Partners HealthCare Policies

Responding to Adverse Events:

Part I. Communicating to Patients
Part II. Supporting Staff
Part III. Investigating and Reporting

This document was derived from policies and practices from the following institutions:
Partners HealthCare Hospital policies
Dana Farber Cancer Institute
Children's Hospital and Clinics, Minnesota
COPIC, Colorado
Catholic Healthcare West
Lexington Kentucky Veterans Administration Hospital
Consensus Statement: When Things Go Wrong: Responding to Adverse Events

This generic policy is currently for discussion purposes only.
Spring.2006
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Purpose

This policy focuses on the three main components of Adverse Events and other Medical Errors.

1. Communication to Patients, with emotional support to patients and families who experience Adverse Events.
2. Support of Clinicians and all Staff who are involved in Adverse Events.
3. Investigation and Reporting of Adverse Events.

Adverse Events are purposefully broadly defined in this policy to encompass serious close calls to sentinel events, and other incidents, errors, or accidents because the desired perspective regarding harm is that of the patient. This document outlines the administrative components of a comprehensive institutional policy, and supports an organizational culture that values transparency, safety, new knowledge, unfettered reporting, structured analytics, and information dissemination.

Part I. Communication to Patients

POLICY: This policy applies to the communication, by caregivers to patients, of Adverse Events. The policy applies to events that are immediately apparent as well as to those that become evident only after a period of time. The policy applies to all Adverse Events that are purposefully broadly defined to encompass the spectrum of events from those that cause actual harm to those with only the potential for harm.

When an act or substance reaches a patient resulting in harm, patients and family members, or designated representatives ***must*** be fully informed.

When a significant Adverse Events do not result in harm, consideration should be given to discussing these with patients, taking into account the circumstances of the event and the patient.

Adverse Events that are intercepted prior to reaching the patient may also be appropriate for communication to patients if, on balance, there would accrue from the discussion a perceived benefit to the patient.

1. Get advice and designate a primary communicator

Involved senior clinicians and administrators should designate a primary communicator and that individual should talk with the patient and family as soon as possible.

The initial communication should be by or at least in the presence of a caregiver with a prior relation of trust with the patient. In most cases, the clinician with overall responsibility for the patient's care, i.e., the attending physician or nurse manager should handle the decision to disclose, as well as the actual disclosure of information and any subsequent discussions with the patient and/or family. However it may be appropriate to delegate this responsibility to another clinician involved in the event, such as the attending in charge of the involved service, or a senior administrator. Factors in this decision would include that another healthcare professional has the most information about the event, or has an existing relationship with the patient and family. The Chief Medical or Nursing Officer should be consulted when there is any uncertainty with regard to the need to disclose an event to a patient and/or family, and also informed when a decision is made to disclose an Adverse Event.

Close Calls (Appendix A – Definitions) 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. The clinician is encouraged to discuss the event with a colleague. Other resources available to the clinician include the Ethics Service, Administrator-On-Call, Chief Nursing Officer and Chief Medical Officer. In addition, the Department of Psychiatry and Employee Assistance Program are also available for debriefing and processing of the event.

2. Ascertain who else should participate

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 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.

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. In these situations another hospital staff member (either clinical or administrative) should be present at the initial disclosure discussion or at subsequent planned discussions with the patient and/or family. Including someone identified as a "Risk Manager" in these first discussions can set the wrong tone.

3. Ensure primary communicator is capable

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 it is anticipated that the appropriate staff may have difficulty or are apprehensive about communicating with patients and families, someone with experience and competence in this area should accompany or coach them ahead of time. The Chief Medical or Nursing Officer (or Risk Management Department or Partners attorney on call through the hospital paging system if after regular business hours) is available as a resource if the clinician has questions about appropriateness of discussion, timing of discussion, involved parties, consideration of financial reimbursement, etc.

4. Communicate ASAP and always within 24 hours of event or discovery

The occurrence of an Adverse Event should be communicated to the patient immediately when feasible or as soon as possible once appropriate supports are available for caregivers, patients and their families, and certainly within a maximum of 24 hours after the event is discovered. 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. Patient confidentiality should always be considered prior to discussions with family members. Disclosure should take place at the appropriate time, i.e., when the patient or their representative/proxy is able to understand the information and to ask questions. In situations where the patient has suffered permanent injury or death, information should be provided to the patient's family or legal representative in a timely and considerate manner.

5. Take responsibility

Whether or not the Adverse Event resulted from a specific act, the attending physician should make a statement of responsibility to the patient and/or family. 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 event more likely. However, he/she should not blame "the system" or use such terms as "systems problems" as an excuse to avoid responsibility. Identify who will manage ongoing care of the patient (including an offer to obtain a second opinion or the option of transferring care to another physician if the MD-patient relationship seems no longer viable.) Identify who will manage ongoing communication with the patient and/or family, including names and phone numbers of individuals to whom the patient and family may address questions, complaints or concerns, i.e., Patient/Family Relations Department, Care Coordination Department, Clinical Quality Assurance Department.

6. Apologize

When there has been an error - apologize. Explain the event, communicate remorse, and make a gesture of reconciliation ("*I'm sorry this happened.*"). 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 Adverse Event was caused 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.

Note: Patients often appreciate an expression of regret and empathy. Saying "I'm sorry" may help to strengthen, rather than undermine, the physician-patient relationship.

If the event was clearly not caused by an error (See Appendix A - Definitions), 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 (See Appendix A - Definitions).

7. Assure ongoing care

Amongst patients greatest fears are that they will not be told the truth and that an Adverse Event will fracture the provider-patient relationship and lead to abandonment. Assure the patient that regardless of past events the clinicians and hospital will be consistently available to them for care and support.

8. Tell the patient and family what happened

For unpreventable events (See Appendix A - Definitions), provide a full explanation about what happened, even when it seems very straightforward to the caregiver. Ensure that the patient and family understand that although unpreventable the injury is being taken seriously.

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 or to blame oneself or another 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 (See Appendix A - Definitions), 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.

Acknowledge that the Adverse Event has occurred and describe it in a truthful and compassionate manner. Tell *what* happened and *when*; leave details of *how* and *why* until the information is clearly known. Don't speculate.

Explain the nature of the event as it is understood at the time of the conversation (See Appendix A – Definitions). Describe the time, place and circumstances of the event. Explain the known, definite consequences of the event for the patient. Describe the corrective actions taken in response to the event, which may include ongoing communication with the patient/family as necessary.

9. Explain what will be done to prevent future events

It is often important to patients and families to know how harmful Adverse Events can be prevented from occurring to others in the future. Inform patients and families about any pending or ongoing investigations and planned corrective changes.

10. Pick an appropriate setting

The choice of the setting for communicating Adverse Events is important. 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 in ambulatory settings. 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.

11. Follow up communications

One or more subsequent discussions are always indicated following a serious Adverse Event or other Medical Error.

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.

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

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.

12. Follow-up care of the patient and family

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.

For serious events, a series of follow-up encounters with the patient (or family) should be planned, including a 6 month follow-up after resolution of major issues, 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, and organized through the Office of the Chief Medical Officer, or designee per that office.

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.

Needed psychological and social support should be provided.

13. Exceptions to communication of adverse events and other medical errors

In extremely rare situations where it can clearly be demonstrated that the interests of the patient may be harmed by discussion of an Adverse Event, the information may be withheld until the benefits of communicating are greater than the harms. An ethics consultation should be required in such circumstances. The Chief Medical Officer should also be consulted, and at his/her discretion, may designate Risk Management or other groups to assist in this determination. Any exception to disclosure must be specifically justified and documented in the Medical record. Justification and documentation should be recorded in a way that patients and patients' families can understand

Part II. Guidelines for Support of Involved Staff and Relief from Work Assignments

POLICY: Caregivers are the backbone of all health care delivery. When in the course of delivering care patients are harmed, the extraordinary empathy and sense of responsibility that defines caregivers also increases the likelihood that the emotional toll of these events may render the caregiver less capable of carrying on their immediate responsibilities. Support of staff includes the acknowledgement that this type of trauma may occur, the assessment of trauma, and ensuring that appropriate support is available.

1. Assess the Impact of the event on the involved clinicians

The unit manager or nursing supervisor, in consultation with the Hospital officials managing the response to the event, will assess the event and the impact on the individuals involved regarding the advisability of relief from current or immediate future work assignment. Events involving deaths or significant morbidity, physical violence, or threat of extreme physical harm should always be assessed regarding immediate relief from work assignment. Other events should also be assessed as deemed appropriate by hospital officials, unit manager or nursing supervisor or the directly involved team members. This assessment should be based first on the needs and expressed preference of the individual directly involved team member, and should reflect the broad individual differences in coping style in response to traumatic events.

2. Assume relief is appropriate after serious events

To protect the directly involved team members, the manager and risk management team should begin with the presumption that relief from current work assignment should occur for any serious traumatic event, although that presumption can be overcome based on the individual's preference to remain on assignment. If a directly involved team member expresses a preference to remain on assignment and officials feel that individual endangers him/herself or others by continuing to work, input from a second responsible individual (such as unit manager, Administrator On-call, Nursing Supervisor) should be obtained. If the second responsible individual is in agreement, the directly involved team

member can be required to leave the work assignment. A directly involved individual can request relief from current and immediate future assignments.

3. Identify appropriate supports for clinicians

If relief from assignment is made, consideration should also be given to any immediate support or mental health needs that should be provided by EAP, regional crisis center or referral for mental health services through the individual's health insurance coverage.

If relief from assignment is chosen, the hospital officials and unit supervisor must make appropriate arrangements for continuity of patient care, and all staff members including those directly involved must assure safe and adequate staffing before relief from assignment begins.

Relief from assignment is considered paid administrative leave when approved or requested in the above manner.

Part III. Investigation and Reporting Policy

Adverse Events ***must*** be investigated. Consideration of the extent of harm, severity and likelihood of recurrence will determine the extent and degree of the investigation. Minor Adverse Events may be evaluated in aggregate. This policy is superimposed on, and in addition to, other regulatory requirements.

The policy applies to events that are immediately apparent as well as to those that become evident only after a period of time. The policy applies to the entire spectrum of such events from those that cause actual harm to those with only the potential for harm.

Essentials

- Initial efforts should stabilize the patient, mitigate any injury and prevent further harm.
- 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.
- Immediately secure implicated drugs, equipment. Secure or copy records.
- Document all actions in the medical record.
- If the primary provider is impaired or unavailable, immediately provide a substitute and inform the patient and family of the substitution.
- Report the event to the Risk Manager and appropriate Patient Safety Officer. The office of the Chief Medical Officer maintains oversight of internal reporting, is available to assist, and should be informed of serious or difficult cases.
- Ensure all members of the care team are fully aware of the issues so that subsequent communications with the patient and family are consistent.
- Establish who will have primary responsibility for communicating with the patient and family about the event. As soon as possible the patient and family should learn of the event and the facts as initially known.
- Provide access to emotional and psychological support for the patient and family.
- Determine the circumstances surrounding the event and the contributing factors as quickly as possible while memories of those involved are fresh.
- As soon as practical, if the event is determined to be serious or to have significant learning potential, a root cause analysis should be conducted and to the extent possible, should include involved staff and, when feasible, patients.
- In follow-up meetings with patient and family, appropriate staff should communicate the results of the analysis and corrective action plans.

1. Ensure patient safety

The employee(s), professional staff, and manager(s) involved in an Adverse Event should take immediate action to ensure the safety of the patient, staff and others in the

environment. The Chief Medical Officer, or his/her designee, participating with staff, should determine if any immediate procedural or other change in delivery of care is necessary and determine whether and how to communicate such information.

2. Preserve evidence

If concerns arise that equipment and supplies, including but not limited to, unused medications, sheets, towels, syringes, samples from the lab, unused blood products, and equipment might be involved or implicated in the Adverse Event, then they should be sequestered by the institution (NOT supplier or manufacturer) after the event. Questions about this should be addressed to Clinical Managers or the Risk Management Department. These items are required to accurately understand how an event occurred. Medical device malfunctions should be identified and the devices tagged. Equipment is not to be returned into service until it has been determined to be safe by review by appropriately qualified staff.

3. Report the event internally

Employees, professional staff members, all patient caregivers, trainees, managers and volunteers are all individually responsible to report Adverse Events to the Office of Quality and Patient Safety, or Risk Management Office or equivalent, and to comply with, and assist the hospital, in meeting all external reporting requirements to regulatory bodies and insurers (see Appendix E). The Office of the Chief Medical Officer maintains oversight of reports and the reporting process and is available when assistance is needed.

All Adverse Events must be internally reported. A Safety Report should be completed and submitted as soon as possible after the event by the staff member who observes, discovers, or is directly involved. The safety report is considered a working document of the Hospital's peer review committees, and is protected as a confidential document. Safety reports are not part of the patient medical record and so should not be copied or distributed unless authorized by the Risk Management Department.

Staff members who appropriately report an Adverse Event are not subject to retaliation for reporting. This does not remove the hospital's responsibility to take appropriate action to protect patients, or to take steps to appropriately address the performance of staff members who are impaired or practicing in a reckless or negligent manner.

4. Document the adverse events in the medical record

(From ASHRM, 2001)

1. Clinical details concerning the event should be recorded in the medical record by the most involved and knowledgeable member(s) of the health care team with first-hand knowledge of the situation, and include:
    - Objective details of the event, including date, time, and place
    - The patient's condition immediately before the time of the event
    - Clinical intervention and patient response
    - Notification of physician(s) and patient/family

2. The documentation should include the following:
    - Time, date, and place of discussion and signature of author.
    - 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 and family.
    - 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.

3. Document follow-up conversations in the medical record or an Event file, as appropriate.

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

5: Identification, investigation, and communication of adverse events

i. Determination of Adverse Events Status

This section applies to the identification, investigation and communication of Adverse Events and is superimposed on other policies pertaining to regulatory requirements about Sentinel Events (as defined by the JCAHO "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." See Appendix E – Regulatory Reporting).

ii. Notification of Hospital Officials Regarding Sentinel Events

The Chief Medical and Nursing Officers in coordination with the Risk Management Department are responsible to assure the prompt notification about Adverse Events to appropriate executive staff within the organization. The Chief Executive Officer or their designee (per individual hospital bylaws) is responsible to communicate to the Board of Directors all Adverse Events in aggregate, and, when deemed appropriate, individual Adverse Events. This communication should be regarded as privileged. In addition and when appropriate:

- The Pharmacy and Therapeutics Committee Chair and the Director of Pharmacy are notified of events involving medication use.
- The administrator of the Institutional Review Board (IRB) is notified if a patient enrolled in an investigational study is involved. The IRB chair is, however, only notified of the study name, the IRB study number (if known) and/or the research investigator. Per standard IRB policies and procedures and Federal regulations, it is the responsibility of the research investigator to promptly notify the IRB in writing, providing a complete description of the event and other information as requested by the IRB
- The News and Public Affairs Office (or equivalent) is notified of major Adverse Events to facilitate any external communications including contact with the media or requests for public information. The communications staff provides consultation regarding communication with the family and staff regarding the event and assists in internal communication of appropriate information in keeping with patient and peer review confidentiality requirements.

iii. Formation of an Analysis Team

The Chief Medical and Nursing Officers, in coordination with their Risk, Quality and Safety Staff, are responsible to determine when a focused review will occur, and the team that will be responsible for event review, analysis, and follow-up. While the creation of a review team is mandatory when Sentinel Events occur (Appendix E – Regulatory Reporting), a team may also be commissioned to analyze other events when a systematic review of processes is felt to be beneficial or warranted.

iv. Responsibilities of the Analysis Team Following Adverse Events

1. Perform formal root cause analysis for events that are fatal, cause serious morbidity, represent a serious breach in practice, or for which investigation is requested by a clinical team member. Other events with high injury risk or significant learning potential should be analyzed in a similar manner.

2. The Chief Medical Officer, in coordination with Risk Management and Quality/Safety Departments, should jointly perform or direct the investigation of the incident in order to ensure confidentiality and peer-review protection of the process while ensuring an integrated perspective.

3. 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. (i.e., Chief Medical Officer, Chief Nursing Officer, Risk Management staff, patient safety leaders, quality improvement leaders, and clinical leaders). Input of clinical and systems experts should be obtained as needed.

4. Ideally participation will include all involved in the event. Leadership, including managers, directors and those with departmental responsibility, should also participate in order to ensure follow through of corrective actions.

5. Patients and families should be interviewed concerning the facts and circumstances of the events and be informed of the institution's commitment to keep them informed.

6. The results of all root cause analyses should be reported to senior clinical and administrative leadership and the representatives of the board of trustees.

Corrective actions developed as a result of the root cause analysis are a high priority, and should be tracked to ensure that the changes occur. Corrective actions should include a plan to monitor both the effectiveness and possible undesirable effects of the changes. Results should be fed back to the board in a timely way.

v. Timeline for Adverse Event Analysis

The analysis of an Adverse Event should be initiated as soon after the events as possible, and ideally within the first 48 hours of notification or discovery of the accident/event and the initial fact finding commenced. The causal analysis is completed as soon as possible to preserve an accurate account of events, discover the multiple factors contributing to the event and decreasing system vulnerabilities for other patients. Generally, the initial summary report to the Professional Executive Council, Patient Safety Steering Committee, and representatives of the Board of Directors, Quality Committee (or equivalents) is completed within 30 days, but not later than 45 days.

Appendices

Appendix A. Definitions

DEFINITIONS**:** The American Society of Healthcare Risk Management (ASHRM)[4] definitions are primarily used in this policy:

***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 close calls. (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.

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

Preventable adverse event (PAE): 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:

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

PAE 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

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

Unpreventable adverse event (UAE): 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:

UAE 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

UAE 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*.

Appendix B. Medical Response Algorithm

(Thanks to Childrens Hospital Minnesota for this algorithm)
This algorithm is a basic guide to what level of response is appropriate to Adverse Events.
Judgment is always needed, and some basic principles that guide your response are:

- **All** Adverse Events should receive a written, telephone or on-line Patient Safety Report
- **Any** event which reaches the patient or a close call that affects patient care should be disclosed.

If unsure of what level of response is appropriate, call Risk Management.

Type of Event	**Immediate action to protect patient**	**Disclosure to family**	**Safety report**	**Call Risk Management**	***Notify Dept Mgr***
Events without potential for serious or immediate harm • Hazardous situation • "Accident waiting to happen" • Improvement idea or safety lesson learned • "Close Call" without harm, serious potential for harm, alteration in care plan or apparent to family	IF NECESSARY	NOT REQUIRED	YES	NOT REQUIRED If any doubt call Risk Mgt for advice	YES, NEXT WORKING DAY
• "Close Call" with minor potential for harm, was apparent to family, or altered treatment plan	YES	YES	YES	NOT REQUIRED If any doubt call Risk Mgt for advice	YES, NEXT WORKING DAY
• Accident with minor and temporary harm • "Close Call" with potential for harm that is more than minor or unknown • Repeated accident, even if minor • Failure of anticipated safety defenses (e.g. technology failure, no procedure) • Final caregiver or parent discovers or prevents accident with more than minor harm	YES	YES	YES	YES	YES, NEXT WORKING DAY
• Sentinel Event (including but not limited to unanticipated death, suicide, infant abduction, rape, hemolytic transfusion reaction, surgery on wrong patient or body part) • Other significant medical accident with major or permanent harm	YES	YES	YES	YES	YES, IMMEDIATELY

Appendix C. First Hour Checklist

(Thanks to Childrens Hospital Minnesota for this algorithm)

Adverse Events and Disclosure 1st Hour Checklist

(Nurse Manager/Nursing Supervisor responsible for overseeing checklist completion)

Patient's label **Date of event:** _____

Time Begun	Task	Initials/Time Completed
_____	❑ **Assure patient stabilization**	_____ _____
_____	❑ **Equipment/Medications Collection** (Do not change settings, contents, or clean) ❑ Equipment/Machines θ Syringes ❑ IV bags/Tubing θ Medication Containers/Vials ❑ Samples from lab	_____ _____
_____	❑ **Notifications** ❑ Nursing Supervisor/Clinical Manager ❑ Managing MD _____ Phone: _____ ❑ Attending MD _____ Phone: _____ ❑ Risk Management ❑ Administrator On Call	_____ _____
_____	❑ **Disclose to & support of family** (attending MD or designee – see **Guidelines**) ❑ Social Work for mental health crisis ❑ Chaplaincy for spiritual support ❑ Referral for ongoing mental health support	_____ _____
_____	❑ **Support staff & offer relief** from work assigned	_____ _____
_____	❑ **Documentation and Information Collection** ❑ Initiate Patient Safety Report ❑ Medical Record Note ❑ List of Involved Persons	_____ _____
_____	❑ **Immediate communication** with staff on unit	_____ _____
_____	❑ **Signatures** of staff involved with completing checklist _____ _____ _____	_____ _____

Appendix D. Regulatory Reporting

Any physician, staff member or employee who becomes aware that any of the following events has occurred shall report the event immediately to the Office of Quality and Patient Safety, or Risk Management Office or equivalent, or the Administrator-on-Call if after regular business hours. The Chief Medical Officer maintains oversight of reporting and the reporting process, is available to assist and should be informed of serious events or difficult cases.

1) Massachusetts Department of Public Health (DPH) requires licensed facilities to report certain events immediately. Most events are not related to quality of care (a through d below) and occur infrequently. During regular business hours, the Risk Management Department reports these events by telephone, with a written report sent to the DPH within one week. After hours and on weekends the Administrator-on-Call (AOC) will confirm reportability with appropriate senior hospital leadership prior to calling the event to the DPH at 617-727-5860. The AOC will also contact Public Affairs at 617-534-1600 or via the page operator to notify them before reporting the event.

    a. fire
    b. suicide
    c. serious criminal acts
    d. pending or actual strike by employees

    A fifth type of event, relating to quality of care will be reported during regular business hours only after a case review has been performed.

    e. serious physical injury to a patient from an accident or unknown cause, or an injury that is life-threatening, results in death, or requires the patient to undergo significant diagnostic or treatment measures.

In addition to the events described above, the DPH also requires licensed facilities to report maternal deaths, defined as "*the death of a pregnant woman during any stage of gestation, labor or delivery, or the death of a woman within 90 days of delivery or pregnancy termination".*

Maternal deaths are reported initially through Patient Admitting Services, upon their receipt of a "Report of Death" form indicating maternal death.

2) Board of Registration in Medicine (BRM) requires quarterly reporting of:

- Specified outcomes without regard to underlying circumstance:
    1) maternal deaths related to delivery;
    2) deaths related to elective ambulatory procedures;
    3) any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part.

All deaths or major or permanent impairments of bodily functions that are not ordinarily expected as a result of the patient's condition on presentation.

3) Food and Drug Administration (FDA)

Under the Safe Medical Devices Act of 1990, the FDA mandates reporting of any serious patient injury or death that is caused by a medical device within 10 days of discovery of the event.

4) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

JCAHO defines a "sentinel event" as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The subset of events subject to review through root cause analysis includes, but is not limited to:

- Unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition;
- Death or major permanent loss of function associated with a medical error;
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock setting or within 72 hours of discharge;
- Infant abduction or discharge to the wrong family;
- Abduction of any patient receiving care, treatment and services;
- Rape;
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;
- Surgery on the wrong patient or wrong body part;
- Any perinatal death unrelated to a congenital condition in an infant weighing greater than 2500 grams;
- Death resulting from nosocomial infection;
- Unintended retention of a foreign object in a patient after surgery or other procedure.

The JCAHO does not mandate the reporting of sentinel events, but rather encourages voluntary reporting of the event. As required by JCAHO, a thorough and credible root cause analysis and action plan will be facilitated by the Risk Management Department within 45 days of the event. Failure to complete a root cause analysis can result in an organization being placed on Accreditation Watch.

5) Other agencies, such as the Massachusetts Department of Mental Health (DMH), Department of Social Services (DSS), Office for Child Care Services (OCCS), Disabled Persons Protection Commission (DPPC), and Office of Elder Affairs (OEA), have specific reporting requirements for certain Adverse Events including the abuse of children, disabled persons, and elders.

Appendix E. Financial Issues

After an Adverse Event, patients and their families may require psychological, social, or in some cases, financial support.

This policy addresses the medical, psychological and social needs of patients and their families. Partners HealthCare acknowledges fully that 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, patients 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.

This policy does not address financial support because, while patients often also need financial support, how to provide it is less clear. Current systems for health care financing do not provide a simple and effective way to provide financial support – and this policy specifically does not address this issue. Partners HealthCare acknowledges that compensation mechanisms for patients subject to serious Adverse Events require further evaluation, research and regulation, and will continue to work with legal, regulatory and ethical groups to find mechanisms to adequately address the financial issues that arise after Adverse Events.