient relations

Physicians were included in the training, in part, to accommodate clinicians who prefer a physician-coach in the aftermath of an adverse event. BH informed trainees that participation in the workshop would entail a commitment for supporting and coaching staff in the event of unanticipated outcomes. The advisory group favored selection of trainees who had the ability to temporarily put aside most other work responsibilities in the immediate aftermath of a serious adverse event. The selected trainees became the BH health communication consultation team.

The outside trainer first provided a 90-minute invitational overview lecture for BH leaders. Intensive training of 25 staff, which took place at an off-site venue, provided not only fundamental concepts about the importance and utility of disclosure and/or apology but also basic skills in counseling and coaching clinicians following an adverse event. The format consisted of didactic sessions, critiques of the adequacy of disclosure communication skills using videos of enacted disclosure conversations, role-playing small-group exercises, tutorials on "reading" the various emotions displayed by patients/families and clinicians in disclosure conversations, and practical suggestions about the composition of disclosure teams, timing of disclosure conversations, and so on. The program specifically differentiates approaches to disclosure for unanticipated outcomes without injury versus unanticipated outcomes with injury.

Five trainees received an additional 1.5 days of exposure to disclosure and apology and to more-in-depth disclosure techniques. These five persons were asked to provide training to colleagues in the health system to help spread the concepts.

Policy and Program Enhancements

Wu characterized clinicians involved in a medical error as "second victims."[21] Even when a hospital adopts a "blame-free" approach, clinicians do not necessarily stop blaming themselves.[22–24] Patients may experience profound feelings, including a loss of trust, humiliation, anger, and abandonment.

These feelings sometimes manifest in full force months after the adverse event, similar to other posttraumatic disorders. State-of-the-art disclosure programs go beyond addressing the factual needs of patients, families, and involved clinicians to also provide emotional support.[25]

BH previously established a provider support program for physicians involved in a claim or lawsuit. This program, which is funded through the health system's self-insured professional liability program, was expanded and made available as a service for any provider involved in an adverse event. Also, clinicians may seek counseling from the Employee Assistance Program, from psychiatrists employed by BH or in the community, or from hospital chaplains or social workers.

BH contracted with an outside vendor to provide referrals to community therapists for patients and families affected by an adverse medical event. Services are reimbursed by BH's professional liability program.

BH expanded the existing written disclosure policy. During the approval process, patient care policy committee physicians asked for more clarity about the situations in which they were expected to disclose or apologize. The project leaders suggested that a list of National Quality Forum "never events"[26] would be a natural minimum set of adverse events requiring disclosure and/or apology. However, the BH policy (Appendix 1, available in online article), which went into effect May 1, 2007, does not restrict disclosure or apology to those never-events. At the same time, clinicians are not routinely expected to disclose errors in which no injury occurs. Information regarding these events, however, is requested to be entered in the safety reporting system. Near misses or close calls may be worthy of disclosure and discussion in those situations in which the patient or family witnesses the near miss. The BH policy does not suggest or require that every adverse event be handled with an apology.

The project leaders recommended to the policy committee that in most cases a physician should be the lead person for the actual disclosure and/or apology. Physicians on the policy committee expressed concern about being expected to assume responsibility for disclosure or apology (1) when another member of the team made the error or (2) when an error was directly due to system failures. Following the approval of the policy, the project leaders stated that physicians of record should usually accept responsibility for disclosure conversations with the patient and family, even if they are not prepared to accept responsibility for the error on behalf of the system and/or other clinicians.

Although disclosing errors to patients can be challenging for physicians, BH did not consider relegating follow-up disclosure conversations for all serious errors to a senior leader, such as the chief medical officer. Although such a model potentially provides consistency and increased practical experience for a small contingent of leaders, it does little to attempt to repair the broken trust that is often inherent in a medical error.

BH leaders decided not to compel clinicians to consult with a communication consultation team member before disclosing and/or apologizing. Requiring consultation in all situations was felt to add unnecessary delay and complexity to situations in which an adverse event results in minimal harm, suffering, or inconvenience. Rather, clinicians are encouraged to employ the techniques taught by BH trainers and on-line resources and to adhere to the disclosure and apology policy.

Before training occurred, project leadership contemplated a model of just-in-time consultation with advisors or coaches, all of whom would serve on an as-available basis.

Before the establishment of the disclosure and apology program, risk managers often served as informal confidantes and counselors to distraught clinicians after learning about a potential claim made against them. This emotional support role was complemented by their traditional risk management and mal-

Sidebar 2. Investigation of an Adverse Event

After a serious adverse event, risk managers are responsible for conducting an investigation to assess the liability exposure to the organization and to, whenever possible, mitigate any future losses. The objectives of an investigation are to obtain the relevant facts, preserve information, sequester involved devices or equipment, identify the circumstances that led to the error, determine the nature and cause of the event, and to assess potential liability. This is accomplished by many different means, including interview of the involved individuals, review of medical records, and expert or peer review.

The performance improvement process may involve either a parallel investigation or a collaborative review with risk management. The goal of any root cause analysis performed by the Division of Healthcare Quality is to identify the underlying cause(s) of the event and to identify failures in systems or processes. Peer review focuses on the practice of individual providers to determine whether or not these providers met accepted standards of care. Although risk management and Healthcare Quality may differ in their respective roles after an adverse event, the underlying prime purpose of postevent investigations is patient safety.

practice claims processing roles. After training to become communication consult team members, the risk managers continued their pivotal role in the early management of unanticipated adverse events (Sidebar 2, page 490).

Dissemination

In a dissemination campaign that started in March 2007 and lasted through the year, descriptions of the disclosure and apology program were disseminated through in-house publications in both print and electronic (intranet) formats. Project members presented to departmental meetings, grand rounds, the board of trustees quality committee, the residency programs, and so on.

BH has placed reference materials on its intranet, including a list of "Do's and Don'ts" for clinicians preparing to disclose (Table 1, page 492), information regarding formal emotional support available to patients/families and clinicians, the BH disclosure policy, a link to the Harvard Teaching Hospitals Consensus document,[20] and other on-line educational resources.

Ongoing Work

The communication consultation team meets quarterly to share challenges and lessons learned from newly identified cases of medical errors. The stories and experiences acquired from responding to new cases provide a rich source of discussion material.

BH currently maintains a database of all identified disclosure and apology cases, including patient demographics, the nature of the event, and any bill adjustment or payment made to the patient or family. In addition, reports are generated from BH's safety reporting system about the cases in which the reporter or unit manager indicates that a disclosure was made to the patient or family.

The Experience so Far

BH has built a disclosure and apology system with formal support for patients and families as well as clinicians. Physicians are actively participating and usually willing to apologize promptly after a medical error. A well-trained communication consultation team is now in place to help respond to adverse events. On-line just-in-time resources are available for clinicians. Patient and family members, some of whom are BH employees, are increasingly learning about the program. BH is experiencing an increase in early, open communication with patients and families. Leadership, including the BMC board of trustees, has embraced the program. However, two years into the program, it is too early to assess overall patient, family, and clinician satisfaction with the program.

One of our early disclosure cases involved the use of an improperly sterilized endoscope. After the error was recognized, two patients were informed (including the patient on whom the endoscope was used before the failed sterilization), and the organization began its root cause analysis (RCA). The organization advised both patients that we were committed to determining what happened, why it happened, and what could be done to reduce the likelihood of recurrence. In the interim, appropriate steps for follow-up evaluation and testing of each patient were taken, and the patients were kept apprised of not only their own clinical findings but also the results of the RCA and subsequent quality improvement measures that were implemented. The active involvement of the patients and clinical team demonstrated to us the power of patient participation and the impact of full disclosure.

In another case, a patient contacted a representative of the health system after reading about BH's program. This patient experienced several complications following surgery and believed that the surgeon was aware that she had caused these complications. The patient was very angry that these complications had occurred. Neither an internal nor external review established evidence of medical error. The findings were communicated to the patient. BH began to recognize that the patient had expectations that BH could not meet. Patients and families may expect an apology that acknowledges responsibility and/or compensation, even when liability is unclear or absent as a result of an investigation. For some families, it appears that the new disclosure program has created unrealistic expectations.

A new disclosure system can trigger unanticipated reactions from staff. A social worker involved in a recent case with medical error perceived the offer of early service recovery money as a form of "hush money" to decrease the chances of the patient and family filing a lawsuit. Feedback was provided to the social services department that offers for early compensation are not in any way intended to prevent open communication between the patient and family and any other parties.

The new disclosure process has also changed the approach toward managing adverse events. Historically, medical experts are called on to defend a claim or lawsuit. Traditionally, these expert opinions are withheld from patients. However, in a transparent culture, such a review should be shared with the patient. This sharing may not be fully embraced by the physician who performs the review or by the attorneys who may be asked to defend the case. Organizations need to facilitate expe-

Table 1: Key Recommendations During the Disclosure Process*

Do	Don't
Initiate the disclosure process as soon as possible after an unanticipated event.	Don't lie or cover up. Don't appear to be insensitive, misleading, or mysterious. Patients want honesty and are more willing to forgive an error than a lie.
Ask the patient whether he or she would like to include family members or friends in the conversation.	Don't oversimplify the explanation of the error.
Determine how much information the patient wants to know, or whether the patient prefers that someone else receive the information.	Don't speculate or guess. Speculation and guesses may lead to false accusations that will be difficult to withdraw at a later time.
Have a second person from the hospital attend the meeting (a nurse or someone who has established good rapport with the patient).	Don't express or imply causation. Focus on what happened, not what you think happened.
Introduce everyone in the room.	Don't blame someone else. Blaming someone else is an almost certain way of implicating oneself.
Sit down and lean in to the patient and/or family. Pay attention to your own body language.	Avoid words such as *error, mistake, fault,* and *negligence* unless you are absolutely certain that an error or mistake has occurred.
Make eye contact.	Don't confess. Apologies for having caused the outcome should be avoided unless responsibility is unmistakably clear.
Determine what information the patient already has.	Don't use a communication style that is sermonizing, haughty, condescending, patronizing, or authoritative.
Speak in simple language, not in medical jargon.	Don't be defensive. Try to meet anger with professionalism and objectivity.
Disclose the facts surrounding the event as you understand them at the time of the disclosure.	Don't offer compensation without first discussing it with Risk Management.
Be straightforward, truthful, concise, and respectful.	Don't disclose to a plaintiff attorney unless a defense attorney is also present.
Discuss what went wrong but do not speculate.	
Pause frequently.	
Accept responsibility when appropriate.	
Listen to the patient without interruption. Try to anticipate/ascertain the major feelings in play beyond the frequent anger or vulnerability that patients experience in this situation.	
Be prepared for anger and absorb it rather than becoming defensive or responding to it in kind.	
Respect and use the therapeutic power of silence.	
Invite and answer all questions as honestly as possible.	
Welcome and value what family members have to say.	
Let the patient know how his or her care will be managed from now on.	
Ensure preventive action to minimize the risk of a similar occurrence in the future.	
Express empathy with the patient or family, sympathy for the pain and suffering.	
Remain open and let the patient/family know you are available to answer their future questions.	
Offer emotional support to patient/family/providers.	
Document the meeting, including date, time, those in attendance, substance of disclosure, outcome, and next steps.	
Follow up and get back to the patient/family if appropriate.	
Ask when appropriate, "Would an explanation of [this particular aspect of the care provided] be useful to you?" OR "Would it help if we went over the steps in the care to better understand how this happened?"	

* Adapted in part, from Joint Commission Resources (JCR): *Disclosing Medical Errors.* Oakbrook Terrace, IL: JCR, 2007.

dited expert review, and, when liability is clear, be prepared to offer early compensation.

Utilization of some members of the communication consultation team has not occurred to the extent originally expected. Additional concerns were voiced about the ability of some team members to "drop everything else" and devote virtual full-time concentration to a case in the immediate aftermath of an unanticipated adverse event.

Start-up expenses for the disclosure and apology system were projected at approximately $92,000 for consultation fees, training, patient/family support, and a recovery fund for the first year. The program was primarily funded by a grant from the system's self-insured professional liability program. The projected budget did not include salary expenses for existing staff. The project leaders estimate that staff spent 600 hours on implementing the program in the first year. Staff primarily involved in the implementation included the medical director, quality and patient safety (200 hours); the director of risk management (200 hours); and other risk managers (200 hours). Because BH is self-insured for professional liability, our system has the ability to manage disclosure and apology cases through the captive insurance program. BH decided that adverse events brought to the attention of risk management would be treated as claims and that the associated costs such as expert reviews and compensation to a patient/family, would be funded out of the professional liability program. Patients and their health insurers have not been billed for cases that involved medical error. Since the program's initiation, there have not been any significant events, such as loss of life or substantial permanent disability associated with clear medical error. Therefore, we are not yet able to project the potential savings associated with the early resolution of a serious event in our current disclosure and apology program.

Discussion

Educating the vast majority of clinical employees in a large health system is challenging. Because of the size of the organization, BH decided to not train all staff. In lieu of detailed training for all clinicians, BH has spread the following key messages:

1. Prompt, open, and honest disclosure is the policy of the institution.

2. Coaching, advice, and feedback are available before any disclosure conversation with patients and family (just-in-time training and coaching).

3. Emotional support is available for both patients/families and staff in the aftermath of an adverse event.

For some, mostly minor, medical errors an initial disclosure (and sometimes apology) discussion occurs before consultation with the team or risk management. Conversely, significant events are preferentially reviewed in advance of disclosure because clinicians may struggle with these more difficult conversations. Liebman and Hyman found that physicians committed to disclosure and comfortable with participating in difficult conversations were nonetheless ineffective listeners during the disclosure conversation.[27] Members of BH's communication consultation team are trained to coach clinicians in such listening skills either before a patient/family communication session or during the session. In light of this research, BH is compiling internal stories about disclosure experiences so that clinicians will be more aware of the just-in-time training and coaching available in the aftermath of a medical error.

As BH experiences new adverse events, team members are likely to have quite different opinions about the proper course to take following the adverse event, especially in terms of whether or not to offer early recovery resources. In the previous litigation-oriented model, time was generally available to collect data in a more deliberate fashion. Disclosure systems that place an emphasis on providing appropriate early recovery resources challenge risk managers and others involved to collect clinical data and expert opinions in a more expedited fashion. Disclosure and apology systems are most easily applied to cases of clear medical errors in which the extent of harm (both short- and long-term) is very clear. However, many cases involve a significant amount of uncertainty about system or human culpability and about the degree of harm to the patient. Although disclosure should be prompt even in those cases having a significant amount of uncertainty, decisions about fair compensation for the patient and family are often complex and may take a considerable amount of time—and will usually require an extended series of conversations with the patient and family (Sidebar 3, page 494).

When liability is clear, BH provides for early compensation for patients and families after an event that may result in disruption of daily activities, for example, funding for hotel accommodations and transportation. BH usually does not provide early financial assistance in the absence of significant evidence of culpability. Many institutions, such as the University of Michigan, adhere to a similar approach. Despite an innovative disclosure policy, Michigan actively defends claims felt to have no merit.[29]

Berlinger suggested that clinicians consider acting as personally accountable even in cases of systems error, "bearing in mind that some patients may comprehend error in all cases as an indi-

Sidebar 3. Early Compensation and Late Compensation

This ongoing process is managed primarily by risk management. During the initial phases, patients and families may be offered compensation for out-of-pocket expenses such as lodging, meals, and travel incurred because of the adverse event. Medical expenses may be waived or written off, and patients and families may also be offered emotional support services through the outside vendor. These forms of support may be offered as a good-will gesture, even when it is unclear whether the adverse event was preventable.

The claims department, in conjunction with risk management, assumes responsibility for evaluating preventability and has ultimate responsibility for determining whether compensation in the form of an early settlement will be offered. In the cases that we have managed thus far, we have not formally consulted with outside counsel. As a self-insured captive, BH can value such cases and establish appropriate reserves early in the process. The valuation is managed in the same way as any other claim or lawsuit. The goal has been to offer compensation in those cases where it is clear that a preventable error has caused serious harm or injury and/or financial loss.

vidual rather than a collective or systemic failure."[28(p. 32)] However, some BH clinicians were not comfortable with this approach. Accordingly, about a year into the program, to address reservations of some physicians and still meet the spirit of our program, a consensus was reached (although not put into any policies) that physicians with major responsibility for ongoing patient care after a suspected system error do not *automatically* or *solely* own or assume culpability for that error by taking responsibility for leading the disclosure or apology conversations. The Harvard Hospitals Consensus Statement phrases this eloquently, as follows:

> In assuming responsibility for the event, the physician and the hospital leaders accept responsibility for future action: trying to find out the causes of the event, informing and updating the patient and family, and monitoring and managing any complications of the adverse event.[20(p. 9)]

Some physicians are reluctant to apologize. If these physicians remain adamant against apologizing, the health system may wish to exclude them from any formal disclosure and/or apology conversations, in the expectation that an insincere apology may make the situation worse for all involved parties.

Physician apology laws allow for open and honest communication between a physician and patient following an unanticipated outcome. As of this writing, seven states (California, Florida, Maryland, Nevada, New Jersey, Pennsylvania, and Vermont) have passed laws requiring providers to notify patients and/or families of an adverse event.[29] In addition, a number of states have laws that exclude an expression of sympathy after an adverse event as proof of liability.

Physicians should be aware of subtle differences among individual state laws. Some state statutes render apologies that are passive expressions of sympathy (for example, "I am sorry that you suffered") inadmissible in court, whereas others clearly address the admissibility of apologetic expressions that also take responsibility for the cause of the injury (for example, "I am sorry that I caused this").

Lessons Learned and Key Challenges

Lessons learned and key challenges are summarized in Table 2 (page 495). Not all physicians practicing at BH are covered by the system's professional liability program. Medical errors involving a team of clinicians covered under different malpractice insurance carriers will challenge the coordination, communication, and negotiation skills among those carriers to provide a prompt and compassionate response.

After a medical error, patients and families expect the organization to make changes to the system to prevent other patients from being harmed by the same mistake. To minimize the chance that patients and families feel that their suffering has been "in vain," health care systems will need to put systems in place to deliver on the promise to reduce the risk of future harm. Fulfilling patient and family expectations for effective changes is easier said than done—and may represent the most likely place where modern disclosure programs fall short.

The goal of prompt provision of recovery funds, when warranted, also challenges the system to streamline and better coordinate the many investigative groups that often coexist following a medical error (for example, an ad hoc investigative committee called by a department chair, a formal RCA conducted by the Division of Healthcare Quality, an independent investigation by the risk management department). BH is still investigating the most efficient administrative mechanism to allocate a specific pool of money from which early recovery funds can be quickly dispersed for meals, transportation, and lodging.

BH has not fully tapped the use of stories with clinicians to describe how actual cases have been handled in the new disclosure system.[30,31] Such stories have the potential to bring poignancy and immediacy to discussions throughout the institution about the best and most ethical ways of handling cases. Cases that involve BH employees or family members of employees may have the greatest impact with internal audiences. Clinicians are not immune from being on the receiving end of an adverse outcome; more than one-third of surveyed

Table 2. Key Challenges and Lessons Learned

- Liability is not always clear.
- Team may not always be in agreement about what has transpired or what steps should be taken next.
- Expert review may not always be expedited in a timely manner.
- Apology or initiation of process may imply liability (raises patient/family expectations).
- Patient/family may not be able to hear or understand.
- Cases can get lost to follow-up.
- Process is time consuming in the short run but may save litigation costs in long run.
- Apology may not be accepted.
- Organization may not be able to do what is asked.
- Patient advocate should be neutral and should not be part of the investigation.
- Program improves organizational communication.
- Implementation of a program reinforces principles of trust and truth-telling.

doctors have reported that they, or a family member, have experienced an error.[32]

A just culture of organizational fairness and personal accountability by clinicians is required for an ideal disclosure system. A "blaming and shaming" environment undercuts disclosure systems. BH is currently diffusing the TeamSTEPPS[33] communication skills model throughout the system and has begun to use team culture survey assessments and employee satisfaction survey data to measure the safety climate.[34,35] BH could not have successfully implemented a disclosure program without some level of perceived organizational fairness. Yet medical errors can profoundly test, and retest, the organization's commitment to elucidate system contributory failures and the equally important commitment to make substantial system changes in the aftermath of preventable adverse events. Use of a well-designed accountability matrix (such as James Reason's decision tree[36]) is increasing among BH managers when assessing clinical performance following an adverse event, with the support of human resources.

Conclusion

A prompt disclosure and apology system is likely a major cultural change for any health care organization. The necessary shifts in knowledge, attitudes, and behaviors among clinicians and health care leaders require time to diffuse through the organization. BH is proud to have done some of the hard work of challenging the premises on which previous adverse event cases were managed. Yet, reinforcing "system operating principles," such as integrity, respect, and supportive hospital leadership, made the journey easier than it otherwise could have been. J

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Online-Only Content

See the online version of this article for

Appendix 1. Informing Patients and Families About Adverse Events

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Online-Only Content

Appendix 1. Informing Patients and Families About Adverse Events*

POLICY

Baystate Medical Center's clinical and medical staff will inform patients of adverse events supporting open, truthful and prompt disclosures of all pertinent information so that patients can make informed decisions about their current and future care.

PURPOSE

To maintain open and honest communication with patients and their families regarding adverse events including events caused by medical errors.

SCOPE

This policy applies to all BMC health care providers including but not limited to physicians, residents and nurses.

PROCEDURE

A. Definitions

Adverse Event: An injury that was caused by medical management rather than by the expected progression of a patient's underlying disease or condition. An adverse event may or may not be due to medical error and may or may not have been preventable.

Medical Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

Communication Consultants: BH [Baystate] has trained a number of individuals to act as "communication consultants" in the aftermath of a serious adverse event, with or without patient harm. These individuals are available to assist the care team in debriefing the event to focus on what facts are indisputable about the event, to help prepare 1 or more clinical team members for a skillful, empathic disclosure, and to help mobilize any immediately needed emotional support for any care team members or the patient and family members. Trained communication consultants include a number of physicians and nursing leaders, all risk managers and claims managers, and representatives from employee assistance, social work, and spiritual services. These communication consultants can be accessed by contacting Risk Management.

B. Guidelines for Responding to an Adverse Event

1. The goals in providing information about adverse events and outcomes are open and completely honest communication with patients and families and to maintain or rebuild trust. Often, discussion about adverse events is incorporated into the ongoing clinical communication with the patient and/or family. However, in the event of a serious injury or outcome, providers may seek guidance from members of the Communication Consultation Team prior to disclosure to the patient and/or family,

2. The primary focus and first priority after an adverse event should be protection of the patient from further harm by providing necessary medical care and reducing the likelihood of any further injury.

Online-Only Content

Appendix 1. Informing Patients and Families About Adverse Events (continued)

3. Once the patient's needs have been met, the adverse event should be reviewed as soon as possible by appropriate members of the healthcare team, to collect information and to determine next actions. Healthcare providers may consult the Communication Consultation Team for assistance in initial evaluation of the event and in preparing for communication with patients and families. This consultation may include a debriefing of the events as well as meetings to prepare for disclosure to the patient and/or family.

4. The attending physician or designee should take responsibility for communication with the patient and/or family. Other individuals who may be appropriate include: a senior administrator, a healthcare professional who is knowledgeable about the event or a healthcare professional who has an existing relationship with the patient and family. Communication with the patient or legally authorized representative should occur as soon as possible. The explanation should focus on a factual description of what has happened and how it has or is expected to affect the patient. The discussion should include plans for treatment and/or monitoring. Those involved in the explanation should express regret and explain what steps are being taken to review and better understand the reasons that the incident occurred. In most situations, guideline #3 (i.e., an initial evaluation/debrief of the adverse event by the health care team) should be accomplished before any disclosure/
apology meetings with the patient and family

5. In the event of an obvious error, those who are responsible for the disclosure should admit the error, apologize and express a commitment to find out what happened and why, with a goal toward prevention of recurrence. If the cause of the adverse event is unclear or unknown, an explanation of why the event occurred should be deferred until the investigation is completed. The patient and family should be told that the results of the investigation will be shared with them as soon as they are available. In the event that the investigation is prolonged or delayed, the patient or family should be regularly contacted and updated.

   The physician who is responsible for the care of the patient should also communicate pertinent information and changes in the treatment plan to other members of the health care team.

6. The information that is provided to the patient and/or to the family should include:
   - A truthful and factual explanation of the event
   - Any facts related to the patient's condition which are necessary for the patient to make informed decisions
   - Cause of the event, if known
   - Corrective actions that have been taken in response to the event
   - Contact information for ongoing communication with members of the healthcare team or administration
   - Referrals for support and counseling

7. When appropriate, the event should be referred to Performance Improvement for the purpose of multidisciplinary review to identify the factors that contributed to the event and to determine changes or improvements that can be made to prevent the recurrence of the event.

8. When applicable, the patient and/or family should be offered emotional, psychological, and financial support. Members of the healthcare team should show ongoing concern and provide continuing support. Follow-up

Online-Only Content

Appendix 1. Informing Patients and Families About Adverse Events

communication can also provide more information regarding the event and can include an explanation of system issues that have been or will be addressed to prevent recurrence of the event.

9. Healthcare providers who have been impacted by an adverse event should receive emotional support and should be referred for counseling when appropriate.

10. Resources available to support the process include, but are not limited to, spiritual, social and interpreter services, the BMC Ethics Committee, Risk Management, Division of Healthcare Quality and psychological or psychiatric consultations. The primary focus is maintaining communication with the patient and the family.

11. Examples of adverse events caused by medical error that warrant disclosure can be found in Appendix A.

12 Documentation in the medical record:

The medical record will reflect a complete, accurate and factual record of pertinent clinical information pertaining to the adverse event and should be completed in a timely manner. The documentation should include:

- Objective details of the event, including date, time and place, written in neutral, non-judgmental language
- The intervention and patient response
- Notification of the attending physician

Additionally, documentation outlining the disclosure discussion with the patient and/or family should include;

- Time, date and place of discussion
- Names and relationships of those present at the discussion
- Documentation of discussion of the event

Note: Documentation should avoid speculation about the cause of the event and should not assign blame, make assumptions, or draw conclusions without supporting facts. Safety Reports should not be included or referred to in the medical record. Under no circumstances should the medical record be altered. Late entries about an event should be clearly labeled as such.

APPENDIX A

Examples of adverse events caused by medical error that warrant disclosure may include but are not limited to the following:

- Artificial insemination with the wrong donor sperm or donor egg
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility

Online-Only Content

Appendix 1. Informing Patients and Families About Adverse Events (continued)

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Intraoperative or immediately post-operative death in an ASA Class I patient
- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
- Infant discharged to the wrong person
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of the healthcare facility
- Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility
- Death or major permanent impairment of bodily functions that is not ordinarily expected as a result of the patient's condition or presentation

REFERENCES

CO 4.100 - Peer Review Policy
CO10.960 - Adverse Event Policy
CO 9.100 - Health Care Decisions
CO 9.941 - Patient Safety Management and Reporting
BC 7.430 Release of Information to the Media
Medical Staff Rules and Regulations

*ABO, blood group system consisting of groups A, B, AB, and O; HLA, human leukocyte antigen; ASA, American Society of Anesthesiologists.