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Innovation Series 2010

# Respectful Management of Serious Clinical Adverse Events

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# Respectful Management of Serious Clinical Adverse Events

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## Executive Summary

*You just heard at this morning's CEO leadership meeting that a 40-year-old father of five children died in the Surgical ICU last night, hours after receiving medication intended for another patient. Everyone is upset. Questions are flying around the hospital: What does the family know? Who did it? What happened? What can we say? Would the patient have died anyway? (He was very sick.) Has anyone gone to the press?*

Every day, clinical adverse events occur within our health care system, causing physical and psychological harm to one or more patients, their families, staff (including medical staff), the community, and the organization. In the crisis that often emerges, what differentiates organizations, positively or negatively, is their culture of safety; the role of the board of trustees and executive leadership; advanced planning for such an event; the balanced prioritization of the needs of the patient, family, staff, and organization; and how actions immediately and over time bring empathy, support, resolution, learning, and improvement. The risks of not responding to these adverse events in a timely and effective manner are significant, and include loss of trust, absence of healing, no learning and improvement, the sending of mixed messages about what is really important to the organization, increased likelihood of regulatory action or lawsuits, and challenges by the media.

From time to time, the Institute for Healthcare Improvement (IHI) receives urgent requests from organizations seeking help in the aftermath of a serious clinical adverse event, including: What should we do? Who should do it? What should we say, and to whom? Among the most striking attributes of these requests is that, most often, the organization is building its response from the ground up, not from an existing clinical crisis management plan. In responding to such requests, IHI draws on the fields of patient- and family-centered care, patient safety, crisis management, and disaster planning, as well as from learning assembled from many courageous organizations over the last 15 years that have tried to manage these crises, initially and over time, respectfully and effectively. IHI also has met many patients, family members, and health care staff (the so-called "second victims"), many of whom are rightfully angry and frustrated over the disrespectful treatment they received after clinical adverse events.

The development of this white paper was motivated by three objectives:

- Encourage and help every organization to develop a clinical crisis management plan *before* they need to use it;
- Provide an approach to integrating this plan into the organizational culture of quality and safety, with a particular focus on patient- and family-centered care and fair and just treatment for staff; and
- Provide organizations with a concise, practical resource to inform their efforts when a serious adverse event occurs in the absence of a clinical crisis management plan and/or culture of quality and safety.

In furtherance of these objectives, this paper includes three tools for leaders—a Checklist, a Work Plan, and an Assessment Tool—and numerous resources to guide practice (see Appendices).

## Definition of a Serious Clinical Adverse Event

In any health care clinical setting, adverse events occur frequently. This white paper focuses particularly on those clinical adverse events with an impact of permanent psychological and/or physical harm (or death) on one patient or many,[1] often referred to as sentinel events. These are events that are included in categories G, H, and I in the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index.[2] The National Quality Forum Serious Reportable Events[3] provides another baseline list of serious clinical events. Healthcare Performance Improvement (HPI) has developed the Safety Event Classification and the Serious Safety Event Rate, with common definitions and an algorithm for the classification of safety events based on the degree of harm.[4] For the purposes of this white paper, the type of harm on which we focus is usually, but not exclusively, preventable. In fact, many of the most challenging and poorly handled serious clinical adverse events occur when too much time is spent on determining preventability and not enough on empathy and support.

Although this white paper focuses on serious clinical adverse events, organizations can use many of the principles outlined here to manage all adverse events, not just the serious ones. Ongoing communication, disclosure, empathy, support, resolution, learning, and improvement are important in the management of every event. These concepts are also easily extended to other breaches and non-clinical situations, such as identity theft, behavioral issues, and other operating issues requiring respectful, effective crisis management.

## Audience

This white paper is designed to help health care executives and other organizational leaders (CEOs, COOs, CMOs and CNOs, Legal Counsel, Public Relations/Communications and Quality/Safety/Risk Management professionals) develop a plan to deal with a serious clinical adverse event so that they are able to respond effectively and learn and improve safety as a result of it. Many organizations do not have a plan when a serious clinical adverse event occurs. In these cases, leaders can use this paper and the associated resources to guide their immediate and ongoing response.

This white paper is designed to serve the US as well as the international health care community. Although the regulatory and legal infrastructures in the US may differ from those in countries where IHI has international partners, the underlying principles remain the same. Because most of the organizations we work with are in the US, our approach inevitably reflects this. Yet, in the preparation of this paper, we have worked with, benefited enormously from, and had review by international experts. We believe this document will be equally relevant to our international partners, with perhaps minor adaptations to local culture, context, and approaches.

## Introduction

For any health care leader, there is no telephone call, page, or email message more sobering than the one that says, "I'm sorry to disturb you. We had a terrible problem in the Surgical ICU last night. The patient is dead." Every day, serious clinical adverse events occur in our health care system, as a result of systems failures, human error, intentional damaging acts, rare complications, or other causes. In some cases they are tragic, leading to serious physical and psychological harm to one or more patients, their families, staff members (including medical staff), the community, and the organization.

For any organization, the fact that these events occur doesn't differentiate them; they can occur in any health care organization. In the crisis that often emerges, what differentiates organizations, positively or negatively, is their culture of safety; the role of the board of trustees and executive leadership; advanced planning for such an event; the balanced prioritization of the needs of the patient and family, staff, and organization; and how actions immediately and over time bring empathy, support, resolution, learning, and improvement. The risks of not responding to a serious clinical event in a timely and effective manner include, but are not limited to, loss of trust among patients (not only those directly impacted, but the overall patient population as well), sending of mixed messages to employees regarding the organization's commitment to safety and quality, absence of healing, absence of learning and improvement, increased likelihood of regulatory action or lawsuits, and media that are all too willing to play "gotcha" with an organization that is not prepared to publicly address a serious clinical event.

For years, IHI and the authors of this white paper have taken emergency telephone calls from people in organizations around the world in which a serious clinical adverse event has occurred. They urgently seek counsel on what they should do in the aftermath. In many cases, the event has just occurred. In others, it occurred weeks, months, or years ago and is now exploding due to pressure from the patient, family, a staff member, the media, and/or regulatory and accrediting agencies. These are among the most striking attributes of these calls:

- The personal devastation of the event on the person calling;
- The similarities of the stories, no matter how different the details;
- An organizational response that is being built from scratch, not from a written and tested crisis management plan;
- An operating style that is highly reactive and an approach that is not balanced; and
- A response to date that has underestimated the potential harm to all.

Far too often, in framing their response, organizations are limited by their mental models (the things they believe to be true, such as "They will sue," "It wasn't our fault," "They will go to the media," etc.) or defensive routines (leaders' entrenched habits that protect them from the embarrassment and threat that come with exposing our thinking—"I'll look bad").[5]

IHI has also met patients, family members, and staff who are rightfully angry and frustrated, often for many years, over a lack of resolution and healing and the disrespectful treatment they received in the aftermath of preventable harm or unanticipated outcomes. They have asked us, "Where is the outrage? I walked my son into the hospital and I brought him home dead. Why wouldn't anyone talk to me?"[6]

IHI sees the appropriate response as one of respectful management of serious clinical adverse events. A number of organizations have strived to manage such events sensitively and effectively. Further, some have shown great courage by taking the time to share transparently all their experiences so that others may learn from them and improve (see Appendix D). We also see the appropriate response anchored in the principles of crisis management, currently "a road less traveled" for health care. Organizations and their leaders have a choice: to continue to go into defensive, reactive, survival mode or to go into proactive, learning, developmental mode.

The field of crisis management is less than 30 years old. The 1982 poisoning of Tylenol capsules with cyanide in a suburb outside of Chicago is generally acknowledged as the beginning of the modern field. The fact that Johnson & Johnson (J&J), the makers of Tylenol, responded quickly by pulling all bottles of the medication off the shelves nationwide, thus signaling that it was putting the safety of consumers ahead of profits, served to make J&J an early role model for effective crisis management. Since then, a great deal has been learned about how and why crises occur. Even more important, the components of an ideal or "best practice" crisis management program are much better understood.[7] Kaufmann and his colleagues have reminded us, "Because all crisis situations are not the same, one piece of advice cannot hold for every one."[8] Every event is different, just as every caregiver, every patient, every family member is different.

At the same time, there are some very consistent elements and dimensions that should be considered in every case in the first hour, day, week, month, and moving forward to resolution. After an adverse event, the organization's actions in response to the event—particularly in the first 24 hours—will often help determine whether or not the patient and family feel they are going to encounter truth and receive support.[9]

This paper introduces an overall approach and tools (see Appendices A, B, and C) designed to support two processes: the *proactive preparation of a plan* for managing serious clinical adverse events, and the *reactive emergency response* of an organization that has no such plan.

## What to Do to Prepare for an Event

Augustine suggests that the key steps in crisis management include the following: avoid the crisis, prepare to manage the crisis, recognize the crisis, contain the crisis, resolve the crisis, and profit by learning from the crisis.[10] (In crisis management planning, the ultimate strategy is avoiding the harm

and the crisis.) These steps are consistent with current elements of the US Department of Homeland Security disaster preparedness approach (prevent, protect against, respond to, and recover from all hazards and compromises)[11] and the US Federal Emergency Management Agency model (mitigation, preparedness, response, and recovery).[12] Although IHI has chosen not to ground its recommendations in the Hospital Emergency Incident Command System (HICS), we recommend it for organizations already proficient in that approach.[13]

In the worldwide patient safety movement, considerable attention is being given to the prevention of harm and that must continue. Yet, with the poor system we currently have in place, the defect rates previously referenced, and the level of serious harm resulting from safety events, that strategy is insufficient. Every organization must anticipate and plan for serious adverse events.

#### Leadership and an Organizational Culture of Safety

Michael Leonard, Physician Leader for Patient Safety at Kaiser Permanente in Colorado, offers a simple definition of a culture of safety: "No one is ever hesitant to speak up regarding the well-being of a patient [psychological safety], and everyone has a high degree of confidence that their concern will be heard respectfully and be acted upon."[14] During the past decade, an expanding evidence base in health care has demonstrated that safety culture plays an important role in the safety and quality of patient care.[15] Organizations striving to establish a culture of patient safety are in a better position to deal respectfully and effectively with these tragic cases when they occur. Their organizational culture will enable them to eliminate these events; hear more quickly from patients, family members, and staff about incidents when they occur; and respond with the expectation of respectful communication, disclosure, support, resolution, learning, and improvement.[16]

In his book, *Organizational Culture and Leadership*,[17] Edgar Schein describes the five embedded mechanisms necessary to examine and understand organizational culture, including "how leaders react to critical events and crisis." The answers to the following four questions will have a huge impact on the effectiveness of the response to a crisis: 1) Is there constancy of purpose related to your desired future, or does your strategy change with each critical event or crisis? 2) Do crises cause leaders to lose focus? 3) What happens after that? 4) How well does the organization manage or drive change? Boards, CEOs, and other executive leaders in health care are far better positioned to establish a culture of safety and effectively respond to the most serious of events if there are already well-established practices of transparency, leadership WalkRounds,[18] and open and honest conversations with staff, patients and families, the public, and the media.

In the aftermath of a serious clinical adverse event, the questions come quickly:

- How should we respond?
- What should we say and to whom?
- Who should do it?
- Who is responsible and accountable?

Dealing with the last question first, the United States Business Roundtable explicitly recognizes the role of the board of directors and management in ensuring resiliency through business crisis and continuity management. The organization's board of trustees (or its equivalent) is ultimately responsible for the quality and safety of the organization.[19] As such, the board should be engaged in an ongoing manner to ensure assessment, system learning, and improvement after serious clinical adverse events to fulfill its responsibility to the patient, family, staff, and community. The Board Quality Committee and all board members should be aware of the extent of all harm by severity, including actual patient counts, occurring in the organization. For all serious clinical adverse events, the board should have mechanisms in place as part of the overall quality improvement plan to ensure that findings from all root cause analyses (RCAs) will be followed up with long-term systems improvement, thereby ensuring closure, learning, and improvement.

The chief executive officer is accountable to the organizational governing board for the organization's response.[20] The CEO is the leader who responds to the crisis by turning fear into positive action; being vigilant (watching for new developments and recognizing the importance of new information); maintaining focus on the priorities; ensuring first that people are safe and then assessing the next most critical needs; and assessing and responding to what can be controlled and ignoring what cannot.[21] CEO attitudes can negatively affect crisis response and make matters worse—for example, "What crisis?," "No one will find out," "It will blow over," "I will handle it," "Our attorneys will handle it," "I'm unavailable," and "The media is out to get us."[22]

In their Policy Statement on "The Healthcare Executive's Role in Ensuring Quality and Patient Safety," the American College of Healthcare Executives (ACHE) asserts that health care executives should lead a comprehensive approach to ensuring patient safety and quality, including developing a culture of improvement that includes an organization-wide commitment to continuous learning.[23] The Joint Commission's 2009 Sentinel Event Alert, "Leadership Committed to Safety," recommends actions of senior leadership, including that they regularly monitor and analyze adverse events and close calls quantitatively, and communicate findings and recommendations to leadership, the board, and staff. The alert further notes, "A thorough and appropriate evaluation of adverse events is necessary to help prevent future occurrences."[24] Noting that crisis is the ultimate test of any leader and that "a smooth sea never made a skilled mariner," George, Denham, and colleagues provide strong evidence that a values-grounded focus on personal accountability for leading in crisis situations strongly resonates with those interested in or leading patient safety initiatives.[25]

On June 11, 2010, Ralph Gabarro, CEO of Mayo Regional Hospital in Dover-Foxcroft, Maine, demonstrated this values-based response after a massive medication overdose leading to the death of a patient. His comments to the *Bangor Daily News* included the following:[26]

> It's nothing short of a tragedy… We take full responsibility for this situation.
>
> At the time, we pledged to them that once we knew more we'd sit down with them and let them know what we found.

> We're trying to be very transparent in disclosing what happened and express our sorrow and our apologies.
>
> It's a nightmare for the entire medical community, but our feelings, what we're going through, pales in relationship to what the family is dealing with, and we understand that.

Paul Wiles, CEO of Novant Health in North Carolina, has courageously and bluntly shown the way with values-based leadership in the aftermath of MRSA-related neonatal intensive care unit (NICU) deaths in his hospital, saying at the IHI National Forum CEO Summit in 2008:

> But, I am accountable for those unnecessary deaths in our NICU. It's my responsibility to establish a culture of safety. Up until the time I read the document about the young mother's loss of her newborn son, I had been unintentionally relinquishing that duty—in effect, delegating it to others without letting them know they had a responsibility to perform. I'm responsible, as CEO, for creating the environment in which every staff person prioritizes proper hand hygiene, and mourns the human consequences of failure. That's my job, more so than the clinical staff who provide the care.[27]

#### Policies, Guidelines, Procedures, and Practices

Considerable progress is being made in the areas of empathy, communication, and disclosure of harm to patients and families, yet much more needs to be done.[28] Further, patients, families, staff, and organizations often continue to struggle and lose their way after the disclosure. Respectful disclosure includes not only disclosure at the time of the event, but also ongoing support, resolution, learning, and improvement. To achieve this, a system must build in the above-noted culture of safety and an infrastructure of policies, guidelines, procedures, and practices. Key elements are included in Appendix C in the form of an organizational self-assessment tool. Resources in support of each element can be found on IHI's website.[29] Most organizations have some of these elements in place, but few have all. In a 2010 IHI web-based program, Effective Crisis Management of Serious Clinical Events,[30] organizations frequently commented that they had not previously appreciated the power of all these elements as part of an integrated approach.

#### The Crisis Management Team

In the spirit of "never worry alone," organizations should establish a standing Crisis Management Team (CMT) that can assemble immediately in response to a serious clinical event. The role of the CMT is to ensure that the priorities of the patients and families, staff, and organization are met, as well as to ensure enhanced communication, support, resolution, learning, and improvement following the event. These teams also can meet to test and revise clinical crisis management plans.

While multiple models exist for the structure and composition of Crisis Management Teams, they should be under the direction of the chief executive officer, with membership including the chief

executive officer, chief operating officer, chief medical officer, chief nursing officer, chief public relations officer, legal counsel/legal advisor, patient representative, representatives from Risk Management/Quality Improvement/Patient Safety, the relevant service chief or clinical leader, and others as appropriate for the incident (such as physicians, nurses, pharmacists, mental health professionals, etc.). Depending on the system leadership structure and board structure, there may be other individuals, groups, and boards to consider participating in the process. The Chair of the CMT is most effectively the CEO or COO; the team should determine whether an objective facilitator is also needed. The manager for internal and external disaster preparedness can often provide useful internal consultation, given their knowledge of the organization's Incident Command System.

Activities of the Crisis Management Team in response to a serious clinical adverse event should include the following:

- Check in daily, even multiple times a day;
- Maintain highly disciplined documentation and a daily log;
- Engage outside help through colleagues and consultants who have developed or helped develop effective crisis management plans;
- Listen and be prepared to hear things they don't want to hear, possibly seeking the advice of an objective facilitator;
- Embrace speed and flexibility;
- Stay close to conversations internally and externally;
- Consider implications for hospital and professional billing;
- Imagine the worst and mitigate as possible;
- Communicate internally and externally;
- Be prepared for inquiry from or the arrival of external accrediting and regulatory agencies; and
- Ensure knowledge management and improvement.

Serious clinical events occur 24 hours a day, 7 days a week, and the organizational response should be the same: 24/7. No matter when discovery occurs, the culture of the organization should be such that staff members know that leadership genuinely wants to be alerted at any time, and that staff are prepared to notify executives and activate the response. Organizations may need to have a "call schedule" for these key leaders, with appropriate coverage for absences. Organizations are encouraged to develop back-up response teams whose members are fully trained in crisis management, using table-top drills and practice exercises, simulations, and rehearsals. The competency of the response team should be consistent, with adequate coverage for all times of day and for team member absences. Note that one of the major failure modes in public disaster response is lack of competent and available back-ups, especially in resource-constrained environments. Patients, family members, and staff shouldn't be left to carry the burden and feel unsupported just because the adverse event happened at 3:00 AM on a Saturday morning.

#### The Crisis Management Plan

In a Harvard Business Essentials report,[31] the authors assert that the best way to manage a crisis is to have a plan. Key steps include the following:

- Create a team for planning;
- Determine each potential problem's likelihood;
- Create a plan;
- Simulate the plan; and
- Update the plan.

Health care leaders understand well the role crisis management plans can serve. Internal and external disaster plans are required by regulatory authorities and accrediting agencies such as The Joint Commission.[32] Effectively developed, deployed, and tested, these plans provide a reference (not a blueprint) for guidance through external disasters (e.g., fire, flood, pandemics, train wrecks) and internal disasters (e.g., fires, utility failures). Yet, although leaders understand that serious clinical adverse events will occur, in all likelihood far more frequently than the aforementioned disasters, clinical crisis management plans are rare. Mitroff and Anagnos, in the 2005 book, *Managing Crises Before They Happen*, state that "the vast majority of organizations and institutions have not been designed to anticipate crises or to manage them effectively once they have occurred. Neither the mechanics nor the basic skills are in place for effective crisis management."[33]

Preliminary results from the Society for Healthcare Strategy and Market Development survey in 2008 found that only about one-third of respondents (health care public relations, communications, and marketing professionals) said their organizations had an "independent" crisis communication plan separate from the organization's disaster plan. Another 37 percent of respondents said the crisis communication plan was part of the disaster response plan. One in ten organizations had no crisis communication or disaster plan.[34]

IHI findings are similar; at a 2010 IHI IMPACT Leadership meeting of 50 organizations with advanced levels of quality and safety practice, only 30 percent had clinical crisis management plans. In two IHI 2010 efforts (IMPACT Leadership Community Work Group with six organizations, and an IHI Web&ACTION program with 50), the overwhelming majority had no plans in place. Two other 2010 IHI presentations probing 150 mid-level leaders suggested that only 10 percent had plans to deal with serious clinical events. Of those who did, most reported their plans were not consulted or followed when an event occurred since the expectation wasn't set and the practice wasn't routine.

Key steps in building a crisis management plan include the following:

1. Inventory plans that already exist within your organization, such as internal and external disaster plans, for a model to build on.
2. Assess the last two serious events that occurred in your organization:
    a. What worked?
    b. What didn't work?
    c. What could have gone better?
    d. What did you learn?
3. Prepare a high-level outline of your plan based on your learning (see Appendices A and B).
4. Test the outline with an actual or hypothetical case of a near miss, an adverse event with minor temporary harm, or an event that happened in another organization.
5. Refine and build your plan based on the learning.
6. Continue to test the plan through drills (including surprise ones), using cases noted above in Step 4.
7. Use the plan to respond to clinical crises, and review what worked and what could be improved.
8. Revise the plan.

Organizations have graciously begun to share their crisis management plans with IHI.[35] Catholic Health Partners in Cincinnati, Ohio, is one of those organizations. Jana Deen, Patient Safety Officer, notes, "Our event management guidelines, a basic framework, were created by representatives from across the system, including hospital CEOs, CMOs, CNOs, and Mission, Risk, Quality and Legal staff. They are a work in progress and have been revised several times. We expect our hospitals to integrate and build upon the guidelines. Regular phone calls with our hospital CEOs discussing how specific events have been handled have resulted in increased use of the guidelines and significant improvements and learnings across our system. Most recently, one of our regions has implemented an Event Intervention Team triggered by an electronic notification system and requiring frequent and regular face-to-face meetings of leadership in the hours following the event."[36] Christiana Care Health System in Delaware is another example; Michele Campbell, Christiana Care's Corporate Director of Patient Safety and Accreditation Services offers, "We are continuously learning from events which have contributed to or have the potential to harm our patients. Our proposed Event Management framework builds upon existing processes and is transforming the way we manage adverse events as well as our culture of patient safety."[37]

### *The Prioritized Organizational Response*

The four hallmarks of a strong crisis response are immediacy, transparency, apology, and accountability.[38] Three priorities of response are the patient and family; the staff, particularly those at the front lines of care and the harm; and the organization.

Priority 1: The Patient and Family

When the patient and family visit a health care setting, the last thing they expect is an unanticipated outcome that adds to the burden of illness or leads to death. Listed below are key considerations and questions arising from individual patient and organizational stories[39,40,41,42] and comprehensive reviews.[43,44,45,46,47,48,49,50]

- Has there been appropriate communication and disclosure to the patient and family, most often by a team of two staff persons (or, in some cases, more), including a clinician who has a pre-established relationship with them?
- Has the organization made a statement of empathy and issued an apology in cases where there is fault?
- Has the patient and family been invited to participate in some way in the root cause analysis of the event? Most often, no one was closer to the patient than a family member or caregiver; they may have information no one else has. Inclusion of the patient and family in the analysis also increases its credibility.
- Is there ongoing support to the patient and family, including consideration of reimbursement for any out-of-pocket expenses?
- Has the organization stayed engaged to bring this case to a respectful resolution?
- Is the organization positioned to never lose sight of the patient and family?

Organizations have learned that adverse events don't necessarily erode trust. The way in which the organization responds after such events can and often does.[51,52] Health care professionals invest a lot of money and time in building relationships with patients; an adverse event doesn't mean that investment has to be lost.[53,54] The following elements are offered for organizations to consider to achieve the goal of never losing sight of the patient and family when responding to a clinical adverse event:

- When communicating about the harm that the patient experienced, state what happened, why it happened, and what's being done to prevent it from happening again.
- Appoint a staff member as a patient and family point of contact that is available 24 hours a day, 7 days a week.
- As soon as the organization has new information about the event, inform the patient and family.
- Never let the patient and family encounter a dead end, emotional distance, or inappropriate body language.
- Ensure that all communications are culturally and linguistically appropriate.
- Address any concerns the patient and family have as soon as possible.

Research demonstrates that disclosure of adverse events is often associated with higher ratings of quality by patients[55] and a drop in malpractice suits.[56]

Priority 2: The Front-line Staff

Serious harm to a patient is the last thing that health care staff want to have happen in the delivery of care. There is significant anecdotal evidence and research on the short- and long-term toll these events can have on those involved.[57,58,59] The following are key considerations and questions in the aftermath of an event and over time:

- Are there people and resources available to coach the staff involved as they prepare for disclosure of the event, and to support them through the process?
- Is there ongoing support to the clinicians and team at the front line of the harm? Are they at risk of personal harm? When are they safely able to return to providing care? Would it be helpful for the CEO to meet with the front-line staff?
- Have front-line staff been invited to participate in the root cause analysis (RCA) of the event? This should be decided on a case-by-case basis; front-line staff should preferably participate as full members of the team or, at a minimum, be interviewed as part of the RCA. Inclusion promotes learning and healing; exclusion promotes blame.
- Are staff members actively involved in bringing the case to resolution over time?
- Are there mechanisms to ensure learning across the organization?
- Is the organization determined never to lose sight of the staff at the front line of the harm?

Many health care organizations have learned that, in the aftermath of a clinical adverse event, they could fire all the staff involved and it would do nothing to improve safety or prevent a similar event from happening again. Most harm from such events is the result of bad systems, not bad people. Elements to consider when responding to adverse events include the following:[60,61,62,63]

- Do not jump to conclusions: Ask "What happened?" and not "Who did it?"
- Send clear messages of support to all staff involved: "We'll figure this out together."
- Establish and practice principles of a fair and just organizational culture.
- Appoint a trained staff member who staff involved in the event can contact 24 hours a day, 7 days a week.
- Offer support through Employee Assistance Programs, peer support groups, and other professionals.
- Stay aware: Some colleagues can be supportive and others damaging.

Research has demonstrated that disclosure is met with approval and relief on the part of health professionals, as they can now discuss matters that in the past were often seen as too difficult to discuss. Staff are eager to integrate open disclosure more consistently in everyday clinical practice.[64]

Fighting off "shame and blame" is a huge challenge after serious events. Mitigation requires a fair and just organizational culture, with supporting policies and practices, and appropriate levels of individual

and shared accountability. James Reason's Incident Decision Tree can be helpful in getting to this fair and just treatment, whether policies exist or not.[65]

Priority 3: The Organization

Serious harm can place an organization in significant crisis and lead either to long-term business and reputational risk and degradation. On the other hand, it can also result in enhanced community positioning based on respectful, effective crisis management. The following are key considerations in the aftermath of an event and over time:

- There is a visible CEO ("I care," "I'm accountable").
- The organization has issued a call to action grounded in values, integrity, and doing the right thing.
- The Crisis Management Team is activated under a strong executive leader, with a clear chain of command.
- The board of trustees is notified, as are relevant regulatory agencies.
- A root cause analysis of the event has been activated immediately.
- Careful and rapid preparations of internal and external communications are underway immediately.
- There is a clear understanding of who can make what promises to patients, family members, and staff.

The organization and its leadership never lose sight of patient, family, staff, and community when responding to serious clinical adverse events.

*Root Cause Analysis*

Root cause analysis (RCA) is an essential tool of vigorous system investigation, assessment, learning, and improvement.[66,67] The RCA process should begin immediately after a serious event, under a skilled and trained facilitator. Nothing on the organizational schedule is more important than the patient. Ideally, the RCA should be completed within 30 days. Executive leadership should be included to ensure the RCA is a comprehensive, fair, and balanced process, to remove barriers, and to provide support. Using the "Five Whys Technique" helps provide accurate and complete statements of problems, complete honesty in answering the questions, and the determination to get to the bottom of problems and resolve them.[68] IHI research emphasizes the importance of studying organizational resilience (predesigned defenses and adaptive capability) through structured conversations, in addition to conducting a root cause analysis of adverse events and near-misses.[69]

Given that the RCA's focus is on learning and improvement, staff close to the front line of the event, as well as the patient and/or family, should be included in the process. The extent of inclusion will be determined on a case-by-case, individual-by-individual basis. Staff, patients, and families have all commented that, in addition to informing learning, inclusion supports healing.[70,71] The RCA should be fully integrated into the processes of the board and executive leadership to ensure follow-through on the plan of correction. The board should specifically decide how it wants to be involved in RCAs as a matter of policy.

*Internal and External Communications*

There should be a clear communication team leader, with mechanisms for checking in and coordinating with the Crisis Management Team. Internal and external communications around serious clinical events are essential. The questions that arise include: What can we say? How can we say it? To whom? Essential messages can, when appropriate, include the following:

- The hospital has apologized and regrets that the incident happened (see Table 1 below for language to use in such communication).
- We have disclosed to the patient and family everything we know, and keeping them informed and supported is a priority.
- The board of trustees and leadership are actively engaged in understanding why our systems failed this patient and family and what steps are needed to prevent a similar occurrence in the future.
- We are working with appropriate authorities.
- We are an excellent organization and staff, but not perfect, and we come to work every day to provide the best care we can and continuously seek ways to improve it.
- We will use this tragedy to make this organization a better and safer place for our patients, family, staff, and community.

Table 1. Communicating after a Serious Clinical Adverse Event:
Words of Compassion, Concern, Empathy, and Remorse

| | | |
|---|---|---|
| Alarmed | Humiliated | Tragic |
| Appalled | Let you down | Unfortunate |
| Ashamed | Mortified | Unhappy |
| Concerned | Regret | Unintended |
| Disappointed | Sad / Saddened | Unnecessary |
| Embarrassed | Shocked | Unsatisfactory |
| Empathized | Sorrowful / Sorrow | |
| Failed / Failure | Sympathetic | |

Source: Lukaszewski JE. Establishing individual and corporate crisis communication standards: The principles and protocols. *Public Relations Quarterly*. 1997;42(3):7-15.

In creating communication around any crisis, the organization must respect the privacy of the patient, family, and staff, while also taking organizational risks in support of them and their needs. While privacy rules frequently limit what can be said, an organization should be prepared to detail what went wrong and why, including speaking to policies (past and future) designed to minimize harm. Even when you can't specifically discuss a patient-care issue (which is growing less common, given how regularly state agencies make patient-name-redacted versions of incident reports available online), you can and should be willing to talk about how you typically address similar incidents.

A tried and true rule in public relations is, "Whoever informs the first story informs the overall story." Early information is often incorrect, and misinformation fills a vacuum and is very hard to correct later. Credibility is essential and the organization should never speculate. Public relations (PR) professionals advise that, in telling the story, you should define your essential messages as clearly and concisely as possible, centralize and narrow the flow of information, and determine who will speak on behalf of the institution.[72,73,74] All spokespersons must be briefed and prepared. All staff should be reminded to direct outside inquiries to the PR department, which should review communications to all core audiences.

When serious clinical adverse events occur, communication priorities should include the following: those most directly affected; employees, as sometimes they can be victims, too; those indirectly affected—families, relatives, neighbors, friends; customers, suppliers, government, regulators, third parties; and the news media and other channels of external communications.[75] Those with experience in these matters advise talking to patients, staff, trustees, regulators, supporters (donors, community leaders, and local officials), and interested parties (insurers, etc.). Core constituencies should never learn anything from the news media; they should receive the information directly. Email, Twitter, and other social media have changed everything—most obviously, the speed and content of communications. Many people want and need to believe in you; make that possible. Use all available tools to provide regular updates, including personal calls, email, fax, websites, letters, Q&As, and social media.

Internal communications are also critical. Health care staff often report that, in the aftermath of adverse events, "everyone is talking about it except the organization." All staff are devastated when these events happen, as staff and as members of the public. They want and need to understand what's going on. There is no question that patients and family members will be asking questions. The staff need to be trained to answer them.

*Engaging with the Media*

One of the more complex issues to address with serious adverse events is how to effectively manage the media throughout the crisis. These efforts need to begin long before an event occurs and include at least four steps.

1. The organization should have an up-to-date, tested media plan as part of the overall crisis management plan, with an identified media consultant where appropriate.
2. Executive leadership must keep their own internal communications staff informed; if leaders are worried about something, their PR staff should be aware of it concurrently.
3. Engagement by PR and the organization with the media should begin long before any high-profile event. Health care organizations should be cultivating the media, building relationships, establishing credibility, being available for them both on background and for stories, and honoring their deadlines.
4. Organization spokespeople should be required to go through formal media training to support them in times of normal operations as well as during crisis events.

When a serious adverse event occurs, PR should be notified immediately as part of the core Crisis Management Team; time is of the essence. Calls from the media should be expected at any time—don't let people minimize the possibility that it will go public—and preparations should be made for these inquiries. Organizations can't hide and must engage in the process. Increasingly, organizations, along with the impacted patients and families, are seeking out one or more trusted media outlets to break the story with a focus on what happened, why it happened, and what's being done to prevent it from happening again, and to show empathy. Organizations must be honest and not stonewall; one reporter described "no comment" as a reporter's stimulant. As the crisis evolves, PR should provide updates to the media, telling as much as they can. For the long term, PR should stay engaged with the press and have a story of learning and improvement to tell.

These efforts, in parallel with the content covered in the section above titled *Internal and External Communications*, will help break the destructive cycle outlined below.

- A serious clinical adverse event occurs.
- The organization is not transparent, internally or externally.
- People close to the incident (patients, family members, staff, etc.), frustrated with how the event is being handled, contact the media.
- The media contacts the organization, gets "no comment," or incorrect or superficial information.
- The media go looking everywhere for any information they can find.
- Information is supplied by people who really don't know and is often incorrect.
- The patient, family, staff, organization, and community are further traumatized by the strident, inaccurate media attention.
- The organization's response to the event becomes as big a story as the story of the actual event, if not bigger.

### *External Notifications and Unannounced Visits*

As challenging as these incidents are, they can become much more complex if important external notifications are not made. Although there are differences between regulatory and legal infrastructures internationally, the underlying principles remain the same. All requirements for mandatory or voluntary notifications of state and national law enforcement, and regulatory and accrediting agencies, in the aftermath of a serious clinical adverse event should be made or considered. For state reporting in the US, the 2007 National Academy of State Health Policy report[76] is helpful (note the addition of public reporting in New Hampshire since publication of the report). If there is any question about whether an event should be reported, instead of spending endless time in discussions, it is far easier to just ask the agency if it is a reportable event or to err on the side of over-reporting. In the US, this could include reporting the event to The Joint Commission,[77] FDA's Medical Product Safety Network (MedSun),[78] and sponsored research agencies such as the National Institutes of Health. For international organizations, appropriate agencies should be considered. Before reporting, consider the agency's past history with your organization and their likely response, then report.

The risk insurer and legal counsel, when external, should be near the top of the list for notification when a serious clinical adverse event occurs. Many organizations, including the Institute for Safe Medication Practices, will ensure that others are informed of your event and will benefit from the subsequent learning.[79] Relationships with regulatory and accrediting agencies, as well as the media, can be very strained during these periods. Everyone benefits when these relationships stay constructive and focused on the same questions that are important to the patient and family: What happened? Why did it happen? What is being done to prevent it from happening again?

Organizations should also be prepared for unannounced visits from accrediting and regulatory agencies, which can be triggered not only by organization notifications but by the media, calls from the patient or family, or calls from concerned health care staff from the affected organization.

### *Guidelines for Disclosing Adverse Events Affecting Multiple Patients and/or Where Patients Not Yet Affected May Be at Risk*

As complex as serious clinical events are, many special circumstances can make them dramatically more complicated. At the top are adverse events where tens, hundreds, or thousands of patients may have been affected—major failures of the health care system, including cases around poor sterilization practices or contamination of endoscopic devices, hepatitis outbreaks, interpretations of diagnostic studies, pseudomonas outbreaks, overdoses of radiation, and cases where it can't be determined how many patients were impacted.[80,81,82,83] In management of these cases, it's not just the patients who are affected, but others as well, and rules need to be set regarding when to warn and when to offer patients alternatives to specific patient care units, centers, programs, or even health care organizations.

While a detailed response is beyond the scope of this white paper, a few helpful articles are cited. Chafe, Levinson, and Sullivan have offered exceptional guidance in cases involving multiple patients.[84] The Centers for Disease Control and Prevention[85] and the World Health Organization's Outbreak Communication Guidelines[86] are helpful in a wide range of settings. A comprehensive approach to the management of infection control breaches, including communications to patients, is offered by Patel and colleagues.[87] Rutala and Weber have developed a 14-step protocol to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, they present a model for helping determine how patients should be notified of the potential adverse event, and provide sample statements and letters for communicating with the public and individual patients.[88] Dudzinski and colleagues, in a 2010 Agency for Healthcare Research and Quality supported study, offer a careful review of these events and their disclosures with recommendations. They note that disclosure should be the norm, even when the probability of harm is extremely low.[89]

## What to Do When a Crisis Occurs and There Is No Plan

Many health care organizations have no crisis management plans in place for serious clinical adverse events. For those organizations, we recommend the following actions:

1. Notify the executive leadership and board.
2. Establish a sense of urgency.
3. Assemble an ad-hoc Crisis Management Team led by the CEO or another executive leader.
4. Use Appendices A and B in this white paper as a guide for what should be done overall and in the first hour, day, week, and month, then modify according to your unique needs and circumstances.
5. Review the IHI white paper in full for overall context, references, contacts, and other resources.
6. Strongly consider bringing in outside crisis management help.
7 Contact executive leaders in your local community or nationally who have been through similar situations and are well respected for their response (see Appendix D).
8. Never lose sight of the patient and family, staff, and organization.

## Responding to Serious Events in Other Organizations

### Supporting Organizations Dealing with Serious Clinical Adverse Events

Organizations and individuals dealing with a serious clinical crisis routinely report not only how difficult a challenge it is, but often how lonely it can be. People outside the organization don't know what to say, so they don't say anything. Much like the patients, family members, and staff directly involved in the event, others in the affected organization may encounter distance when they could use support and help. Here are a few guiding principles:

- If a health care organization in your community is going through a serious crisis, send a note, email, or pick up the phone. Let them know you are thinking of them and offer help.
- If one of your friends is involved in responding to and managing a serious event at his or her organization, call and check in.
- Check in again, over time.
- When things settle down, call the organization and ask what they learned so you can ensure it doesn't happen in your organization. Invite principals from the organization to speak at meetings about their learning; this transfer of knowledge also helps healing.

#### Learning from Events in Other Organizations: Could It Happen Here?

The headline is all over the news: a tragic medication adverse event has killed a young child. Increasingly, high-profile tragedies are the fodder for newspapers and all manner of 24-hour electronic media. While the story is unfolding, other health care organizations should be asking themselves, "Could it happen here?"[90,91] As in the recent cases of serious harm to or deaths of infants due to heparin overdoses, the story, the question, and the action didn't spread immediately and reliably across the health care industry despite great transparency. Staying alert to serious clinical events in other organizations provides an additional powerful tool to inform learning in support of safe care for patients, families, and staff. The following are basic steps for learning from events in other organizations:[92]

- Set an expectation that you want to know about outside events.
- Establish a system for learning about such events and agree on the focus of your inquiry.
- Develop reliable sources and get the facts straight.
- Ask yourself, "Could it happen here?" Ask again.
- Tell the story of how you used the event to drive learning and improvement within your organization.

After a 2009 sentinel event in a hospital in the Southwest United States that seriously harmed a number of children, a Midwest hospital system asked the question, "Could it happen here?" They quickly found that in 18 of their hospitals, yes it could, and were able to mitigate the risk quickly and effectively.

## Conclusion

A serious clinical adverse event is a crisis for everyone involved. Governing bodies and executive leadership carry the **burden** of these events forever, but carrying the burden isn't enough. They also have a **responsibility** to ensure that everything possible is done to understand what happened and why it happened, and to prevent it from ever happening again. These crises have the **power** to be used to transform the organization to a dramatically better one.

The individuals and organizations referenced in Acknowledgements, Appendix D, and the references in this white paper help to show us the way. This is the values-based "true north"[93] of respectful management of serious clinical adverse events—the response that leaders would want for themselves and those they love. Health care leaders owe their patients, family members, staff, and community nothing less.[94]

## Appendices

- Appendix A: Respectful Management of a Serious Clinical Adverse Event Checklist
- Appendix B: Respectful Management of a Serious Clinical Adverse Event Work Plan
- Appendix C: Respectful Management of a Serious Clinical Adverse Event Disclosure Culture Assessment Tool
- Appendix D: Respectful Management of a Serious Clinical Adverse Event: Organizations from Which to Draw Courage and Learning

## Appendix A:

### Respectful Management of a Serious Clinical Adverse Event Checklist

| | Element | Dimension | Started ☑ | Completed ☑ |
|---|---|---|---|---|
| 1 | Organizational Culture of Safety | Have expectations been set? Are board and leadership accountable? | | |
| 2 | | Have we established systems, policies, and a crisis management plan? | | |
| 3 | Internal Notification | Have the CEO, Executive Leaders, Risk Management, QI and Patient Safety, PR, Legal Counsel, and other relevant leaders been notified of the event? | | |
| 4 | | Has the board of trustees been notified? | | |
| 5 | Crisis Management Team (CMT) | Has the threshold been met for activation of the CMT? | | |
| 6 | | Is the internal/external team membership in place for this event? | | |
| 7 | | Who from executive leadership will chair the team? | | |
| 8 | | Is there a need for an independent facilitator? | | |
| 9 | Priority 1: The Patient and Family | Who is the organizational 24/7 contact person for the patient and family? | | |
| 10 | | Has the organization assessed the personal safety of the patient and family? | | |
| 11 | | What are we hearing from the patient and family? | | |
| 12 | | Has the organization expressed empathy and regret, and made an apology? | | |
| 13 | | Do we understand what the patient and family want said to others about the event? | | |
| 14 | | Are we providing ongoing support to the patient and family? | | |
| 15 | | Has the family been invited to participate in the root cause analysis (RCA) of the event? | | |
| 16 | Priority 2: The Front-line Staff | Who is the organizational 24/7 contact person for staff involved in the event? | | |
| 17 | | Have we assessed the personal safety of front-line staff? | | |
| 18 | | What are we hearing from the front-line staff? | | |
| 19 | | Has the organization expressed empathy and been visible? | | |
| 20 | | Have front-line staff been invited to participate in the RCA? | | |

| | Element | Dimension | Started ✔ | Completed ✔ |
|---|---|---|---|---|
| | Priority 3: The Organization | **The Event** | | |
| 21 | | Has an organizational point person been established overall? | | |
| 22 | | What do we know about what happened? How do we update? | | |
| 23 | | Has the root cause analysis been initiated? Is there an executive sponsor? | | |
| 24 | | What about the event is known internally and externally? | | |
| 25 | | What is being heard internally and externally in response? | | |
| 26 | | Is there clear and present danger to other patients, given what we know? | | |
| 27 | | What are the priorities to be addressed and who is the point person? | | |
| 28 | | Are there materials that need to be sequestered? | | |
| 29 | | What is the system to be used for urgent updates? | | |
| 30 | | Has billing stopped per hospital-acquired condition policy? | | |
| | | **Internal and External Communications** | | |
| 31 | | What are we prepared to say internally and externally? | | |
| 32 | | Who is (are) on point for communications? | | |
| 33 | | Are we clear on what the patient and family want said to others? Have they had input into all communications materials? | | |
| 34 | | Have we prepared a press release in case it is needed? | | |
| 35 | | Have there been communications to trustees, patients, families, and staff? | | |
| 36 | | Have there been external communications to the media, the community? | | |
| 37 | | Do we have "friendly" experts available to us? | | |
| 38 | | Have, or should, we retain outside media help? | | |
| | | **External Notifications and Unannounced Visits** | | |
| 39 | | Do we have required notifications to state public health, Centers for Medicare & Medicaid Services? | | |
| 40 | | Are we reporting this event to The Joint Commission, others? | | |
| 41 | | Have we notified our risk insurer/outside legal counsel? | | |
| 42 | | Are there federal agencies to be notified (e.g., Health and Human Services, National Institutes of Health)? Do we need to contact the Food and Drug Administration? | | |
| 43 | | Do law enforcement agencies need to be notified? | | |
| 44 | | Are there others that would benefit from learning from this event (e.g., Institute for Safe Medication Practices)? | | |

## Appendix B:

### Respectful Management of a Serious Clinical Adverse Event Work Plan: Elements, Dimensions, and Milestones

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| | **Element** | **Dimension** | **Pre-Event** | **First Hour** | **First Day** | **First Week** | **First Month** | **Activities after First Month** |
| **1** | **Organizational Culture of Safety** | Board and Leadership | Trust, Respect, Human Rights, Forgiveness, Repentance | | | | | Learning and improvement |
| **2** | | Systems, Policies, Procedures, Guidelines, Crisis Management Plan | Approve | Assemble | Annotate | Annotate | Annotate | Revise |
| **3** | **Internal Notification** | CEO, Executive Leaders, Risk Management, QI and Patient Safety, Counsel, Communication, etc. | Learning System | Activated | Engaged and Visible | Engaged and Visible | Engaged and Visible | Learning and improvement |
| **4** | | Board | | Pending | Activated | Updated | Updated | Learning and improvement |
| **5** | **Crisis Management Team** | Threshold Met for Activation | Plan | Activated | Meeting | Schedule | Schedule | Stand down with plan |
| **6** | | Membership | Plan | Activated | Refine | Refine | Updated | Form debrief Revise plan |
| **7** | | Chair | Plan | Activated | Refine | Ongoing | Ongoing | |
| **8** | | Facilitator | Plan | Activated | Ongoing | Ongoing | Ongoing | |
| **9** | **Priority 1: The Patient and Family** | Who's on Point | | | Establish | Report | Report | To resolution and learning, including any external professional or judicial actions |
| **10** | | Personal Safety | | | Assess | Update | Update | |
| **11** | | Hearing What | | | Report | Report | Report | |
| **12** | | Empathy/ Apology Extended | | | Regret | Report | Report | |
| **13** | | What Do They Want Said | | | Establish | Update | Update | |
| **14** | | Providing Ongoing Support | | | Offer | Report | Report | |
| **15** | | Root Cause Analysis (RCA) Participant | | | Activated | Invited | Complete | |

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| | **Element** | **Dimension** | **Pre-Event** | **First Hour** | **First Day** | **First Week** | **First Month** | **Activities after First Month** |
| **16** | **Priority 2: The Front-line Staff** | Who's on Point | | | Establish | Report | Report | To resolution and learning, including any external professional or judicial actions |
| **17** | | Personal Safety | | | Assess | Update | Update | |
| **18** | | Hearing What | | | Report | Report | Report | |
| **19** | | Ongoing Support and Visibility | | | Offer | Report | Report | |
| **20** | | RCA Participants | | | Activated | Invited | Complete | |
| | **Priority 3: The Organization** | **The Event** | | | | | | |
| **21** | | Who's on Point | | | Establish | Report | Report | Revise plan |
| **22** | | What Happened | | | Establish | Update | Update | Learning and improvement |
| **23** | | RCA and Executive Sponsor | | | Report | Report | Report | Closed all risk reduction items |
| **24** | | Who Knows What | | | Activated | Progress | Complete | Learning and improvement |
| **25** | | Hearing What | | | Report | Report | Report | Learning and improvement |
| **26** | | Patient Clear and Present Danger | | | Report | Report | Report | Learning and improvement |
| **27** | | Priorities: What, Who Is on Point | | | Set | Update | Update | All items addressed |
| **28** | | Materials to Be Sequestered | | | Immediate | Update | Update | Ultimate disposition? |
| **29** | | System for Urgent News | | | Set | Update | Update | Revise plan |
| **30** | | Billing Stopped (Hospital-Acquired Condition Policy, etc.) | | | Stop | Update | Update | Per statute/ Patient and family understanding |

**(continued on next page)**

**Appendix B: Respectful Management of a Serious Clinical Adverse Event Work Plan (continued)**

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| | **Element** | **Dimension** | **Pre-Event** | **First Hour** | **First Day** | **First Week** | **First Month** | **Activities after First Month** |
| | **Priority 3: The Organization (continued)** | **Internal and External Communications** | | | | | | |
| **31** | | What Prepared to Say | | | Establish | Update | Update | Learning and improvement |
| **32** | | Who Is (Are) on Point | | | Establish | Update | Update | Learning and improvement |
| **33** | | What Patient/ Family Want Said | | | Establish | Update | Update | Learning and improvement |
| **34** | | Press Release/ Talking Points | | | Prepare | Update | Update | Learning and improvement |
| **35** | | Internal Communications: Patients, Families, Staff | | | Prepare | Update | Update | Learning and improvement |
| **36** | | External Communications: Media, Community, etc. | | | Prepare | Update | Update | Learning and improvement |
| **37** | | "Friendly" Experts On Call | | | Consider | Update | Update | Presentations, articles, etc. |
| **38** | | Outside Media Help | | | Consider | Consider | Consider | Learning and improvement |
| | | **External Notifications and Unannounced Visits** | | | | | | |
| **39** | | State Public Health, CMS | | | Consider | Update | Update | All requirements and conditions met<br><br>Demonstrated learning and improvement |
| **40** | | Joint Commission, Others | | | Consider | Update | Update | |
| **41** | | Risk Insurer | | | Notify | Update | Update | |
| **42** | | Other Federal Agency (HHS, NIH, FDA) | | | Consider | Update | Update | |
| **43** | | Law Enforcement Agency | | | Consider | Update | Update | |
| **44** | | Other Associations (ISMP) | | | Consider | Update | Update | Learning shared externally |

## Appendix C:

### Respectful Management of a Serious Clinical Adverse Event: Disclosure Culture Assessment Tool

| | Element** | Y | Y/N | N |
|---|---|---|---|---|
| **Internal Culture of Safety** | The organization, board, and leadership are grounded in the core values of compassion and respect, and the responsibility to always tell the truth. | | | |
| | Harm is seen as the failure of systems and not people, and is considered in a fair and just culture with policies and practices. | | | |
| **Malpractice Carrier** | There is a commitment to rapid disclosure and support. | | | |
| | There is a written understanding of how cases will be managed with carrier. | | | |
| | Mechanisms are in place for rapid respectful resolution. | | | |
| **Policies, Guidelines, Procedures, Practices** | There is a policy on patient and family communications. | | | |
| | Informed consent policies and practices are up-to-date and effective. | | | |
| | There is a policy on patient and family partnerships. | | | |
| | There are policies on disclosure and documentation. | | | |
| | There are procedures in place for internal and external communication. | | | |
| | Guidelines/policies support a fair and just culture, and reporting of adverse events. | | | |
| | Root cause analyses commence immediately, are closely managed with an executive sponsor. Results are shared, including with the patient/family. | | | |
| | There is a written crisis management plan. This plan is centrally located. | | | |
| **Training** | Training programs are in place for all staff on communication, expectations, policies, procedures, guidelines. | | | |
| | There is just-in-time coaching (training) for disclosures. | | | |
| **Disclosure Processes** | There is rapid notification of patient/family and activation of support—typically, the organization shares what is known about the event. | | | |
| | There is a team to support staff preparing to disclose. | | | |
| **The Disclosure** | The organization is transparent and honest. | | | |
| | Responsibility is taken. | | | |
| | We are empathetic, apologize and/or acknowledge. | | | |
| | There is a commitment to providing follow-up information. | | | |
| | The caregiver is supported throughout the process. | | | |
| | Ongoing support is provided for the patient and family. | | | |

**(continued on next page)**

**Appendix C. Respectful Management of a Serious Clinical Adverse Event: Disclosure Culture Assessment Tool (continued)**

| | Element** | Y | Y/N | N |
|---|---|---|---|---|
| **Ongoing Support** | Resources are available to assist families experiencing unanticipated outcomes—support is defined by the patient and family. | | | |
| | Resources are available to assist staff at the front line of unanticipated outcomes—support is defined by needs of the clinician. | | | |
| | Procedures are in place and are known to ensure ongoing communications with patients, families, and staff. | | | |
| **Resolution** | Procedures are in place and are known to bring the case to closure respectfully, as viewed by the patient and family. | | | |
| **Learning** | Mechanisms are in place to ensure learning by the board, executive leadership, Medical Staff Executive Committee, and across the organization. | | | |
| | Measurement systems are in place to assess the impact of communication, disclosure, and support on premiums, claims, cases, and payments. | | | |

**Adapted from Medically Induced Trauma Support Services (MITSS)

For more information, the Institute for Healthcare Improvement Disclosure Toolkit and Disclosure Culture Assessment Tool is available at: http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/DisclosureToolkitCultureAssessment.htm.

## Appendix D:

### Respectful Management of Serious Clinical Adverse Events: Organizations from Which to Draw Courage and Learning

| Organization | Contact | Incident |
|---|---|---|
| Beth Israel Deaconess Medical Center, Boston, MA | Paul Levy, CEO | Wrong-site surgery http://runningahospital.blogspot.com/2008/07/message-you-hope-never-to-send.html |
| Catholic Health Partners, Cincinnati, OH | Jana Deen, Patient Safety Officer | Preventable death of parent of health system executive |
| Children's Hospital Boston, Boston, MA | Sandy Fenwick, President | Adverse events leading to death |
| Clarian Health System, Indianapolis, IN | Dan Evans, CEO | Heparin overdoses leading to death |
| Dana-Farber Cancer Institute, Boston, MA | Saul Weingart, Vice President, Quality and Patient Safety<br>Steven R. Singer, Senior Vice President of Communications | Chemotherapy overdose; theft of patient information |
| Duke University Health System, Durham, NC | Karen Frush, Chief Patient Safety Officer | Adverse events leading to harm and death |
| Immanuel St. Joseph Health System, Mankato, MN | Greg Kutcher, CEO | Drug diversion from multiple patients |
| Johns Hopkins Medical Center, Baltimore, MD | Peter Pronovost, Director of the Quality and Safety Research Group | Preventable death of a child |
| Mt. Auburn Hospital, Cambridge, MA | Jeanette Clough, CEO | Aberrant physician behavior, credentialing |
| Novant Health, Winston-Salem, NC | Paul Wiles, CEO | MRSA infection in the NICU, leading to the death of children |
| New York City Health and Hospital Corporation, New York, NY | Ramanathan Raju, Executive Vice President and CMO | Unrecognized death in Psychiatric ED |
| Rady Children's Hospital, San Diego, CA | Blair Sadler, Past President | Sexual abuse of children by employees |
| Virginia Mason Medical Center, Seattle, WA | Gary Kaplan, CEO | Preventable death |
| Winchester and Eastleigh Healthcare NHS Trust, UK | Kevin Stewart, Medical Director | Two maternal deaths |

Detailed information on each organization's story and other resources are available on IHI's website at: http://www.ihi.org/IHI/Topics/LeadingSystemImprovement/Leadership/Tools/LeadershipResponseSentinelEventEffectiveCrisisMgmt.htm.

Additional stories are also included in:

- Johnson RL. *Crisis Communication: Case Studies in Healthcare Image Restoration*. HCPro, Inc.; 2006.
- Wojcieszak D, Saxton JW, Finkelstein MM. *Sorry Works! Disclosure, Apology, and Relationships Prevent Medical Malpractice Claims.* AuthorHouse; 2010. [See Chapter 9: The Realized Benefits of Disclosure Success Stories.]

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