VA Butler Healthcare
Butler, PA

Medical Center Memorandum PI-01
March 22, 2013

PATIENT INCIDENT REVIEW PROGRAM (00Q)

I. PURPOSE: To identify and report all patient incidents to appropriate healthcare staff and to ensure timely patient assessment and initiation of any necessary treatment related to the incident.

II. POLICY: In all instances in which there is reason to believe that a patient has been involved in an incident that either has harmed or has the potential of causing harm to the individual, a factual description of the incident will be reported; and in the case of actual harm, the patient or their representative will be fully informed of the circumstances of the incident.

III. DEFINITIONS:

A. Incident: The term "incident", as applied in this policy, would be any unnecessary or unintended event, occurring during any time in the care process, which resulted, could have resulted, or still may result in harm to the patient.

B. Unnecessary or Unintended Events: The terms "unnecessary or unintended event," as they related to an incident, would refer to only events that actually occur and were not caught prior or prevented from occurring. Any errors, actions, or inactions caught prior to a direct occurrence that could be related to unnecessary or unintended patient harm will be reported as potential errors or close calls.

IV. RESPONSIBILITY:

A. Employees are responsible for providing a safe environment for patients and for immediately reporting any incident involving a patient as they become aware of it.

B. Program Managers are responsible for staff education on reporting and for assuring actions have been taken for prevention of similar, future incidents.

C. The Patient Safety Manager (PSM) is responsible for the collection, analysis, and trending of all incidents, for the integration of the Patient Injury Reporting data with other components of the organizational improvement, and for the completion of required reports.

D. The Chief of Staff is responsible for assuring that any necessary treatment is provided for the patients involved and that clinical processes or systems are modified appropriately to assure prevention of "unsafe" practices.

E. The Director maintains the full responsibility and authority for the implementation of the electronic Patient Event Report (ePER) System and makes determinations regarding the need for further evaluation of all adverse events.

V. PROCEDURES:

A. INCIDENT REPORTING:

1. In all instances in which there is reason to believe that a patient has been involved in an incident that either has harmed or has the potential of causing harm to the individual, a detailed and factual description of that incident must be reported in the ePER by the employee who witnesses or is the first to become aware of the incident.

2. The ePER must be initiated and completed within 24 hours of the time the occurrence is known. Examples of types of incidents that require completion of the ePER are described on Attachment A.

3. This reporting requirement applies to:

a. Inpatients/residents under active treatment including patients in the VA Community Living Center (CLC) and Domiciliary,

b. Outpatients receiving treatment from VA facilities (to include all Community Based Outpatient Clinics (CBOCs),

c. Patients enrolled in Home Based Primary Care (HBPC) and Community Care Programs.

d. Patients being treated at another facility if they are currently under our jurisdiction, and

e. Patients in transit between facilities if they are currently under our jurisdiction.

4. The incident report will include, as appropriate to the incident, a description of sufficient detail regarding the incident, the location where the incident occurred, and all pertinent factors such as the diagnosis, date of birth, mental status, medications taken by the patient within 24 hours of the incident, and/or a medical evaluation. Only factual information is recorded on the incident report form and no accusation of guilt or subjective opinion is to be included. No patient or staff identifiers (name, social security number, etc.) will be used in incident reports. Only staff or patient descriptors (e.g., the provider, the nurse, the patient/Veteran, etc.) will be included.

5. If the employee who first becomes aware of the incident is a non-clinical staff member and/or does not have access to the ePER, they must inform their supervisor for additional assistance. Additionally, they may need to confer with the clinical staff regarding the diagnosis and other clinical information required for completion of the incident report form.

6. Patients in the HBPC and Community Care programs will be evaluated by the staff member who first becomes aware of the event. Because the patient may not be seen on a frequent basis, the event may be reported well after the fact. The primary care provider will be notified of major injuries which may require medical or surgical intervention and the ePER will be completed. For events in the patient home where there is no injury or the injury is minor in nature, the primary care provider will be notified. The event will be tracked and trended by the ePER program and reported quarterly to the Environment of Care (EOC) Committee.

7. The provider responsible for the patient's care at the time of the incident will be notified immediately. After hours, the Medical Officer of the Day is the responsible provider.

8. After the eyewitness or person who first becomes aware of the incident completes the ePER, the system electronically alerts the PSM via email. The PSM will review the ePER and electronically send the incident to manager for follow-up. The PSM will assign a severity of injury code (SAC) to the incident thru the ePER, complete the PSM follow-up and enter data into SPOT. Based on severity of injury, reporting to facility leadership will be at the discretion of the PSM. However, if the incident has an actual SAC of 2, 3, or has a potential SAC of 3, the PSM must forward the ePER to the Associate Director for Patient Care Services, Chief of Staff, Associate Director for Operations, and Director for follow-up. The Severity of Injury Scale is divided into the levels as follows:

a. Minor: No injury, nor increased length of stay, nor increased level of care.

b. Moderate: Increased length of stay or increased level of care for 1 to 2 patients. Examples of moderate related injury are described on Attachment C.

c. Major: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission). Examples of major related injury are described on Attachment C.

d. Catastrophic: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime.

9. For incidents involving a provider evaluation, follow-up documentation is required to be placed in the medical record by a provider to indicate the patient's current condition relative to the incident.

10. Incident reports shall not be placed in the medical or administrative sections of the patient's medical record.

11. The ePER is used only for incidents that involve patients. Incidents involving visitors or employees are not recorded in the ePER

12. Informing the patient/resident or the patient's/resident's personal representative about the incident is done informally by healthcare staff members as a routine part of care and may involve disclosure of events that cause only minor harm. If the patient is incapacitated or otherwise unable to take part in the discussion, the patient's personal representative will be notified. The healthcare staff member informing the patient/resident or his representative of the incident must document the notification in a Computerized Patient Record System (CPRS) progress note titled "Clinical Disclosure" and include a brief description of the incident (and any follow-up care), the content of the discussion, who was notified, and method of notification (i.e.,

in-person or via telephone) and the telephone number where the patient/resident or representative was reached, if applicable. Documentation in the medical record will not indicate that an incident report was completed. General guidelines for responsibility of notification of the incident are as follows:

a. Any incident that is the result of patient/resident actions or behavior such as a patient/resident fall without suspected injury, the Registered Nurse (RN) or provider will notify the patient/resident's personal representative.

b. Any incident with suspected injury that requires further treatment or evaluation, the provider will notify patient or patient's personal representative.

c. Any incident that is suspected to be caused by facility circumstances/facility environment, the provider will notify the patient/resident or patient's/resident's personal representative.

d. In the CLC notifications to the resident or resident's family or personal representative will occur under the following circumstances:

(1) All incidents involving the resident which result in injury and has the potential for physician intervention.

(2) A significant change in the resident's physical, mental, or psychological status as a result of either a life-threatening condition or clinical complication.

(3) A need to alter treatment significantly (i.e., discontinue or alter an existing form of treatment due to adverse consequences or to commence a new form of treatment).

(4) A decision is made to transfer or discharge the resident from the facility.

e. Any incident that is suspected to be caused by an ordering/prescribing medication error or medical device/equipment related incident, a provider will notify the patient or patient's personal representative.

f. Any incident that is suspected to be caused by a preparing/filling/dispensing medication error, a pharmacist will notify the patient.

g. Any incident that is suspected to be caused in the course of administration of a product or medication to the patient, the RN will notify the patient or patient's personal representative.

h. If a medication error passes through multiple disciplines (e.g., order written incorrectly by a provider, processed incorrectly by a pharmacist, and administered incorrectly to the patient), the healthcare staff member suspected of initiating the error holds the responsibility of notifying the patient or the patient's personal representative.

13. When an adverse event has occurred as a result of the patient's care and treatment while an inpatient or an outpatient, which has caused, will cause, or has the potential of causing the patient significant harm, disability, death, or other personal loss, the treating or examining provider must inform the Chief of Staff as promptly as possible and a decision will be made regarding who will notify the patient or the patient's personal representative of the situation. Communication with the patient and/or family regarding adverse events will be in concert with the MCM PC-02 Disclosure of Adverse Events.

14. If there is reason to believe the incident is related to a medical device which may have caused or contributed to the patients serious illness, injury, or death, the medical device and associated accessories (such as catheters, tubing, patient lifts, grounding pads, etc.) involved in the incident shall be removed from the area and sequestered for further evaluation (after it has been determined that removal will not cause further injury). (See Medical Device Section C.)

15. The ePER report form will be reviewed by the PSM and electronically forwarded to the appropriate Program Manager for follow-up. The PSM will determine whether the incident meets mandatory reporting requirements as outlined in the VHA Risk Management Program Directive and VHA Handbook 1051/1, Patient Safety Improvement Handbook and will consult with the Chief of Staff and Director about his/her determination.

16. The Director will make the final decision, determine if the appropriate action has been taken, and whether a fact finding, a psychological autopsy, Root Cause Analysis (RCA), or a board of investigation will be done. If an investigation is indicated, the Director will initiate the investigation and ensure that the appropriate process is followed. The Patient Safety and/or Quality Systems Manager will prepare reporting documents for the Director's signature.

17. If warranting leadership review, the ePER will be forwarded no later than 10 days following the occurrence of the incident to the Director.

18. Once completed and signed by the Director, the ePER is forwarded to the Quality Systems Management Section for final review. Quality Systems Management personnel will enter the information from the completed ePER into the computer database.

19. Each type of incident by total and severity level will be tracked monthly by the Quality Systems Management staff, and compiled quarterly to provide aggregate data to the Program Managers. These individuals will review all categories to identify avoidable incidents, methods to prevent recurrences, or opportunities for improvement.

20. The ePER will be maintained by the facility Chief Information Officer (CIO) on a secure server.

B. ALLEGATIONS OF PATIENT ABUSE BY VA EMPLOYEE:

1. All allegations of patient abuse must be investigated. The program manager reporting an incident of alleged abuse is responsible for doing fact-finding to determine if patient abuse occurred in any of the following:

a. Any action or behavior that conflicts with the patient's rights, as identified in 38 Code of Federal Regulations (CFR) 17.34a,

b. Intentional omissions of patient care,

c. Willful violations of the privacy of the patient(s),

d. Intimidation, harassment, or ridicule of the patient(s), and/or

e. Willful physical injury of the patient.

2. A written report of the fact-finding will be forwarded to the Chief of Staff for final determination of alleged patient abuse.

C. MEDICAL DEVICES:

1. VA Butler Healthcare is required to report when made aware of information that reasonably suggests that a medical device has or may have caused or contributed to a patient's death, serious illness, or serious injury. Serious injury is illness or injury that is life threatening; or results in permanent damage to the body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Medical Devices are defined as any item that is used for the diagnosis, treatment, or prevention of a disease, injury, illness, or other condition; and is not a drug.

2. When hazardous conditions associated with the use of medical devices are discovered, facility staff will intervene to assure the patient's safety, contact the PSM, and initiate the ePER. Medical Devices and associated accessories such as catheters, tubing, grounding pads, etc. involved in a patient incident, must be removed from the area and sequestered for further evaluation after it has been determined that removal will not cause further injury to the patient.

3. After staff completes the ePER due to an incident involving a medical device, fact-finding will be completed by an RCA review team including a clinical practitioner familiar with the equipment in question and the facility Biomedical Technician or designee. The QUAD in collaboration with the PSM will select employees for this team. The review team must determine if the injury occurred due to equipment failure or user performance. A summary of the fact-finding including recommendations and actions will be submitted to the PSM. The PSM and RCA Team will meet with the QUAD to review the findings of the RCA and present their recommendations.

4. The Chief of Staff has responsibility for determining whether or not a medical device incident is reportable under the requirements of Safe Medical Device Act (SMDA). If reportable, the incident will be filed within 10 working days from the completion of the ePER. Reporting will be conducted as described in MCM SC-02, Patient Safety Program.

VI. RESCISSIONS: Medical Center Memorandum PI-01 dated September 2, 2010.

VII. REFERENCES:

VHA Handbook 1050.1, VHA National Patient Safety Improvement Program, dated March 2011.

Medical Center Memorandum PC-02 Disclosure of Adverse Events

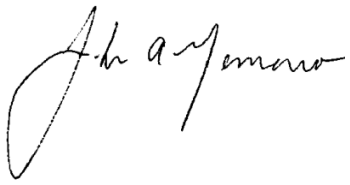
Medical Center Memorandum RI-04, Action in Cases of Abuse of Patients by Employee

The Joint Commission Long Term Care standards 2012

Centers for Medicare and Medicaid Services 483.10 Resident Rights

National Coordinating Council for Medication Error Reporting and Prevention, http://www.nccmerp.org/aboutMedErrors.html

VHA Directive 2012-36 Sexual Assaults and other defined public safety incidents in Veterans health Administration (VHA) facilities.



JOHN A. GENNARO
Director

ATTACHMENTS: A, B, and C

(Automatic Review Date: March 22, 2016)

ATTACHMENT A

DEFINITION OF PATIENT INCIDENTS

NUMBER	CATEGORY	INCIDENT DEFINITION
	Homicide	Death of a patient or staff member intentionally caused by a patient or the death of a patient intentionally caused by another individual.
	Alleged Patient Abuse	Acts against a patient, which involves physical, psychological, verbal, or financial abuse. "Intent" to abuse is not a requirement for patient abuse. The perception of how the patient was treated is an essential component of the determination as to whether a patient was abused. However, the fact that a patient has little or no cognitive ability does not exclude the possibility that a patient was abused.
	Sustained Patient Abuse	Allegation deemed valid by investigation.
	Fall	An event witnessed or unwitnessed, in which the unplanned movement of a patient causes him/her to come to rest either in an unwelcome position or on an unwelcome surface. This does not include patients assisted safely to a lower surface by another individual.
	Transfusion Error	Blood administered to the wrong patient, administered when not ordered, administered using the wrong product, incorrectly administered; or error in the type/cross match process with or without any reaction or evident adverse event. These errors also include blood or blood products. NOTE: Idiosyncratic reactions to blood or blood products are not reportable unless an error, as previously described, was involved.
	Medication Error	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. See Attachment B for a list of types of medication errors.
	Adverse Drug Reaction	Adverse reactions seriously affecting the well being of the patient.

	Incident not Otherwise Listed	Any incident involving a patient not specifically addressed in other categories. This includes procedural complications.
	Patients involved in Fires	This includes patients who set fires, who are involved in fires (with or without injury); who are burned, or are exposed to smoke or fire (i.e. smoke inhalation).
	Patient on Patient Assault	Patient injured by another patient; patient assaulted by another patient. The severity of injury scale will only be applied to the patient that was assaulted.
	Patient on Staff Assault	Staff member(s) is physically struck, injured, temporarily, or permanently disabled by a patient or patients.
	Unexpected Death	Death of a VA patient while an inpatient or an outpatient (within 30 days of treatment) which is not attributable to the course of the patient's disease or a therapeutic misadventure. Do Not Resuscitate (DNR) is not reportable unless death is due to something other than the patient's diagnosis/illness as described.
	Missing Patient	Any patient who is not on privileges whose location is not known. *High risk patients*- are considered missing as soon as their absence is noted. *Low risk patients*- are considered to be missing if their location is not known within timeframes established at the local facility.
	Failure to Obtain Informed Consent	No consent is obtained for procedures or all elements of informed consent as outlined by VHA policy are not complete unless there is documentation of emergency conditions as outlined in VHA policy.
	Reaction to Blood/ Blood Products	N/A at VA Butler Healthcare Reaction to blood or blood product that has been properly typed/ cross matched and administered.
	Diagnostic Error	An error in distinguishing the criterion of disease, based on signs and symptoms, laboratory values, and other clinical findings.
	Inaccurate counts in surgery	N/A at VA Butler Healthcare Includes sponges, instruments, or equipment
	Device Related	An adverse event to the patient due to malfunction of any medical device.
	Miscellaneous	Individual determination for incidents not meeting above definitions

ATTACHMENT B

TYPES OF MEDICATION ERRORS

TYPE	DEFINITION
Prescribing	Incorrect medication selection (based on indications, contraindications, known allergies, existing medication therapy, and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a medication product ordered or authorized by physician or other legitimate prescriber; illegible prescriptions or medication orders that lead to that reach the patient.
Omission	The failure to administer an ordered dose. However, if the patient refused to take the medication, none has occurred. Likewise, if the dose is not administered because of recognized contraindications, none has occurred.
Wrong Time	Administration of a dose of medication greater than plus or minus 90 minutes from its scheduled administration time. Acceptable variances from the 90 minute timeframe are referenced in MCM MM-27, Medication Administration.
Unauthorized Medication	Administration to the patient of a medication not authorized by a legitimate prescriber for the patient. This would include a wrong medication, a dose given to a wrong patient, unordered medications, and doses given outside a stated set of clinical guidelines or protocols (e.g. medication order to administer only if blood pressure above a predetermined level) or given past stop date.
Improper Dose	Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the patient, i.e. one or more dosage units in addition to those that were ordered (excluded would be allowable deviations based on preset ranges established by protocol or order, e.g. not administering a dose based on patient temperature or blood sugar, or topical doses for which medication doses are not expressed quantitatively).
Dosage-Form	Administration to the patient of a medication product in a different dosage form than ordered by the prescriber. (Example: liquid rather than tablet form extended release rather than short term acting).
Medication Preparation	Medication product incorrectly formulated or manipulated before administration. Examples are incorrect dilution or reconstitution, not shaking a suspension, inadequate product packaging (not keeping a light-sensitive medication protected from light), and mixing medications that are visually or chemically incompatible.
Administration/Technique	Inappropriate procedure or improper technique in the administration of a medication. This would include doses administered: (1) via the wrong route (different from the route prescribed); (2) via the correct route but the wrong site (e.g. left eye instead of right); and (3) at the wrong rate of administration.
Deteriorated Medication	Administration of a medication that has expired or for which the physical or chemical dosage-form integrity has been compromised (for example, administration of expired medications and improperly stored medications).
Monitoring	Failure to review a prescribed regimen for appropriateness and detection of problems or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.
Other	Any medication error that does not fall into any of the above categories

ATTACHMENT C

LEVEL OF INJURIES WITH EXAMPLES OF MODERATE AND MAJOR INJURY

Minor: No injury, nor increased length of stay nor increased level of care.
Moderate: Increased length of stay or increased level of care for 1 or 2 patients.

I. EXAMPLES:

A. Fracture of a pinky finger or small bone with no surgical intervention and casting only.

B. Bruises

C. Abrasions

D. Sutures only for a minor laceration

E. Choking

F. Bites/Stings

G. A head CT with no resulting injury would **not** be major, but should be rated according to whatever injury (if any) is determined as a result of the test

H. Increased testing or monitoring

Major: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions(i.e. . acts of commission or omission) or any of the following:

II. EXAMPLES:

A. Disfigurement

B. Surgical intervention required

C. Increased length of stay for 3 or more patients

D. Increased level of care for 3 or more patients

E. Fracture to a shoulder, arm leg, spine, large bone (with or without surgery); Fracture of a rib (with or without pneumothorax).

F. Concussion

Catastrophic: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission). This includes outcomes that are a direct result of injuries sustained in a fall or associated with an unauthorized departure from an around-the-clock treatment setting or the result of an assault or other crime.