When Things *go* Wrong

RESPONDING TO ADVERSE EVENTS

A Consensus Statement of the Harvard Hospitals

MARCH 2006

The concepts and principles in this document are unanimously supported by the Harvard teaching institutions:

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BRIGHAM AND WOMEN'S HOSPITAL

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Foreword

In March 2004, responding to evidence of wide variation in the way both Harvard hospitals and hospitals nationally communicate with patients about errors and adverse events, a group of risk managers and clinicians from several Harvard teaching hospitals, the School of Public Health, and the Risk Management Foundation (Malpractice Captive for the Harvard Teaching Institutions) assembled to explore and discuss issues surrounding this subject. We soon agreed it would be useful to consider all aspects of an institution's response to an unanticipated event and to try to develop an evidence-based statement addressing these crucial issues. The Working Group began to meet monthly and quickly expanded to include patients and legal representatives.

The resulting document was distributed to all of the Harvard-affiliated hospitals in April, 2005 with the request that it be distributed widely within the institutions for discussion, critique and modification as appropriate. The objective was, if possible, to produce a consensus statement that all the Harvard hospitals and the Risk Management Foundation would endorse, and that would serve as the foundation for the development of specific institutional practices and policies.

The responses to the draft document were overwhelmingly positive. A number of modifications were suggested, however, particularly in differentiating between responses to preventable and unpreventable adverse events, reimbursement, and training. The paper was then revised to incorporate these changes and recirculated to all of the hospitals. The concepts and principles in this final document are supported by all of the Harvard teaching hospitals, which will now use them to develop specific policies and practices to implement the recommendations.

The paper is organized into three major divisions: The Patient and Family Experience (Sections II–IV), The Caregiver Experience (Sections V, VI), and Management of the event (Sections VII–XI).

Each of the major sections is organized into three parts:

- A brief summary of expert consensus about the issue

- The reasoning and evidence behind the consensus

- Recommendations

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INTRODUCTION

Since the turn of this century, medical error and tort reform have increasingly taken center stage in the health care debate in the United States. Patients, politicians, policy makers and health professionals grapple with the striking prevalence and consequences of medical error, whether a "near miss" or resulting in patient injury. Debate ranges from legislating restrictions on dollar awards in malpractice trials to ethical and moral imperatives germane to untoward clinical incidents, whether in the hospital or outpatient settings.

Fears of malpractice liability, difficulties in communicating bad news, and confusion about causation and responsibility have long impeded comprehensive and bold initiatives designed to change the patient, family and clinician experience with medical error. Current debate and inquiry provides, however, a special opportunity for investigating the circumstances that breed errors, and for creating, deploying, and analyzing the impact of large-scale change in the way institutions address patient safety and medical error.

This consensus statement examines the potential benefits and risks of an institutional response quite different from what most hospitals choose today. It focuses on rapid and open disclosure and emotional support to patients and families who experience serious incidents. It also addresses ways to support and educate clinicians involved in such incidents and outlines the administrative components of a comprehensive institutional policy.

The purpose of the document is to codify agreement on principles that individual hospitals will use to develop specific institutional policies to implement them. It does not attempt to prescribe those policies or practices, but rather invites elaboration and a wide variety of initiatives in implementation. The goal is to stimulate clinicians and hospitals to develop their own clear, informed, explicit, and effective policies for managing and preventing, where possible, the ongoing pain that such events engender.

Background

It its landmark 1999 report, *To Err Is Human*, the Institute of Medicine (IOM) declared that medical injury is a major cause of preventable deaths and called on health care to make reduction of medical errors a priority.[1] The IOM underscored the lesson from other industries that faulty systems are the major cause of errors and accidents. It recommended strongly that health care organizations greatly increase their efforts to promote safety through redesign of systems. In response, a major national movement has been launched to redesign health care systems.

In a subsequent report, *Crossing the Quality Chasm*, the IOM proposed six aims for the redesign of health care. It called on health care organizations to provide care that is safe, effective, patient-centered, timely, efficient, and equitable.[2] It urged hospitals to work hard to place the patients' interests first. It suggested that how an institution responds to an incident reflects its progress toward becoming a learning organization.

Guiding Principles

Two principles guide the recommendations in this document for responding to incidents: medical care must be safe, and it must be patient-centered.

Medical care must be safe. Hospitals must become "learning organizations," defined by Peter Senge as organizations that "continually expand their capacity to create the results they truly desire."[3] We must commit ourselves to relentless self-examination and continuous improvement. When things go wrong, our obligation becomes two-fold: to intensify our commitment to care for the patient harmed, and to change our systems to prevent future error.

Medical care must be patient-centered. In the aftermath of an incident, the primary objective must be to support the patient and maintain the healing relationship. Patients and families are entitled to know the details of incidents and their implications. Communication should be open, timely, and sustained. We must eliminate the adversarial relationship that a secretive, liability-focused approach to patient communication fosters. The caregiver's role is to provide comfort and support and to consider the full breadth of patients' needs. Openness and collaboration are paramount.

We are making a moral argument here, not a business case or an evidence-based clinical guideline. Where there are published data or empirical evidence to support a practice, we cite them, but our primary justification is moral. We are committed to full disclosure because it is the right thing to do. The patient and family have the right to know what happened. In addition, honest communication promotes trust between the patient and provider, so that the primary focus of the clinician-patient relationship remains patient care. Further, open discussion about errors can promote patient safety by encouraging clinicians to seek systems improvements that minimize the likelihood of recurrence.

How Should an Institution Respond?

A serious incident should trigger a cascade of responses. The first concern should be to minimize further harm to the patient and relieve suffering. Next, to protect evidence, institutions should immediately secure implicated drugs, equipment, and records. Members of the health care team and appropriate administrative and clinical leadership need to learn of the event promptly. As soon as possible, the patient and family should learn of the event and the facts as initially known. They will likely need emotional and psychological support, and this should arrive seamlessly. Finally, the medical record should document clearly all these actions.

Caregivers may also require support, depending on the type of event. As soon as practical, all involved parties should participate in an analysis of the event, as they search for the underlying systems failures. The goals of the analysis are to gain full understanding of the circumstances involved in the event, identify contributing factors, and develop practical recommendations for systems changes designed to prevent recurrence. In follow-up meetings, appropriate staff should communicate the results of the analysis and planned changes. In what follows, we consider each of these elements, focusing on how the institution and the caregivers respond.

We approach these issues from the patient's point of view, asking, "What would I want if I were harmed by my treatment?" While hospitals and caregivers may have competing interests, including legitimate concerns about legal liability, our frame of reference is the simple question, "What is the right thing to do?"

I. DEFINITIONS

Many terms have been used to refer to bad outcomes of care, often causing confusion. For example, in its disclosure policy, JCAHO calls for informing patients of "unanticipated outcomes," in an attempt to distinguish complications of treatment from complications of disease. Yet, this has led to debates over whether the fact that certain complications of treatment, such as postoperative infections, are well known to occasionally occur means that they are "anticipated" and therefore do not require disclosure.

Another source of confusion is the use of terms for injury and error interchangeably. To avoid confusion, we use the following definitions from the American Society of Healthcare Risk Management (ASHRM)[4] in this document:

Adverse Event: An injury that was caused by medical management rather than the patient's underlying disease; also sometimes called "harm", "injury", or "complication".

- An adverse event may or may not result from an error. See further classification of preventable and unpreventable adverse events below.

- "Medical management" refers to all aspects of health care, not just the actions or decisions of physicians or nurses.

Medical Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical errors include serious errors, minor errors, and near misses. (Note: A medical error may or may not cause harm. A medical error that does not cause harm does not result in an adverse event.)

In addition, we define the following:

Serious Error: An error that has the potential to cause permanent injury or transient but potentially life-threatening harm.

Minor Error: An error that does not cause harm or have the potential to do so.

Near Miss: An error that could have caused harm but did not reach the patient because it was intercepted.

Preventable adverse event: An injury (or complication) that results from an error or systems failure. Even if one agrees that individual errors are often the end result of systems failures, they are still perceived by patients and caregivers as very personal events. It is useful to distinguish three categories:

- Type 1: Error by the attending physician.
    Example: technical error during performance of a procedure

- Type 2: Error by anyone else in the healthcare team
    Examples: a nurse gives wrong medication to patient; a resident makes a technical or decision error; a radiologist misses a lesion.

- Type 3: Systems failure with no individual error.
    Examples: IV pump failure that causes drug overdose; Failure of system to communicate abnormal lab results to ordering physician.

Unpreventable adverse event: An injury (or complication) that was not due to an error or systems failure and is not always preventable at the current state of scientific knowledge. There are two major categories:

- Type 1: Common, well-known hazards of high-risk therapy. Patients understand the risks and accept them in order to receive the benefit of the treatment.
  Example: complications of chemotherapy

- Type 2: Rare but known risks of ordinary treatments. The patient may or may not have been informed of the risk in advance.
  Example: side-effects of medications; certain wound infections

Incident: An adverse event or serious error. Also sometimes referred to as an *event*.

Disclosure: Providing information to a patient and/or family about an incident. Because this term suggests revealing of privileged information and implies an element of choice, in this document we use instead the term *communication*, by which we wish to convey a sense of openness and reciprocity.

Reporting: Providing information to an appropriate authority, internal or external, regarding adverse events or errors. (See section on Reporting for more details on what events are to be reported.)

The Patient and Family Experience

II. COMMUNICATING WITH THE PATIENT AND FAMILY

Prompt, compassionate, and honest communication with the patient and family following an incident is essential. Unfortunately, this is the one aspect of the response to an incident that is most often managed poorly.

Because of the emotional effects of these events on both the patients and the caregivers, communication can be difficult for all parties. Communication failures compound the injury for the patient, as well as for the caregivers, and are thought by some to be the major reason patients file malpractice suits.

Consideration of this complex subject is divided into three sections:

A. Initial Communication: **What** is communicated and **when** it should be done

B. Initial Communication: **Who** provides the information and **how** they do it

C. Follow-up communication while in the hospital

Communication and follow-through after discharge are considered in Section IV.

A. Initial Communication: What and When

The patient and/or family should be fully and promptly informed of any incident—that is, any adverse event or serious error that reaches the patient. There is general agreement among patients and caregivers that it is not appropriate to inform patients of minor (harmless) errors. Near misses, errors that could have caused harm but were intercepted, are a special case and responses need to be individualized. Caregivers and administrators need to discuss and agree on the threshold for informing and the rationale for choosing that threshold. This can be a difficult task, but consistency requires a clear institutional policy.

The occurrence of an incident should be communicated to the patient as soon as it is recognized and the patient is ready physically and psychologically to receive this information. Typically, this should occur within 24 hours after the event is discovered. Early acknowledgement is essential to maintaining trust. If it is not possible to communicate with the patient, the initial communications should begin with those members of family or health-care proxy who will be representing the patient in further discussions.

Initial explanations should focus on what happened and how it will affect the patient, including immediate effects and the prognosis. The caregiver should acknowledge the event, express regret, and explain what happened. If an obvious error has been made, the caregiver should admit it, take responsibility for it, apologize, and express a commitment to finding out why it occurred.

The caregiver should also explain what is being done to mitigate the effects of the injury. Explanation of how or why the event occurred should be deferred until the investigation is completed. However, the caregiver should inform the patient and family that the causes of the event are being investigated and that information will be shared with them as soon as it is available.

Reasoning and Evidence

Communication about incidents to patients and families is a crucial part of the institution's response to adverse events. Open, honest communication is essential to maintaining and restoring trust, and to providing appropriate ongoing care. It is not difficult to preserve trust when times are good—when there have been no problems in the delivery of care. The real test is preserving the relationship when something has happened that may strain it. How the communication process is handled profoundly influences the reactions of patients and their families.

Even in the absence of adverse events, many patients feel vulnerable by virtue of their being ill or requiring medical care. Thus, when adverse events do occur, patients may have particularly severe or complex emotional reactions. Fear, anxiety, depression, anger, frustration, loss of trust, and feelings of isolation are common reactions.[5,6] And after particularly traumatic and life-threatening events, intrusive memories, emotional numbness, and flashbacks are possible.[6] These reactions may occur even when the event was not due to an error and even when the possibility of it occurring was discussed during the consent process.

Moreover, the patient-physician or patient-nurse relationship often becomes complicated in the aftermath of an adverse event when it is due to an error. Patients are unintentionally harmed by the very people whom they entrusted to help them. And, subsequent to the adverse event, they are often cared for by the same clinicians who were involved in the injury itself. Even when caregivers are sympathetic, supportive, and open, patients are likely to experience conflicting emotions about their caregivers.[6]

The reactions of patients and their families to incidents are influenced both by the incident itself and the manner in which the incident is handled.[5,7] Inadequate or insensitive management may cause further emotional trauma, while open acknowledgement of the injury, sensitivity, good communication, and skillful management of corrective actions may reduce emotional trauma.[5,7]

Data in the medical literature suggest that most patients wish to be informed of adverse events. In a survey conducted among 149 patients from a U.S. academic internal medicine outpatient clinic,[8] patients responded to three medical error scenarios (minor, moderate, and severe). Ninety-eight percent wanted some acknowledgment of errors, even if minor. For both moderate and severe errors, patients were significantly more likely to consider litigation if the physician did not disclose the error.

In one British survey, 92% of patients believed that a patient should always be told if a complication has occurred, and 81% of patients believed that a patient should not only be informed of a complication but also be given detailed information on possible adverse outcomes.[9] In a British survey of 227 patients and relatives who were taking legal action in malpractice cases, plaintiffs wanted greater honesty, an appreciation of the severity of the trauma they had suffered, and assurances that lessons had been learned from their experiences.[7]

When they are injured by physicians' mistakes, patients may feel hurt, betrayed, devalued, humiliated, and afraid. By taking responsibility and apologizing, the physician acknowledges these feelings, shows an understanding of their impact, and begins to make amends. The apology helps to restore the patient's dignity and begin the healing process. It also helps the physician deal with his own emotional trauma. On the other hand, failing to admit error and express regret "adds insult to injury" by not fully respecting the patient's situation.

Open communication by individual clinicians and risk managers should be strongly supported by institutional leaders with clearly stated and agreed-upon policies and directives. It is difficult for a clinician to be honest and open about problems that have occurred if he or she is not supported by senior management.

Recommendations

Caregivers should promptly inform the patient and/or family about any adverse event or error that reached the patient even if no harm was done. Minor errors that do not reach the patient do not need to be disclosed. Discussion of near misses, serious errors that were intercepted, should be individualized. If the patient is aware of the error, or if knowledge of it can help prevent a recurrence, the patient should be informed. When in doubt about whether communication is called for, a caregiver should consult an internal expert, such as the risk manager, safety leader or senior administrator.

General Principles Regarding Disclosure in the Immediate Aftermath of an Incident:[11]

Report only the facts of the incident – what occurred, not how or why you believe the outcome occurred.

Disclose reliable information in timely fashion as it becomes available.

Explain your recommendations for further diagnostics and therapeutics.

Explain the implications for prognosis.

Caregivers should be honest and open about the incident and about what is being done to mitigate the injury and to prevent a recurrence. Honest communication conveys respect for the patient. Failure to acknowledge the event can be very distressing for the patient and is a powerful stimulus to complaint or litigation.

If the event was clearly not caused by an error (i.e., a Type 1 or 2 unpreventable adverse event), or the cause is unknown, the caregiver should express regret (We're sorry this happened to you.), explain what happened and discuss what will be done to mitigate further harm. It is important to make sure the patient understands that the injury is not the result of a failure of care, but an inherent risk. This is relatively easy when the risk of complications is high and well-known to the patient, as in chemotherapy (Type 1).

For less common unpreventable events (Type 2), even when full attention has been given to obtaining informed consent, the patient's initial reaction is often to assume that someone made an error. Therefore, it is important to provide a full and patient explanation about what happened, even when it seems very straightforward to the caregiver. It is very important for the patient to perceive that the staff take the injury seriously and are sorry that it happened, but also to understand that preventing it was not under their control.

If it is not clear whether an injury was due to an error, the event still should be acknowledged and regret should be expressed as above. However, it is important not to jump to conclusions, to blame oneself or another, nor to take responsibility for an event, before all the facts are known. A full investigation should be promised, together with a commitment to report back to the patient when more is known.

When an event is caused by an error or other type of systems failure (preventable adverse events Types 1–3), a fuller explanation is indicated, as well as an apology and explanation of what will be done to prevent recurrence in future patients. Regardless of who made the error or what system failed, the major responsibility for communication with the patient falls on the attending physician who is responsible for the patient's care.

There are four essential steps in the full communication of preventable adverse events:

1. Tell the patient and family what happened. Tell *what* happened now; leave details of *how* and *why* for later.[10] Determining the causes of an adverse event requires careful analysis and is time-consuming. However, patients and their families are likely to want immediate answers. Therefore, early after an adverse event, limit discussions to known facts and avoid speculation. Speculation and preliminary conclusions are often interpreted by patients and families as definitive. The nature of incident investigations is such that early impressions are frequently contradicted by subsequent, careful analysis. If speculative information is shared with patients and

families and later contradicted by the results of careful analysis, clinicians are forced to correct themselves, which may cast doubt on their credibility and the credibility of future information. The conclusions of the adverse event analysis and the system changes recommended to prevent future adverse events should be discussed with the patient and family later when this information becomes available. On the other hand, withholding available information that the patient must know immediately is inappropriate.

2. Take responsibility. Whether or not the incident resulted from a specific act, the attending physician should make a statement of responsibility to the patient and/or family. Taking responsibility for an adverse event is an essential step in the full communication of an event. As the person the patient entrusts their care to, the attending physician must assume responsibility even when he/she did not actually make the mistake that caused the injury. The overall responsibility and accountability for an adverse event rests with the hospital. Thus, following a serious event it is incumbent upon the organization and its leaders to also accept responsibility and communicate that responsibility and remorse to the patient and family. Because every event is unique, organizational leaders and clinicians should coordinate communications with the patient and family.

On first consideration, it may seem odd that in situations where the physician had nothing to do with an adverse event, s/he should take responsibility for it. In this circumstance, taking responsibility does not mean assuming sole culpability for the adverse event. A host of factors likely contributed to the adverse event—many of them beyond any one person's control. However, as the leader of the team, the physician is an integral part of the clinical system that delivers care to the patient in question. S/he is, understandably, the person who the patient and family assume is responsible for the care. Patients look to their physician for care and comfort, and to make things work for them. The patient

wants to know that someone is in charge and has control over the situation.

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. They communicate the institution's responsibility to do whatever possible to improve systems to prevent future similar events from happening to other patients.

If the physician was directly involved in the adverse event, he/she should take responsibility for his/her own role, but also explain the contributing systems factors that made the adverse event more likely. However, he/she should not blame "the system" or use such terms as "systems thinking" as an excuse to avoid responsibility.

There are several ways to say this:

- "We failed you."

- "This shouldn't have happened."

- "Our systems broke down. We're going to find out what happened and do everything we can to see to it that it doesn't happen again."

- "I'll let you know what we find as soon as I know."

3. Apologize. When there has been an error, one of the most powerful things a caregiver can do to heal the patient—and him/herself—is to apologize. Apologizing is an essential aspect of taking responsibility for an injury, even if, as is common, several systems failures are responsible for the error rather than one person. Explaining the event, communicating remorse, and making a gesture of reconciliation can do much to defuse the hurt and anger that follows an injury.[11]

Immediately after an event, the primary caregiver should express regret for what happened—even if

the causes of the event are not all known. Patients are likely to feel hurt and vulnerable after an event, and the expression of empathy and compassion is an essential, humane response to an adverse event, regardless of its cause. ("*I'm sorry this happened. It's terrible.*")

If an obvious error has occurred, whoever made the error should disclose it promptly, apologize, and communicate his or her commitment to finding the reasons for the error ("*We made this error. I apologize.*") Although errors by individuals usually result from systems failures (which need to be identified and addressed), few patients understand that. They hold the individual responsible. As a result, it is immensely valuable for the person who made the error to apologize and show genuine remorse. However, consideration must be given to the caregiver's ability at the time to emotionally handle the situation. If the caregiver is unable to adequately communicate with the patient, it may be desirable to have another party step in.

The attending physician should also apologize if the error was made by someone else. In these cases, it may be wise to make the apology a joint effort, i.e., for the person who made the mistake (resident, nurse, radiologist, etc.) to meet with the patient together with the attending for the apology.

Contrary to what many physicians believe, there is little evidence that apologizing increases the risk of a malpractice suit.[12] In fact, experience in malpractice cases indicates just the opposite: that the failure to communicate openly, take responsibility, and apologize contributes to patients' anger. Some malpractice lawyers contend that two-thirds of malpractice suits stem from a failure to take responsibility, apologize, and communicate openly.[13]

4. Explain what will be done to prevent future events. Once the investigation is completed and corrective changes are planned, it is important to inform the patient and family of these plans. Injured patients have a strong interest in seeing to it that what happened to them does not happen to someone else. Caregivers often underestimate the importance of this aspect of the response to an event. Knowing that changes were made and that some good came of their experience helps the patient and family cope with their pain or loss. It gives a positive meaning to their experience to know that their suffering is not in vain.

B. Initial Communication: Who and How

A serious incident represents a major threat to the patient's sense of control and trust in the caregiver. Thus, it is essential that the communication be from a person with whom they have a trusting relationship, and that it convey care, concern, and control over the patient's care. Because the purpose of these discussions is to support and inform the patient, they should be held in private, in a manner that empowers the patient and avoids the barriers or demonstration of rank that may intimidate or discourage them.

In the usual situation, the physician responsible for the patient's care is the person most suitable to make the apology. However, in some situations, other health care professionals or administrators may be more appropriate for disclosing the error and apologizing. These individuals may include a nurse who made the error or another staff member who has an existing relationship with the patient and family. If the clinician responsible for apologizing is absent or emotionally unable to do so, other trained individuals, such as a hospital vice president or senior clinical leader, should substitute. An ombudsman/mediator can play a valuable role in these situations.

Subsequent discussions with the patient and family may be appropriately held by the attending physician or by leadership personnel. Under special circumstances, members of the quality and safety reviewing team may be involved. In all cases, staff should be adequately and appropriately prepared, both as to the content and style of the communication. All such discussions should be conducted with the patient's concerns primarily in mind, and in private, to make the patient and family most comfortable.

Reasoning and Evidence

When the same physician is responsible for care before and after the event, this is clearly the person to assume this role. When the site of care is different (as in transfer to an ICU), it is appropriate for caregivers from both settings to be present and conduct the discussion together.

Ensuring coherence and consistency of communication requires that subsequent discussions be conducted by whoever will address the patient's concerns most knowledgably. In many cases, this will continue to be the attending physician. However, information about improvement efforts or institutional responsibility may more appropriately be provided by leaders in these areas.

> **Who and How to Communicate**
>
> A trusted caregiver should lead initial communication.
>
> The person responsible for next steps in care should lead subsequent communication.
>
> Include patient's primary nurse in communications.
>
> Provide staff with coaching in communication techniques.
>
> Choose a quiet, private area for communication.

Recommendations

1. The initial communication should be by or at least in the presence of a caregiver with a prior relation of trust with the patient. Ideally, this will be the attending physician or the physician who planned and carried out the treatment.

2. At the same time, to define the next steps in care, it is also often helpful to the patient and family to have present the person most responsible for those steps. If this is someone different from the primary caregiver, e.g., the ambulatory patient wakes up in an ICU, the physician now responsible for their care should also be present to assure them (patient and family) of the commitment to continue to provide care. If the discussion is anticipated to be complex or difficult, the patient should be encouraged to have another person available or present to provide support.

3. It may also be helpful to have the patient's primary nurse present, to participate, observe, and support. It is not recommended at this initial stage that a higher-level administrator participate, except in the most catastrophic situations. Similarly, including someone identified as a "risk manager" in these first discussions can set the wrong tone.

4. Discussion with patients and families under these circumstances may be difficult, and not all physicians and nurses will be comfortable and capable of doing this. When the appropriate staff are anticipated to have difficulty, or are apprehensive themselves, someone with experience and competence in this area should accompany or coach them

ahead of time. Institutions need to develop training in these techniques and make sure all staff are aware of sources of assistance for these discussions.

5. The choice of the setting for communicating incidents is important, particularly if apology or restitution is appropriate. When possible, the meeting should be prescheduled, and arranged in a private and quiet area that supports both confidentiality and the feelings of the patient and family. A single room in the hospital is ideal, as is a private office for ambulatory communications. A visit to the patient's home may be indicated if the patient has been treated in a clinic or has been discharged. A double room, or any open space, such as a hallway or waiting room in the ambulatory arena should never be used. Moreover, it is not appropriate to summon the patient and family to an executive suite.

C. Follow-up Communication

One or more subsequent discussions are always indicated following a serious event. In addition to continuing to show support and concern, and identifying further opportunity for amelioration, the primary purpose of follow-up communication is to provide fuller description of the events that occurred and the nature of systems changes that have been identified to address them. This discussion should be open-ended, and not limited by time or interruptions.

> **Follow-up Communication**
>
> Conduct follow-up sessions promptly.
>
> Primary physician or team members should lead sessions.
>
> Involve CMO or CEO in serious or difficult cases.

Recommendations

1. Follow-up sessions should be arranged as soon as significant additional information is available. If delay is encountered, the patient or family should be frequently apprised of the situation, with apology for the delay.

2. The attending physician and team members may conduct these follow-up meetings as appropriate.

3. In especially serious or highly charged cases, higher officials in administration, including the CMO or even the CEO, should be involved. Senior administrative involvement is especially indicated if faith in the primary caregiver has been compromised or he/she has not been fully successful in communicating.

III. SUPPORT OF THE PATIENT AND FAMILY

Support of the patient should be psychological, social, and in some cases, financial. Following a serious event, patients expect, need, and are entitled to receive timely, accurate, empathetic explanations, as well as evidence of diligence in investigating the situation. In addition, they need attention to their emotional and social needs. At a minimum, this entails sympathetic care from all caregivers, but may also entail professional counseling and psychological care, as well as social services.

Patients often also need financial support, but how to provide it is less clear. Many believe that patients should receive reimbursement for expenses they incur as a result of a preventable injury. These might include initial out-of-pocket expenses, such as family housing, travel, and child care, but also even disability aids, housekeeping services, and transportation to doctor appointments. Unfortunately, current systems for health care financing do not provide for these types of payments, so if they are provided costs must be born by the hospital. If payment is to be provided, the offer should not take place during the initial discussions, but when extra expenses become known during the course of the recovery.

Reasoning and Evidence

For many patients, just being hospitalized places them in a vulnerable psychological state even when treatment goes according to plan. Post-traumatic stress disorder can occur even following "routine" procedures. When they experience harm or an unexpected event, their reaction is likely to be particularly severe.[6]

In a study of injury following surgery, the overwhelming majority of patients felt a severe negative impact on their life following the event. In addition to physical disabilities, psychological trauma was a significant component.[14]

As Vincent notes, medical injury differs from other types of trauma in two ways. First, patients are unintentionally harmed by the people in whom they have placed trust. Therefore, their reactions may be especially powerful and complex. Second, they usually continue to be cared for by the same clinicians who were involved in the injury itself. As a result, they may be frightened and have conflicting feelings about their caregivers, even when they are sympathetic and supportive.[6]

Thus, following medical injury, fear, anxiety, depression, anger, frustration, loss of trust, and feelings of isolation are common reactions.[5,6] Inadequate or insensitive management of incidents may cause further emotional trauma, while open acknowledgement of error and harm, sensitivity, good communication, and skillful management of corrective actions may reduce emotional trauma.[5-7]

Prolonged hospital stay or disability may lead to substantial additional, unexpected expenses. Even if an analysis shows no error or systems breakdown, if the injury is caused by treatment, the patient may feel let down by the hospital and entitled to some special consideration.

In difficult situations, involvement of an ombudsman/mediator may be indicated. Experience at Kaiser Permanente indicates that an ombudsman/mediator program can improve the patient experience by acknowledging their hardship, helping all parties exchange information, and bringing issues forward to help minimize the chance of recurrences.[15]

Patients may expect hospital and physician fees to be waived when there is a complication. This is especially likely to be so if the injury is perceived to be caused by an error or other failure in the treatment process. (Why should I have to pay for the hospital's mistakes?) In this situation, waiving fees and providing reimbursement for extra expenses begins to "make up" for the injury, demonstrates a hospital's sense of fairness, and helps restore or preserve the patient's self-esteem. Anecdotal evidence suggests that payment of even relatively small sums

to meet additional expenses incurred as a result of the injury can have a powerful positive effect on the patient's response to the event.

Whether hospitals should compensate patients for predictable and long-term continuing expenses following discharge from the hospital is more controversial. Such expenses can be considerable. In the United States, patients have few avenues of recourse other than to file a malpractice suit. Many believe that compensation for the costs of medical injuries is not only the fair thing to do, but, together with full disclosure, would dramatically reduce the number of suits that are filed. If so, it would also be the financially smart thing to do.

There is a growing body of experience with effective models for providing compensation outside of the courts. The foundation for these models is an emphasis on maintaining the physician-patient relationship, where possible, and open and truthful communication. Although data are limited, results thus far are promising. Not every incident can be managed through these innovative programs, but data from pilot programs suggest that many can.

Three programs provide successful examples of how this can work:

1. Since 1997, the Veterans Affairs Medical Center (VAMC) Lexington, Kentucky has used a policy of open disclosure when patient injury is the result of a medical error or negligence. In these cases, the error is disclosed to the patient or family and a settlement is offered. Prior to implementation of the disclosure policy, malpractice claim payments at the Lexington VAMC were among the highest when compared to its peer group of other VAMCs. Following implementation of the disclosure policy, Lexington VAMC moved to the lowest quartile of its peers.[16] Although these data are compelling, generalizing to nonfederal medical centers is limited by the fact that federal employees cannot be held liable for medical errors. Further, the federal government cannot be held legally responsible for punitive damages.[12]

2. In 2002, the Ann Arbor-based University of Michigan implemented a policy to simply to have doctors admit mistakes and apologize. Since implementation, the average time to resolve complaints has decreased from 1000 to 300 days, attorney fees have been reduced by two thirds, and pending complaints and suits have decreased. In this program, an emphasis is placed on addressing the needs of patients and families as quickly as possible including the provision of fair compensation.[17]

3. COPIC Insurance Company, based in Denver, Colorado, has successfully negotiated payments to selected patients without attorney involvement. COPIC's 3Rs™ pilot program of recognize, respond, and resolve began in 2000. As of December 31, 2004, there have been 930 qualifying incidents of which 305 patients received reimbursement. Payments have averaged $1747.00 per qualifying incident and $5,326.00 per paid incident. Most notably, none of these cases has gone to litigation. Early findings indicate not only a major cost-savings potential, but also improved physician/patient communication and sustained relationships, and improved satisfaction of all parties involved.[18]

See Appendix B for an illustrative case history from a Harvard hospital.

Recommendations

1. Patients and families should be specifically asked by members of the team assisting in their case about their feelings related to their injury and about any anxieties they may have about future treatment and prognosis. Even when patients receive explanations, an apology, and assurance that actions will be taken to prevent recurrence of any medical errors, the emotional trauma of the event and anxieties about future treatment may necessitate psychological treatment.

Supporting the Patient and Family

Ask patients and families about their feelings about the injury.

Take all patient concerns seriously and address them completely.

Maintain the therapeutic relationship with the patient and family.

Provide patients and families with contact information for clinical and financial counseling and support.

Put all billing on hold pending analysis of the event.

Investigate possible means for providing financial support.

Psychological support may need to be provided by social workers, psychologists or psychiatrists, as determined by assessment of the team of caregivers who have been involved in the management of the case and in communication with the patient and family.

2. Clinicians should be attentive to patients who say their treatment has harmed them, even when a complication appears to have resulted from the patient's disease. Given the risk of harm from medical treatment, such a claim should be considered seriously. The patient may have information the caregivers lack or the patient may not fully understand the clinical circumstances. If the patient's concern is groundless, a complete and sympathetic explanation is essential therapy. Being ignored can be distressing to a patient and may delay remedial treatment.

3. Following injury, it is important for clinicians to take extra pains to ensure continuity of care and to maintain the therapeutic relationship. Following an injury, patients and families need more support, not less, even though sometimes both patients and clinicians may feel a natural wish to distance themselves from one another.

4. Patients and families should be provided with the names, phone numbers and contact information of individuals of the institution who are available at all times to address their questions, complaints, and concerns. These include individuals who can provide internal and external support and counseling, as well as financial counseling. Financial pressures may contribute to emotional concerns. Coordination of psychological and financial support may be best served by individuals in the social work department. It is important that the care team discuss the support of the patient and family in advance.

5. Following an incident, all billing for hospital or physician services (including "ancillary services" such as radiology and cardiology) should be put on hold, pending the outcome of the analysis of the event. Receiving an invoice at this juncture can be viewed by the patient as an insult, add frustration, and further erode the patient's confidence that the institute is properly handling the situation.

6. Hospital should investigate ways to provide financial support for short term expenses stemming from preventable injuries. Important issues include defining the types of expenses to be reimbursed, the source of funds, who is empowered to offer them, and the value of a consistent approach within and among related hospitals. If financial assistance is provided, the institution should provide it promptly. An immediate response can make a substantial difference after an injury, whether it provides for childcare or disability aids or is used to alleviate financial hardship.

7. The advisability of liability insurers providing compensation for long-term disability and continuing expenses, also known as "no-fault" compensation or "early offer" programs also needs careful consideration. There are many issues to be settled, including, among others, defining compensable events, establishing an administrative mechanism, defining patients' continuing legal rights, and whether a viable system requires statewide adoption and a legislative mandate.

IV. FOLLOW-UP CARE OF THE PATIENT AND FAMILY

Following discharge from the hospital, it is essential to provide further opportunity for inquiry and communication for patients who have suffered an incident. Patients are entitled to, and should receive, the following:

- Scheduled times for clinical follow-up visits

- Scheduled times for follow-up communications

- Continuing psychological and social support

- Communications about the final results of investigations, remedial actions. Frequently, the analysis of the event is not completed by the time of the patient's discharge from the hospital. It is essential that findings be communicated as soon as they are available.

Reasoning and Evidence

When patients are discharged following a serious incident, they continue to carry with them the fears and concerns engendered by the event, but also may be forced to cope in the outside world with new disabilities, pain, and uncertainties about the future. In many ways, their psychological and social support needs may be greater than when in the hospital.

Unfortunately, they may receive much less. Too often, the word "discharge" means just that to the hospital: that it no longer has responsibility for the patient's welfare. For some patients, this can be a disaster, both physically and emotionally. A sense of abandonment can add to the anger and frustration already experienced. Patients and families need continuing support.

If follow-up of these events is to be appropriately managed, institutions must establish a structure that includes a well-managed series of follow-up encounters with the patient (or family) to provide continuing care and to give them updates on all findings from internal investigations and any remedial actions taken.

Recommendations

1. The patient and family should be provided with appropriate business cards and phone numbers to facilitate easy access to the principals involved in the prior communications around the event.

2. A series of follow-up encounters with the patient (or family) should be planned, both to check on their clinical status and to give them updates on findings from internal investigations and any remedial actions taken. These encounters should occur not in an ad hoc way, but as scheduled, pro-active overtures to the patient and his/her family.

3. A home visit may be indicated, particularly if extensive follow-up information must be communicated. Alternatively, the patient and family can be invited back to the hospital, accommodating the patient's needs in terms of transportation, meals, and overnight accommodations if appropriate.

4. Needed psychological and social support should be provided.

5. Continuing reimbursement for injury-related expenses may be indicated. Those responsible for the patient must be able to arrange for these efficiently. (See previous Section)

Follow-up Care of the Patient and Family

Provide patients with contact information to facilitate communication after discharge.

Plan a series of follow-up meetings with the patient and family.

Schedule a home visit to communicate extensive follow-up information.

Provide psychological and social support.

Provide continuing financial support for injury-related expenses, if needed.

The Caregiver Experience

V. SUPPORT OF CAREGIVERS

Like patients and families, caregivers are significantly impacted, emotionally and functionally, following an adverse event. They should be provided with institutional support that enables them to recover, to communicate and apologize effectively to the patient, and to return rapidly to their professional duties.

Reasoning and Evidence

Caregivers are especially likely to be deeply affected by an adverse event if they made a serious error. Frequently they are unrecognized "second victims" in these events, and receive little understanding or support. The absence of a structured support system can have a longstanding and detrimental impact on a clinician's ability to provide patient care following an adverse event.[5, 21-23]

The need for an organized support structure for caregivers is typically not recognized by either caregivers or the health care institution. Reasons for this are complex and include a medical culture that expects physicians particularly to remain strong, objective, and emotionally detached from their patients afflicted by illness;[5] a health care and legal system that blames the caregiver rather than the care process when an incident occurs;[24] and internalization of the dictum to "first do no harm" that leads physicians to expect infallibility and that reinforces the adverse outcome as a taboo event.

As a result, following a serious adverse event caregivers often feel isolated and experience profound shame and guilt. They may be unwilling or unable to talk about the event or to report it, which inhibits analysis and learning. Many have not been trained to communicate effectively with the patient and family members or with other clinicians following an adverse event, and may have great difficulty in communicating openly and honestly.

A comprehensive institutional support system is needed to assist caregivers in preparing for and quickly responding to an adverse event. Such support is also critical if an organization is to fully embrace a policy of full communication and apology.[25]

Recommendations

1. The hospital should have a program designed to provide "aid to normal people who are experiencing normal stress after experiencing highly abnormal events."[25] The objective is to help professionals manage the stress of the adverse event so that they can better care for their patients, so healing can occur, and so the caregiver can comfortably return to the work environment with normal productivity.

2. Because caregivers' needs vary, the support system should incorporate a variety of offerings, including both private and group counseling and short- and long-term counseling.

3. Administrative policies should ensure that caregivers are provided with appropriate adjustment of responsibilities and time off if needed so that healing can occur.

Support of Caregivers

Establish a program to provide support to caregivers involved in the event.

Offer a variety of support services to meet different needs.

Adjust responsibilities and time off for caregivers as needed.

Provide for structured debriefing and documentation of the event.

Coach caregivers in communicating with the patient and family.

Instruct caregivers in peer review, QA/QI, and root cause processes.

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4. Caregivers should have structured assistance in debriefing the adverse event as a team and should be given instruction in documenting the event for the medical record.

5. Coaching in communicating with the patient and family during the emotionally intense period immediately following an incident can be critical for maintaining the relationship of compassion and trust.

6. Training programs need to be developed to teach doctors, nurses, and other clinicians, as well as department chairmen and managers, how to provide support for colleagues when they are "second victims".

7. Finally, caregivers will benefit from support during the peer review, QA/QI, and root cause analysis processes. This might include instruction in the process, as well as direct support during the events themselves.

[For more details, see Appendix C]

VI. TRAINING AND EDUCATION

Institutions have an obligation to provide their health care staff with the education, training, and resources to manage an incident. Among the most important is training in communicating bad news.

Many caregivers have not been adequately educated or trained in the skills needed to effectively deliver bad news, apologize, and counsel patients in distress. As a result, they often fail to communicate compassionately and effectively with their patients following an incident. Caregivers, including physicians, nurses, and other staff, are frequently inhibited in their ability to empathize with patients because of their own feelings of shame and guilt, compounded by fear of liability.

These problems are compounded by the fact that patients and caregivers often have different perspectives on what information should be disclosed about adverse events. As a result, clinicians may fail to meet the expectations of patients and families following an adverse event,[5] causing misunderstanding and a breach of trust during this critical time.

Effective communication between caregivers and patients at the time of an incident is crucial for patient welfare and for maintaining the trust and confidence in the institution and the providers.[26] Effective communication skills can be learned and specific competencies that ensure a successful dialogue can be identified.[27]

Reasoning and Evidence
A provider's ability to communicate effectively with patients and families in a compassionate and thoughtful manner, especially when disclosing information about an incident, is a crucial part of the therapeutic relationship. If it is done well, it can mitigate anxiety and enhance the patient's and family's trust in the caregiver, the institution, and the health care system. If it is poorly done, the patient may experience additional suffering, the

bonds of trust may be ruptured, and the chances of filing a malpractice suit are increased.

A caregiver cannot optimally support the patient and family during a health crisis unless he or she is prepared to discuss all aspects of the patient's care, including incidents.

Caregivers vary tremendously in their effectiveness in communication and discussing unpleasant topics. These skills should be taught in medical and nursing school, but often they are not. However, they can be learned.

Institutions should provide their health care staff with the training and other resources needed to manage incidents. Education and training on a regular basis will both help ease providers' anxieties about communicating unpleasant information and improve the patient's experience following an adverse event.

For example, Kaiser Permanente has developed a communication-training curriculum, in collaboration with the Bayer Institute, for its network of physicians. Following a centralized "train the trainer" program that includes representatives from the provider network, the individual institutions offer the curriculum to their physicians within the context of the local hospital culture.

It is worth noting that in addition to providing the communication skills needed when a patient is harmed, this training also benefits the physician-patient interaction during routine care. When the communications recognize and incorporate both the concerns of the patient and the physician, relationships are developed that foster a collaborative approach to treatment plans. Then if a patient is harmed during their course of care, the relationship that has already been developed serves as a solid foundation upon which to maintain trust and compassion during this difficult time.

Training and Education

Develop programs in communication with patients and families for all levels.

Train doctors and nurses in dealing with their own feelings.

Educate board and senior staff in their responsibilities.

Provide training as part of orientation and annually for all caregivers.

Develop a broad array of interactive training methods.

Provide "just-in-time" training for caregivers.

Provide expert assistance for caregivers to call after a serious incident.

Establish a cadre of crisis communicators.

Recommendations

1. Hospitals need to have education and training programs for professionals in communicating with and managing patients and families when things go wrong. These should be specifically designed at appropriate levels for caregivers (doctors, nurses, pharmacists, etc.) and for senior administrators and board members.

2. Both for consistency and for economies of scale (in terms of costs and needed expertise) the development of these training programs should be carried out at a system-wide level. (At Harvard, the Risk Management Foundation could facilitate this effort.)

3. In addition to technical training in how to communicate with the patient and family, doctors and nurses also need training in how to deal with their own feelings when they are the proximal cause of a serious patient injury.

4. Doctors, nurses, and other clinicians, as well as department chairmen and managers, need to be trained in how to provide support to colleagues when they are the focal point of a serious incident.

5. Board and senior administrative staff need to be educated in their responsibilities, legal exposure, and the importance to patients of transparency and accountability.

6. Courses on general principles and practices to be followed should be required as part of orientation for all new nurses and doctors, including residents, and also be provided for all caregivers annually.

7. A broad array of training methods is indicated, including lectures, role-playing, interactive web-based tutorials, etc. Interactive computer programs should be developed for this purpose as part of continuing education.

8. Because busy clinicians are unlikely to attend courses annually or maintain their skills, "just-in-time" refresher modules should be developed for caregivers to be given when needed at the time of a crisis.

9. Physicians should know who to call when they have a serious incident and be able to count on receiving expert assistance immediately.

10. More extensive training should be provided to a cadre of crisis communicators who can ensure that all patients receive appropriate care and who can supervise and train others when the need arises.

[For more details, see Appendix D.]

Management of the Event

VII. ELEMENTS OF A HOSPITAL INCIDENT POLICY

Successful management of a serious incident requires an institutional framework supported by institutional culture and policy. Each hospital should have a written policy to guide staff about how to respond to serious incidents. The purposes of the policy are twofold:

- To set expectations and provide guidance for the staff in responsible, empathetic, and supportive care of the injured patient, care that restores and justifies their continuing trust.

- To improve patient safety by learning from errors and adverse events and changing systems to minimize the likelihood of recurrence.

To accomplish these aims, the policy must:

1. Communicate the organization's philosophy and commitment to open and honest communication of adverse events.

2. Provide for just-in-time consultation and guidance to clinical staff at the time of an adverse event.

3. Enable the education of caregivers in methods for responding and communicating about mishaps.

4. Ensure empathetic and honest communication of the event to the family, as well as later communication of system improvements to family and caregivers involved.

5. Provide a framework for analyzing and learning from the event, including redesigning systems when appropriate.

6. Emotionally, professionally, and legally support the staff who have been involved in events.

7. Ensure necessary documentation and reporting.

8. Address methods of communication with the public that demonstrate transparency and restore community confidence that systems are in place to minimize the likelihood of future accidents.

9. Address methods for decision making for institutional communication and reporting of events both within the hospital/healthcare setting and externally to any relevant regulatory bodies.

Elements of a Hospital Incident Policy

Communicate commitment to open and honest communication.

Provide just-in-time guidance to caregivers.

Educate caregivers in responding and communicating.

Ensure empathetic and honest communication of the event to the family.

Provide emotional support to staff.

Ensure necessary documentation and reporting.

Communicate openly with the public.

Develop methods for communication and reporting of events.

VIII. INITIAL RESPONSE TO THE EVENT

When an incident occurs, the clinician's first obligation is to protect the patient against further harm by providing the medical care required and mitigating any continuing injury.

After the patient's initial needs are met, clinicians should turn their attention to the details of the event and obtain all of the information needed to understand its causes. For this to occur reliably, institutions must develop and disseminate clear policies specifying exactly who is responsible for each of the following.

Recommendations

1. Take whatever action is needed to stabilize the patient, mitigate any injury, and prevent further harm.

2. Take urgent action if necessary to eliminate any obvious remaining threat to patient safety, such as an impaired provider, faulty equipment, an unsafe system of care, or a seriously deficient protocol.

3. Immediately secure implicated drugs, equipment, and records.

4. If the primary provider is impaired or suspended, immediately provide a substitute and inform the patient and family.

5. Brief all members of the care team as soon as possible, so all members are fully aware of the issues and all subsequent communications with the patient and family are consistent.

6. Decide immediately who will have primary responsibility for communicating with the patient and family about the event.

7. Determine the circumstances surrounding the adverse events and factors contributing to it as quickly as possible while memories of those involved are fresh. This information can be crucial to the immediate clinical treatment plan for the patient.

8. Report the event to the appropriate hospital officer.

Initial Response to the Event

Stabilize the patient, mitigate injury, prevent further harm.

Eliminate any remaining threat such as impaired provider or unsafe system or equipment.

Secure implicated drugs and equipment.

Provide a substitute if primary provider is suspended.

Brief the care team promptly to ensure consistent communication with the patient and family.

Decide who will have primary responsibility for communicating with the patient and family.

Investigate quickly while memories are fresh.

Report the event to the appropriate hospital officer.

IX. ANALYSIS OF THE EVENT

Health care providers and organizations should develop policies, procedures, methods, and expertise for the investigation and analysis of incidents. Analyses should be thorough, multi-disciplinary, and non-judgmental, and utilize current methods that reflect the science of patient safety and best clinical practice.

The objective of the analysis is to uncover the multiple factors that contributed to the event and, where possible, develop systems changes to make it less likely that the event will recur. For this reason, individuals or committees responsible for analysis should work closely with those empowered to effect systemic institutional change.

Mechanisms also need to be developed for implementing the systems changes and for assessing them objectively to determine if improvement has resulted.

Reasoning and Evidence

There are three reasons why serious incidents need to be investigated and analyzed:

First, to prevent, if possible, a recurrence in a future patient. A thorough investigation and analysis of all possible contributing factors is the first step in identifying and correcting those systems failures. Institutions that are committed to safety regard incidents as evidence that their systems have failed.

Second, patients harmed by adverse events have a right to know, to the extent it is possible, what the causes of the event were and what is being done to remedy them. Most patients are very concerned that actions be taken to prevent another patient from suffering from a similar event. While there may be a therapeutic value to receiving this information, the primary justification is the ethical obligation to fully inform the harmed individual.

Third, health care institutions also have an ethical obligation to future patients elsewhere, in other institutions, to identify hazards and disseminate information about possible corrective remedies. This should be a major purpose of state mandatory reporting systems. In order to for this to work, the information reported to accrediting agencies, certifying boards or public health authorities must be complete and accurate. (See Section XII for details)

In addition, hospitals have an internal obligation to thoroughly understand the event in order to be prepared for potential litigation.

Productive analyses and learning from an event require that the institution have well-established policies and procedures for investigating and analyzing events. Those who perform the analysis must be well trained and either empowered to effect systemic changes or work closely with those who are.

Recommendations

1. Because few institutions have the capacity to investigate every incident, they need to develop criteria for selection of events for formal root cause analysis. Priority should be given to events which are fatal, cause significant morbidity, represent a significant breach in practice, or for which investigation is requested by a clinical team member. Near misses with high injury risk or learning potential should also be analyzed.

2. The institution's risk management department should perform or direct the investigation of the incident in order to ensure confidentiality and peer-review protection of the process.

3. The institution's medical staff bylaws should provide peer-review protection for physicians and other health care providers participating in root cause analyses. To promote institutional learning, clinicians and administrators should also be encouraged to request or conduct root cause analysis whenever desired, observing the confidential/peer review process.

4. The root cause analysis process should be facilitated by a senior staff member who was not directly involved in the event and who can thus maintain objectivity and lead discussion in a non-punitive, supportive manner. Risk management staff, patient safety leaders, quality improvement leaders, and clinical leaders can all be trained to fill this role. The input of clinical and systems experts is also vital for an organization to thoroughly understand the circumstances of the event.

5. Participants should include physicians and other staff members involved in the event. Participation of all involved in the event should be encouraged in order to have input from as many perspectives as possible. Leadership, including managers, directors and those with departmental responsibility, should also participate in order to ensure follow through of corrective actions.

6. Patient safety is an evolving discipline, and the best analysis strategies and techniques will change over time. The organization should incorporate best available practices in its analysis of adverse events and design of interventions.

7. While patients and families do not typically participate in root cause analysis, they should be interviewed concerning the facts and circumstances of the events and be informed of the institution's commitment to keep them informed.

8. Serious incidents and the results of all root cause analyses should be reported to senior clinical and administrative leadership and the board of trustees as a critical step in the institutional learning loop.

9. Organizations need to establish processes to ensure that corrective actions developed as a result of the root cause analysis are implemented and that feedback is provided to stakeholders regarding the corrective actions. Because not all departments have good systems of accountability, it may be necessary to develop additional mechanisms to ensure that recommended systems changes receive a high priority, are tracked to ensure that the changes do, in fact, occur, and are assessed for effectiveness.

10. Systems changes made in response to analysis of adverse events may have unanticipated negative effects. Therefore, any major changes should include a plan to monitor both the effectiveness and possible undesirable effects of the changes.

11. Data from root cause analyses should be aggregated and tracked to identify patterns and trends and to prioritize improvement initiatives.

Analysis of the Event

Develop criteria for selecting events for formal root cause analysis.

Have the risk management department perform the investigation.

Provide peer-review protection for participants in root cause analysis.

Have a non-involved senior staff member facilitate root cause analysis.

Include all caregivers involved in the event.

Incorporate best practices in analyzing events and designing interventions.

Interview patients and families as input for root cause analysis.

Report results of root cause analysis to senior leadership and board.

Establish processes to ensure that corrective actions are implemented.

Monitor both the effectiveness and possible negative effects of changes.

Aggregate and track data from root cause analysis to prioritize improvements.

X. DOCUMENTATION

Following an incident, a complete, accurate and factual description of pertinent clinical information related to the event should be entered in the medical record by the appropriate caregiver. This should include actions taken to care for the patient and ongoing treatment plans.

All communications with the patient and family should also be documented, including location, date and time, participants, contents of the conversation, patient reaction, the level of understanding exhibited by the patient, and the next steps to be taken by the patient and any providers or the facility staff.

Reasoning and Evidence
Documentation is essential for the appropriate care of the patient, to facilitate learning from the event, and to provide an accurate record if legal or regulatory action ensues.

To prevent potentially confusing and contradictory communications following a serious adverse event, it is essential that all parties have access to accurate and complete information concerning the event, the patient's clinical course, and what has been communicated to the patient and family.

This documentation also serves as historical information for future reference in the event of litigation.

Documentation of the discussion of the incident with the patient and family need not be a cause for concern if it is completed in the context of the communication process with those who are involved. Proper documentation supports the best interests of both the patient and the health care providers and advances good patient care.

Recommendations: (From ASHRM, 2001)[10]
1. Clinical details concerning the event should be recorded by the most involved and knowledgeable member(s) of the health care team, and include:

- Objective details of the event, including date, time, and place

- The patient's condition immediately before the time of the event

- Medical intervention and patient response

- Notification of physician(s)

2. The person designated as the primary communicator should talk with the patient and family as soon as possible after the discussion. This individual may be the physician involved in the event or the attending in charge of the service involved. (See Section II B, page 10.)

3. The documentation should include the following:

- Time, date, and place of discussion.

- Names and relationships of those present at the discussion.

- The discussion of the event.

- Patient reaction and the level of understanding exhibited by the patient.

- That additional information has been shared with the patient and family or legal representative, if appropriate.

- Any offer to be of assistance and the response to it.

- Questions asked by the patient or family and responses to the questions.

- A notation that as further information becomes available, this information will be shared with patient, family, or legally authorized representative.

- Next steps to be taken by the patient and any providers or the facility staff.

- Any follow-up conversations.

4. Documentation should avoid derisive comments about other providers and entries that appear self-serving.

XI. REPORTING

Incidents should be reported promptly to supervisors, risk management, and other concerned parties to ensure appropriate treatment and communication with the patient and family and to facilitate institutional learning. Reporting is also necessary to comply with specific mandates established by various external regulatory agencies, such as the Department of Public Health (DPH), Board of Registration in Medicine (BRM), Food and Drug Administration, (FDA) or JCAHO.

Patients should be informed of reports made to regulatory agencies.

Providers and hospitals also have an obligation to notify their liability insurance carriers of certain types of incidents, especially if there is a potential for future malpractice claims or compensation.

Reasoning and Evidence
Reporting is the first step in learning from an incident. In a hospital committed to safety, reporting leads to a thorough investigation to uncover the systems failures underlying the event, with the goal of re-designing systems to reduce the likelihood of patient injury.

This approach is based on the recognition that adverse events and errors are symptoms of defective systems, not defects themselves. Reporting provides the entry point into investigation and analysis of systems defects, which, if skillfully done, can lead to substantial system improvements.

Although reporting to external regulatory agencies, such as the DPH, BRM, FDA, or JCAHO, is necessary for licensure and certification purposes, it is also essential if lessons learned from incidents are to be widely shared among other institutions. For instance, in Massachusetts, both the DPH and BRM regularly issue safety alerts and advisories derived from reported incidents to Massachusetts health care institutions. JCAHO communicates these lessons through its Sentinel Events Alerts. Regulators, such as the FDA, also require reporting

as part of their oversight function to identify particularly hazardous situations needing urgent corrective action.

Recommendations
1. Hospitals need to have internal reporting systems that:

- Identify the individuals or departments who should be notified of an incident.

- Specify how the incident should be reported.

- Define who is responsible for reporting.

- Define the process for what happens after the incident is reported.

2. The system should be responsive, i.e., those who report perceive that the report leads to investigation and corrective action where possible.

3. The system must also be viewed as safe, without risk of censure or discipline to the person who reports the incident.

4. Hospitals must also have procedures in place to report those incidents that meet reporting requirements to the various regulatory agencies, as well as to address the hospital's fiduciary obligation to its insurers.

5. Because some incidents attract media attention, hospital public relations departments should be promptly informed of serious events so requests for information can be handled appropriately.

The reporting system should:

Identify who is to be notified

Specify how incident is reported

Define who must report

Define process for responding to the incident

Reporting should lead to investigation and corrective action

Reporting must be safe

Have procedures to ensure required reporting to regulators

Inform public relations department

Appendix A

THE WORDS FOR COMMUNICATING WITH THE PATIENT

Even after reviewing the guidelines above on disclosing adverse events to patients, you may find it helpful to consider some model language. In the case of a medication error, one might say this:

> Let me tell you what happened. We gave you a chemotherapeutic agent, carboplatin, instead of the pamidronate you were supposed to receive.
>
> I want to discuss with you what this means for your health, but first I'd like to apologize.
>
> I'm sorry. This shouldn't have happened. Right now, I don't know exactly how this happened, but I promise you that we're going to find out what happened and do everything we can to make sure that it doesn't happen again. I will share with you what we find as soon as I know, but it may take some time to get to the bottom of it all.
>
> Once again, let me say how sorry I am that this happened.
>
> Now, what does this mean for your health? You received only a fraction of the usual dose of carboplatin, so it is unlikely you will have any adverse effects from the infusion. However, I would like to monitor you closely over the next weeks. In patients who receive a full dose, the side effects we expect include….We usually monitor patients for these side effects by….We treat these side effects by….I want to see you in my clinic tomorrow so we can….

Appendix B

A CASE STUDY IN COMMUNICATING WITH THE PATIENT AND FAMILY

Dr. Smith was a 42-year-old patient who became concerned while vacationing about a possible recurrence of her breast cancer. As a result, she returned early from vacation to be evaluated at Dana Farber Cancer Institute. Diagnostic testing confirmed the recurrence and revealed metastases to her liver. Dr. Smith was anxious to begin treatment and elected to participate in a clinical trial. She was the first patient enrolled in this trial and received her initial dose of chemotherapy without event. Three weeks later, at her second visit for chemotherapy, she suggested to her oncologist that things were a little worse. That same evening, Dr. Smith's oncologist received a phone call from the investigational pharmacist reporting that at the initial visit, the patient had received the diluent without the active chemotherapeutic agent.

The oncologist recognized the need to disclose this error to his patient and elected to go to her home since he resided in a nearby community. He felt that by doing so, his patient would not have to make an unnecessary visit to the clinic. He disclosed the error and apologized. He noted that there were no data to suggest a long-term negative impact. Dr. Smith and her husband requested that the process for administering this investigational agent be changed to minimize the risk of this from ever happening again to another patient. In addition, they requested some type of compensation. From the beginning, Dr. Smith and her husband made it very clear that

they were not litigious people by nature or by their experience in medicine and chose not to involve an attorney nor seek any publicity.

In response to this event, senior medical and nursing leadership met with Dr. Smith and her husband to discuss further their concern about the error and request for compensation.

Because of the request for compensation, an internal team meeting with broader institutional representation was held to review the case. In attendance were the patient's oncologist, a claims representative from the liability insurer, legal counsel, risk management, senior leadership from medicine, nursing, and administration, and the hospital ethicist. The team was somewhat surprised that the patient had requested compensation beyond payment for out-of-pocket expenses associated with additional visits. The team tried to guess what the patient was looking for and concluded that the patient should simply be asked. It was determined that senior leadership from nursing, medicine, and administration should meet with the patient and her husband. The patient's oncologist believed he shouldn't be present so that the patient would have an opportunity to express any concerns without reservation; moreover, he did not want this event to affect his ongoing therapeutic relationship with the patient and family.

The meeting was held with Dr. Smith and her husband, and there was a full and frank discussion concerning the investigation into the event, potential factors that contributed to the error, and plans for error reduction. In addition, the patient and husband

were asked why they were requesting monetary compensation. They explained that they felt this would be an appropriate gesture on the part of the institution in recognizing both the error and the emotional impact on the patient and family. The sum requested was modest and clearly a "token." The Institute offered compensation in exchange for a release of claims.

Dr. Smith and her husband agreed with this request. Dr. Smith was clear that she was comfortable with her physician and the institution. She desired to continue her care with the same team and subsequently did so. The meeting was considered positive both by the patient and husband and by the institution staff, as the settlement reached brought closure to this event.

Appendix C

ELEMENTS OF CAREGIVER SUPPORT

1. Emotional Support

Adverse medical events are a time of charged emotions and frenetic activity involving a variety of clinical services. A clearly defined process is required to assess, activate and to oversee an effective support response for clinicians in these situations. Since adverse events occur in a variety of circumstances and settings, a flexible response is necessary to provide the most appropriate emotional support. This can be accomplished if a qualified group of individuals are trained and available as first responders to triage the adverse event at hand and to coordinate the appropriate support services. First responders should be experienced in crisis counseling and should be available 24 hours a day, seven days a week (24/7).

The timing and duration of emotional support services should be customized to the individual needs of those clinicians involved in the adverse event. This includes immediate and short-term support that can be provided on-site and within the institution by services such as Employee Assistance Programs (EAP), Risk Management, or Psychiatry. Long-term support may include hospital affiliated or independent services off-site such as those offered by private counselors or by organizations such as Medically Induced Trauma Support Services (MITSS). It would be beneficial for short and long-term support services to be linked such that caregivers have seamless access to services throughout the continuum as appropriate.

It is important that caregivers affected by an adverse event are comfortable with the forms of support being made available to them if they are actually going to take advantage of these services. Educating caregivers in advance about available support services and the response mechanism to adverse events is a critical component to achieving this. The need for emotional support varies by individual and it is important that caregivers remain connected to the support services offered so that intervention is available when the caregivers are ready and in need of assistance. It may be helpful to have designated departmental advocates for respective caregivers to initiate and maintain links to the support interventions. It is also important to offer individual counseling as well as group sessions depending on the needs and comfort levels of the caregivers.

The emotional impact that an adverse event can have on a caregiver can affect their ability to function safely in a clinical environment. Emotional support services are intended to minimize the detrimental sequelae to caregivers and to facilitate a timely and healthy return to normal activity. In addition to emotional support services, institutions should consider developing policies that allow an affected caregiver to utilize benefit time, leave of absence or to engage in alternative clinical responsibilities until they are comfortable resuming their regular duties.

2. "Post-Event" Management Support

A support response to adverse medical events should also include services that facilitate the affected caregiver's ability to engage effectively in the evaluation of the adverse event. Capturing the factual details surrounding the event is critical in having consistent communication with the patient and family and in establishing a relationship of trust. It is also critical in maximizing the collaborative learning from an event to prevent its recurrence. As with emotional support services, it is important to have an organized process in place that can be activated 24/7. Debriefing the caregivers involved should be initiated within a short period (24-48 hours) of the event and should be conducted individually or in a group session, depending on the circumstances of the event and the comfort level of the caregivers.

Accurate documentation of the event is important both to facilitate transparent communication with the patient and family as well as to serve as a solid foundation for patient safety improvement initiatives that follow an event. Education and resources should be available for caregivers before an event occurs, and direct support may be helpful when an event occurs. Documentation should occur as soon as possible following an event while chronology and details remain clear to the caregivers involved.

The initial communication with the patient and family is a critical period in establishing or maintaining a relationship of trust and transparency. It is always an awkward, emotional and uncomfortable interaction for everyone involved in an adverse event. If caregivers are not trained or coached in how to manage these situations, a caregiver's best intentions can lead to misunderstanding and a rapid deterioration in open communication. Caregivers should receive training in advance in the requisite skills for effective communication following adverse events, and coaching and support should be available to the caregivers by trained counselors following adverse events to facilitate the communication process. It is critical that communication occur in a safe, private and comfortable environment for the patient, family and caregivers.

The event evaluation process is a stressful period for caregivers. There are a number of processes that are activated following an adverse event and caregivers are often uninformed about their roles and responsibilities as the evaluation progresses. Pre-event education and resources should be available to provide process overview and following an event it may be very helpful to have an advocate for the caregivers involved to guide and to support them during the evaluation process.

Appendix D

TRAINING FOR COMMUNICATION

Basic Steps for Medical Dialogue[28]

- Preparing

- Initiating conversation

- Actively listening

- Acknowledging what you have heard

- Responding

Communication Using a Skills-Based Model[26]

- Preparation
  Review the facts
  Identify and involve the appropriate participants
  Use an appropriate setting

- Verbal initiation of the conversation
  Determine patient and family readiness to
   participate
  Assess the patient and family's medical literacy
   and ability to understand
  Determine the patient and family's level of
   medical understanding in general

- Presenting the facts
  Simple description of what happened
  What is known of the outcome at that point
  Describe the next steps
  Sincerely acknowledge the patient and family's
   suffering

- Concluding the conversation
  Summarize
  Repeat key questions raised
  Establish the follow-up

- Documentation
  Describe the event
  Describe the discussion

Other Communication Considerations

- No medical jargon

- Cultural/language barriers

- Speak slowly

- Be aware of body language

- Don't overwhelm with information—don't
  oversimplify either

- Allow ample time for questions—don't
  monopolize the conversation

Appendix E

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