DEVICE INCIDENT REPORTING and INVESTIGATION
at the
MASSACHUSETTS GENERAL HOSPITAL

Created: 1994
Revised: 2009, 2010

DEVICE INCIDENT REPORTING and INVESTIGATION
at the
MASSACHUSETTS GENERAL HOSPITAL

CONTENTS

1.0 Introduction

Whenever it is suspected that a device may be associated with a patient injury or has failed in a way that is likely to cause an injury, an investigation should be conducted to determine if a malfunction or misuse contributed to the event. Adherence to a protocol during the investigation will improve the possibility that accurate and sufficient information is gathered so that the causes can be identified and remedial actions suggested. Measures for compliance with the Safe Medical Devices Act considered. (Is this missing a word?)

2.0 Device Investigation Team (DIT)

The Center for Quality and Safety (CQS), in conjunction with Director of Biomedical Engineering (DDBE) and Biomedical Engineering Quality and Safety Manager (QSM) shall assemble a team of clinical and technical personnel to conduct investigations and determine reporting requirements.

3.0 Notification of Device Related Events

3.1 General Requirements

Any individual who discovers, witnesses, or otherwise becomes aware of information that reasonably suggests that a medical device has or may have caused or contributed to a death, serious illness or injury to a patient under treatment shall immediately notify his or her supervisor. The individual shall file a hospital safety report or have reasonable assurance that a report is filed by someone who has direct knowledge of the event. The supervisor receiving such information shall notify immediately the DDBE and Biomedical Engineering Quality and Safety Manager, the Center for Quality and Safety (CQS), the Hospital Risk Manager (HRM) or, if unavailable, an appropriate designate.

3.2 Immediate Actions Following Notification of Event

3.2.1 Upon being notified of an event, the DDBE or alternate shall determine, with the advice of at least one clinical member of the Device Investigation Team, if there is reasonable cause to suspect that the device may have been materially related to the patient's adverse outcome or otherwise warrants a detailed investigation. If the disposition of the event is unclear, the DDBE/QSM shall consult with the CQS. If further investigation is warranted, the DDBE or designate shall (not necessarily in this order):

3.2.1.1 Call the CQS or HRM.

3.2 1.2 Initiate actions to assure that information is gathered in preparation for an investigation.

3.2.1.3 Conduct all investigations on behalf of Safety Committee; report findings to the hospital Safety Committee. If relevant, notify the service QA chair of the involved department.

3.2.1.4 Obtain assurance that a safety report has been or will be filed.

3.2.1.5 Assure that someone has or will notify the attending physician.

3.2.1.6 Determine if immediate sequestration of the device is necessary and act to assure that it is done if so determined.

3.3 Action by the attending clinical personnel

The attending clinical personnel will document in the patient record the occurrence of any event that may have substantive impact on the patient's care and should note any actions taken in relationship to the event.

4.0 Investigation

4.1 Assignment of Investigator

The DDBE, in consultation with the CQS, will assign someone with appropriate skills and experience to lead the investigation. The investigator will help determine if the event is reportable to external agencies: an event that appears to warrant investigation because of possible need for SMDA reporting or because the event is of an otherwise serious nature. The investigator should not be someone who has possible conflicts of interest unless those conflicts are identified and deemed not to be of substantial importance.

4.2 Conducting the investigation

4.2.1 Collect Information Quickly: Information should be collected as quickly as is reasonable from individuals who directly observed the event or related circumstances.

4.2.2 Documentation

Document all pertinent information in handwritten or typed notes in any format. (See Section 5). Although note-taking may be sufficient, it may be replaced or augmented by video taping or audio recording. If video taping is not used, photographs should be taken to record the initial condition and stages of inspection and disassembly of the device. Mark all written notes and other documents created during the investigation with the phrase "Confidential Peer Review".

4.2.3 Interviews

Conduct interviews with focus on ensuring that observers report only what they observed. Open-ended questions are preferred; follow with specific questions to elicit more detail. Interviewers should obtain some training or experience with interviewing technique, including reviewing published recommendations. The interviewer takes notes, or uses a tape recording when practical and acceptable to the Interviewee.

4.2.4 Sequestration

Sequester any device involved in an event as soon as practical. Do not move device from site of event if that alters or disturbs conditions that could be useful in determining cause. This is especially true for large or permanently installed devices. In such cases, if practical, conduct investigation with the device in situ. Where possible, do not alter device settings. Do not unplug device if this would alter information material to determining cause. Label the device when removed and place in area where it will not be disturbed. A device may be released to a manufacturer for inspection and repair if on-site inspection determines cause or

documents information to a reasonable degree. When a device is released to the manufacturer, a receipt of acceptance should be obtained.

4.2.5 Precautions

Inspect devices involved in an event with attention to many precautions. Investigators should consult guidelines suggested by ECRI (Safe Medical Devices Reporting Act Brochure, page 23-33, 1991) or other sources of information about device-related investigation. Depending upon the possible severity of injury, association of the device with the event and possible medical-legal implications, different levels of precaution may be required.

4.2.5.1 During an inspection, care should be taken to avoid permanent alteration of the condition of the device in a way that would hinder further analysis. When destructive actions are necessary to assist in determining cause, careful documentation is necessary. During audio or video documentation as well as in written documentation, avoid judgmental comments. Note only the facts as they are observed.

4.2.5.2 If the cause of the event is not immediately obvious, notify the manufacturer and invite to participate in the inspection. If the event may have medical-legal consequences, it may be advisable to have a hospital attorney and/or a representative from the hospital insurer observe the inspection. For potentially serious events in which the DBE may have some involvement, consideration should be given to have an outside consultant supervise, observe or conduct the inspection. The CQS makes this determination.

4.3 Expedited Investigation

When it is unlikely that injury has been associated with the device and there is reasonable a priori evidence of the causes of the event, simple inspection by hospital technical personnel will usually suffice.

5.0 Reporting

5.1 For Hospital Use

A summary of the events and device inspection should be written by the leader of the device investigation and submitted to the DDBE/Biomed Safety Officer and CQS and to the appropriate QA Chairperson. In most cases, a report should be presented for discussion at a meeting of the Safety Committee and, if appropriate, at a meeting of the relevant service QA meeting. A written summary is not required for a simple failure for which it is obvious that no injury has occurred and the failure is routine or not uncommon. In such cases, a routine work-order report may suffice. When a safety report has been submitted, written summary is provided to the QSM to include in the online safety reporting system.

5.2 SMDA Reporting to the FDA or Manufacturer

The CQS and DDBE, in conjunction with Corporate Compliance Officer and Hospital Health Risk Manager, determine if a report is required under the provisions of the SMDA. The Investigation leader. in conjunction with the CQS and hospital attorney, when deemed appropriate, completes the report. Actual filing of an SMDA report

shall be done only in consultation with the Director of Corporate Compliance and the Hospital Risk Manager. An SMDA report must be in the format required by the FDA. Refer to Medsun Users Manual 2007 for reporting requirements.

5.3 When Must an Event be Reported?
If an event is required to be reported to the FDA and/or to the manufacturer according to SMDA, filing must occur within 10 working days after there is reasonable information to believe that the event requires such a report. "Reasonable information" may mean that investigation is required to determine if the event is reportable.

5.4 If an SMDA report is not required, the DDBE or QSM shall determine if reporting through other mechanisms is useful, e.g., Medsun (voluntary reporting to FDA) or to the ECRI Hazard Alert System.

6.0 Quality Assurance Follow-up
Device related events usually require follow-up to institute corrective action. DBE personnel coordinate or delegate responsibility for device-related changes. The affected departments institute other forms of corrective actions, e.g. procedural changes, education. The QA leaders in affected departments are responsible for follow-up in their areas with the DBE advising on technical issues. QA leaders are responsible for dissemination of the findings/corrective actions to appropriate staff.

7.0 Placing a device back into service
The DDBE, or designee, determines when a device suspected of being involved in a patient injury may be returned to clinical use. Sequestration should be continued if serious injury is suspected or medical-legal action may arise from the event or if there is reasonable doubt about the safety of the device. Pressing clinical need for the device may preclude sequestration that would otherwise be desirable, with the exception of serious safety concerns.

8.0 Miscellaneous Issues

8.1 Thorough investigation may not be required for FDA or manufacturer reporting but may be prudent to identify issues primarily related to hospital procedures. The same general procedures outlined above should be followed with the exception of reporting to personnel outside the affected departments.

8.2 Follow-up with personnel who report the event
The leaders of the device investigation, in conjunction with the CQS inform anyone who reported the event about the findings and actions taken.

8.3 Protection of Information
The process of device investigation, because it operates under the auspices of the MGH Safety Committee, is generally protected from disclosure. Alternatively, an investigation may proceed under the auspices of a specific departmental QA Committee. In either case, an appropriate report should be made to the responsible committee during or at the conclusion of the investigation.

9.0 Definitions

9.1 Medical Device

A "device" is defined as an instrument, apparatus, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
(1) recognized in the official National Formulary, or in the United States Pharmacopoeia or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its intended principal purposes.
(This definition is taken from Federal Law, 21 U.S.C. 321(h). Examples of medical devices: catheters, infusion pumps, hospital beds, patient restraints, suture material, syringes, defibrillators, pacemakers, wheelchairs, in vitro diagnostics.)

9.2 Serious Illness or Serious Injury

The terms serious illness and serious injury are defined as an injury or illness that:
(1) is life threatening,
(2) results in permanent impairment of a body function or permanent damage to a body structure, or
(3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
(This definition is taken from Federal Law, 21 U.S.C. 360[i][b][5][B] as amended.)

10.0 Abbreviations

CQS: Center for Quality and Safety
DDBE: Director, Department of Biomedical Engineering
QSM: Biomedical Engineering Quality and Safety Manager
DBE: Department of Biomedical Engineering
DIT: Device Investigation Team
QA: Quality Assurance
SMDA: Safe Medical Devices Act of 1990