Policies & Procedures
Library: MGH1
Folder: Clinical Policy & Procedure Manual
Document: Adverse Events and Medical Error

1. POLICY

1.1 It is the policy of the Massachusetts General Hospital (MGH) and the Massachusetts General Physicians Organization (MGPO) to identify and respond promptly to unexpected adverse outcomes of medical care and to internally report and investigate all events inconsistent with optimum care of patients or routine operations of the Hospital, and to support open and thorough communication with patients and families.

1.2 This policy has four purposes:
- To improve the care of patients by systematic and structured review and study of these adverse events,
- To promote appropriate communication with patients and families about adverse events,
- To provide support for patients, families and staff who have been involved with, or affected by, adverse events, and
- To meet all regulatory requirements related to reporting adverse events to oversight agencies.

2. SCOPE

2.1 This policy applies to the Massachusetts General Hospital and the member practices of the Massachusetts General Physicians Organization.

2.2 This policy includes several components, including:
- Identification and reporting,
- Care and Support of the patient and family involved,
- Communication and Transparency,
- Support of involved and affected providers,
- Study, review, and analysis of reported events,
- External reporting.

2.3 Oversight of this policy is the joint responsibility of the Chief Medical Officer, the Chief Nursing Officer, and the Vice President for Compliance.

3. DEFINITIONS

3.1 An adverse event is one which is unexpected and results in harm or injury to a patient.

3.2 An internally reportable incident is any occurrence inconsistent with quality care or the routine operations of the hospital, including incidents where no harm has occurred. A report should be completed whenever there is an injury or potential injury to a patient, visitor, or staff member. An internally reportable incident expressly includes errors that are recognized as occurring in the course of care, even if they never reach or affect the patient or do not cause injury to the patient ("near misses" or "close calls").

4. IDENTIFICATION AND REPORTING

4.1 All adverse events and internally reportable incidents should be promptly reported. In general, the best and first line of communication of such events and incidents is to the reporter's immediate supervisor.

4.2 The reporter and/or his/her supervisor should report the event or incident to the Quality Assessment Program in any of the following ways:

- By the web-based safety reporting system (rL solutions),
- By direct communication with Quality assessment staff at any level, e.g. the QA Chair of the department involved,
- By direct contact with the Directors of the Office of Quality and Patient Safety.

4.3 Safety reports are confidential and peer review protected. Investigation of such reports shall be pursued and maintained in a confidential manner and shall be subject to all applicable legal protections, including peer review.

4.3.1 A safety report is not routinely shared with other providers, and the reporter's identity, and the content of the report should never be shared outside of formal QA activities of the institution.

4.3.2 Similarly, they do not serve as documentation for the medical record, and should not be referred to or mentioned in the medical record.

4.3.3 Safety reports should not attribute or speculate on specific blame or fault for two reasons:

- The specific elements contributing to the event or condition will later be identified on further evaluation, and
- Such attribution in an initial report may inadvertently be contrary to the main principles of this policy.

4.4 The reporting of any adverse event or incident shall not result in disciplinary action against the reporter unless it is clearly demonstrated that such reporting was fraudulent or otherwise made in bad faith.

5. CARE AND SUPPORT OF THE PATIENT AND FAMILY

5.1 The first concern when an adverse event is recognized is for the well-being of the patient and support of his/her family, and shall include the following:

- Provide immediate care and support to the patient, including stabilization, management of the clinical situation, mitigation of injury and prevention of further harm,
- Eliminate any further immediate hazards to further care, including personnel and equipment, and provide appropriate replacement when indicated,
- Secure and sequester any involved equipment or records,
- Document the event in the medical record,
- Report the event to supervisors and to the Quality Assessment system, (See reporting, above),
- Tell the patient and family what happened, to the extent that it is understood, with the recognition that this information is usually preliminary and may lack full understanding, and further inform them of the other steps in the process described in this policy,

- Assure the patient and family that further analyses of the event will occur (see # 8, below), and that the providers will participate fully in these evaluations, and assist in any appropriate further communications that are indicated. (See # 7, below).

6. COMMUNICATION AND TRANSPARENCY

6.1 Principles of communication with patients: Communication to patients begins with free and open communication between the primary providers and the patient, during which they will be encouraged to describe the clinical situation, as they know it, in a non-judgmental manner.

6.2 Events: Patients should be informed of events resulting in harm to a patient. Under some circumstances, adverse events or errors do not result in harm, but some communication with the patient may still be appropriate. Advice regarding these circumstances may be obtained from the Office of Quality and Patient Safety or from Senior Leadership.

6.3 Communication: In general, the first and preferred communication is between the provider and the patient. Advice about situations in which this may be less desirable may be obtained from the Office of Quality and Patient Safety, and/or the Chief Medical Officer, or the Chief Nursing Officer, or Risk Management. In those situations, consideration should be given to the following. Designating a primary communicator, considering issues of trust, responsibility for the patient, and capability, skills and experience.

- Evaluating whether others should participate, and identifying who would be most appropriate in the specific incident,
- Evaluating the appropriate circumstances for the communication, including, place, timing, with initial communication beginning within 24 hours of the event or discovery.

6.4 The communication should include several parts:

6.4.1 An assurance of ongoing care, and discussion of, or introduction of who would provide it,

6.4.2 A description of the event or reason for the adverse outcome, insofar as it is understood at the time of the discussion,

6.4.3 Any understanding as to the underlying reasons known for the event,

6.4.4 Possible means for prevention of similar events in the future,

6.4.5 There should be specific consideration for each event, of the appropriate role for any of:

- A statement of regret (nearly always), for significant events, and any causing injury,
- Of responsibility (and by whom, and on whose behalf), and
- Apology.

6.4.6 Description of the anticipated timing of further communications, and the mechanism, sources, and contacts for further communication should always be provided, to complete the communication either as more facts become available, or as the patient's course and understanding progresses, as well as further support for the patient and family.

7. SUPPORT OF INVOLVED PROVIDERS

7.1 Severe or unexpected injury to patients may have an adverse effect on the health and functionality of the providers involved. Therefore:

7.1.1 The impact on providers should be part of the initial assessment of the event and should be discussed with the person in charge of the evaluation.

7.1.2 There should be active communication between the leader of the analysis of the event and the supervisor(s) of all employees actively involved, including both staff members and any trainees. If trainees are involved, the director of the relevant training program should be informed.

7.1.3 For any significant event, the effect on the employees will be discussed both with the principal team leader of the evaluation and with senior leadership.

7.1.4 Employees involved can expect and request support, which is available from:

- The Employee Assistance Program (Ext # 6-6976),
- Occupational Health (6-2217),
- Their supervisors, Chiefs, or, directors of training programs, as applicable.

7.1.5 Support will be provided to all affected personnel through collaborative discussions between the individual's supervisor(s), training program director, and Human Resources. Relief from current and future work assignments should be evaluated, along with the provision of appropriate additional support.

8. STUDY AND ANALYSIS

8.1 The principal reason for further analysis is to identify means of preventing future adverse events or internally reportable incidents from occurring.

8.2 All adverse events or internally reportable incidents should be reported to the Office of Quality and Patient Safety. The extent and depth of the evaluation of each event, or type of event, should be evaluated under the direction of the Office of Quality and Patient Safety, which also will consider the appropriate distribution of the information and classification of events in order to allow further study of critical cases and accurate tracking of events.

8.3 All serious adverse events will immediately be brought to the attention of the appropriate levels of senior administration, which will assist in the immediate decisions concerning external reporting (see below), and advise on the evaluation and analysis.

8.4 When further study or evaluation of adverse events is indicated, the Office of Quality and Patient Safety, working with Departmental QA Chairs, will define the method of evaluation. The forms and formats of these reviews will be directed by the Office of Quality and Patient Safety, but in general will include:

- Notification of the appropriate quality leaders,
- Formation of an analysis team to direct and coordinate the evaluation and analysis,
- Development and oversight of the preparation of a report, including potential contributory causes and opportunities for improvement.

8.5 The methodology used for these analyses is evolving and should be directed by processes and/or personnel of the Office of Quality and Patient Safety.

8.6 The results of all formal analyses should be discussed with senior leadership of the Hospital, and may include direct discussion with the Board of Trustees.

8.7 These evaluations typically are intended to identify opportunities for improvement, not to attribute blame for the individual event. Therefore, the evaluation seeks, whenever applicable, systems improvements and not to attribute blame or apply discipline to individuals for errors that systems could have protected against.

8.7.1 Not all such opportunities can be accomplished in a time of limited resources. Therefore these recommendations should be forwarded to clinical leadership who are in a position to determine priorities for selection of initiatives that warrant further review or implementation.

8.7.2 While emphasis of the evaluation is on systems to improve and support safe care, individual responsibility remains important. Therefore, guiding principles must determine which events may require disciplinary intervention.

8.7.3 With respect to providers for whom a robust on-going measure of performance is available and routinely used, as approved by a responsible hospital body, any involvement in a reported quality incident will not be used for purposes of credentialing or disciplinary action, except in four circumstances:

- There is reason to believe a criminal act has occurred,
- There is reason to believe that the provider is impaired (see a more complete definition in the Policy of the MGH Physician Health Program),
- The provider is known to have recklessly or knowingly and willfully used unsafe practices,
- Review of aggregate or individual data has indicated an unacceptable number of adverse outcomes.

8.8 Any disciplinary action considered as the result of participation in an adverse event should be reviewed with the Office of Quality and Safety and the appropriate Human Resources advisor in order to assure equity and fairness, unless this event follows a sequence of performance issues for which appropriate consultation and advice has already been provided.

9. EXTERNAL REPORTING

9.1 It is the policy of the institution to comply with all external reporting requirements.

9.2 Understanding of the reporting requirements shall be the responsibility of the Vice President for Compliance and the Office of Quality and Safety, who will be responsible, with the advice of senior leadership and the Office of the General Counsel, for the decision to report individual cases outside the institution.

9.3 Decisions for reporting to the Board of Registration of Medicine are made by the Patient Care Assessment Committee.

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