JAMES E. VAN ZANDT VA MEDICAL CENTER
ALTOONA, PENNSYLVANIA

MEDICAL CENTER MEMORANDUM (MCM) 00Q-28
DECEMBER 2012

PATIENT SAFETY IMPROVEMENT PROGRAM (PSIP)

1. **PURPOSE**: To prevent injuries to patients, residents, visitors, and employees to manage those injuries that do occur, and to minimize the negative consequences to the injured individuals. This will and should be a continuous process. In this way a "culture of safety" can be formed and assure timely and consistent reporting and review of adverse patient/resident events and close calls.

2. **SUMMARY OF MAJOR CHANGES**: MCM being updated to comply with VHA Handbook 1050.1 VHA National Patient Safety Improvement Handbook and to incorporate the Electronic Patient Event Report (ePER) process for reporting adverse events.

3. **POLICY**: Medical center leadership is committed to reducing the occurrence of medical error, increasing safety within the medical center environment, and changing the health care culture to embrace error reporting and identification of close calls. The Patient Safety Improvement Program consists of three major components:

a. The identification, analysis, and understanding of adverse events; and the implementation of change in systems or processes to reduce the probability of future events.

b. The ability to learn lessons from the event analysis and to apply those lessons learned in other areas of the organization.

c. The implementation of a proactive safety movement with the aim of preventing errors before they occur.

4. **DEFINITION**:

a. **Patient** for the purpose of this MCM includes inpatients, outpatients, and residents.

b. **Adverse events** are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment.). Some examples of more common adverse events include: patient falls, medication errors,

procedural errors and/or complications, completed inpatient suicides, para-suicidal behaviors (attempts, gestures, and/or threats), and missing patient events. All adverse events require reporting and documentation in the Electronic Patient Event Reporting (ePER) System, SPOT (national database), and/or via secure email/phone call to the VISN Patient Safety Officer. The type of review required is determined through the Safety Assessment Code (SAC) matrix scoring process.

c. **Aggregate reviews** allow the gathering of individual adverse events into one review process so that the information from each event may be analyzed as part of the whole. The National Center for Patient Safety (NCPS) developed this approach to address specific adverse events with a Safety Assessment Code (SAC) rating of "potential 3". The events that are clustered for aggregate review are: falls, missing patients, and medication errors.

d. **Wild Card** is a review of events which are not included in the three main aggregate reviews (falls, missing patients, and drug events). If a facility has zero events in one of the three aggregate reviews, an individual Root Cause analysis (RCA) or a 'wild card' aggregate review may be performed to achieve the minimum number of eight individual RCAs or aggregate reviews.

e. **Close call** is an event or situation that could have resulted in an adverse event, but did not, either by chance or through timely intervention. Such events have also been referred to as "near miss" incidents. Close calls are opportunities for learning and afford the opportunity to develop preventive strategies and actions. Close calls receive the same level of scrutiny as adverse events that result in actual injury. All close calls require reporting. Close calls may be reported through the Electronic Patient Event Reporting System, via the Close Call Reporting Form, which is available in all patient care areas and workstations, or by contacting the appropriate supervisor, Facilities Service emergency number (extension 7314), Risk Manager, Patient Safety Manager, Safety Manager, or VA Police; however, as for adverse events, the SAC matrix (the probability and severity of the event) determines the type of review required.

f. **Focused reviews** are a comprehensive gathering and analysis of facts and other information centered on a specific issue. Focused reviews generally have a very narrow scope and generate in-depth knowledge regarding the topic or event studied. The term focused review is sometimes used generically to include specialty studies such as root cause analyses, psychological autopsies, etc.

g. **Proactive Risk Assessment** is a method of evaluating a product or process to identify systems vulnerabilities, and their associated corrective actions, before an adverse event occurs. Proactive Risk Assessment models include Healthcare Failure Mode and Effects (HFMEA) and Failure Mode Effect Analysis (FMEA).

h. **Intentionally unsafe acts**, as they pertain to patients, are any events that result from: a criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider and/or employees; or events involving alleged or

suspected patient abuse of any kind. Intentionally unsafe acts are to be dealt with through avenues other than those defined in the Patient Safety Improvement Program (i.e., Administrative Investigation Board (AIB) or other administrative methods as determined by the Director). The goal of these investigations is to focus upon determining what happened, why it happened, and what can be done to prevent it from happening again. Guidance on what to do when criminal or intentionally unsafe acts are suspected is addressed later in this policy. Medical centers are required to maintain a log of all such events, including disposition of all the cases. If an event involves what appears to be an intentionally unsafe act, an AIB or similar review may be appropriate and a RCA may be inappropriate. However, in some cases it may be appropriate to do both types of reviews, e.g., an AIB might review a procedure or aspect of care performed by a provider who might not have had the appropriate credentials or privileges, and an RCA on the same topic might review the local processes for credentialing and privileging. An RCA can use information gleaned from an AIB, but due to confidentiality constraints of RCAs, an AIB cannot use information from an RCA. If there is an intention to perform both types of reviews on the same incident, the RCA should normally be performed after the completion of AIB. In the event that an AIB is performed after an RCA is started, members of the RCA team are not to serve on the AIB team or review group to ensure that the confidentiality of the RCA process is appropriately maintained and that the perception of the integrity of the RCA process is preserved.

i. **National Center for Patient Safety (NCPS)** was established by VHA to develop, lead, and/or oversee activities and programs concerned with improving patient safety. Specifically, the NCPS works to measure, develop, and implement methods that minimize the chance of untoward outcomes consequent to medical care. NCPS employs a systems approach that emphasizes error prevention as the preferred method to accomplish this goal. NCPS staff identify, plan, test, and implement programs aimed at ensuring that safety is viewed as a continuum throughout the organization, encompassing employees, trainees, patients, and visitors.

j. **Patient Safety** is ensuring freedom from accidental or inadvertent injury during health care processes.

k. **Root Cause Analysis (RCA)** is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. This specific type of focused review is used for all adverse events and close calls requiring analysis, since it further refines the implementation and increases the quality and consistency of focused reviews.

(1) RCAs have the following characteristics:

(a) The review is interdisciplinary in nature with involvement of those knowledgeable about the processes involved in the event.

(b) The analysis focuses primarily on systems and processes rather than individual performance.

(c) The analysis digs deeper by asking “what” and “why” until all aspects of the process are reviewed and contributing factors are considered.

(d) The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes and systems that would improve performance and reduce the risk of the adverse event or close call recurrence.

(2) To help adhere to these characteristics the following five guidelines need to be considered when developing root cause statements:

(a) Root cause statements need to include the cause and effect.

(b) Negative descriptions are not to be used in root cause statements.

(c) Each human error has a preceding cause.

(d) Violations of procedure are not root causes, but must have a preceding cause.

(e) Failure to act is only a root cause when there is a pre-existing duty to act.

(3) To be thorough, an RCA must include:

(a) A determination of the human and other factors most directly associated with the event or close call and the processes and systems related to its occurrence. There is rarely only one underlying root cause.

(b) Analysis of the underlying systems through a series of “why” questions to determine where redesigns might reduce risk.

(c) Identification of risks and their potential contributions to the adverse event or close call.

(d) Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination after analysis that no such improvement opportunities exist.

(4) To be credible, an RCA must:

(a) Include participation by leadership. This can range from chartering the RCA team, to direct participation on the RCA team, or participation in the determination of the corrective action plan.

(b) Include individuals knowledgeable about the processes and systems under review.

(c) Exclude individuals directly involved in the adverse event or close call under review. In the interest of objectivity, these individuals are not to be part of the RCA Team. However, their experience and knowledge of the situation is vital to the RCA process, so they need to be interviewed as part of the RCA process and asked for suggestions about how to prevent the same or similar situations from happening again.

(d) Be internally consistent (i.e., not contradict itself or leave obvious questions unanswered).

(e) Include consideration of relevant literature.

(f) Include corrective actions, outcome measures, and top management approval.

(g) Meet the NCPS and The Joint Commission (TJC) requirements. NCPS provides a computer-assisted tool that must be used to guide RCA teams, document the RCA, and communicate to NCPS and Veterans Integrated Service Network (VISN).

l. **Safety Assessment Code (SAC) matrix** is a grid developed by the NCPS that measures the severity and probability of an event to evaluate the event's level of significance and determine the type of review required.

m. **Sentinel events** are a type of adverse event. Sentinel events, as defined by The Joint Commission (TJC), are unexpected occurrences involving death, serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase "risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcomes. Sentinel events signal the need for immediate investigation and response. Some examples of reviewable sentinel events include:

(1) Events that have resulted in an unanticipated death or major permanent loss of function not related to the natural cause of the patients illness or underlying condition.

(2) Suicide of a patient receiving care, treatment, or services in a staffed, around-the-clock setting or within 72 hours of discharge.

(3) Surgery on the wrong patient or wrong body part regardless of the magnitude of the operation.

(4) Unintended retention of a foreign object in a patient after surgery or other invasive procedures.

(5) Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities.

(6) Abduction of any patient receiving care, treatment, and services.

(7) Sexual abuse/assault (including rape).

(8) Prolonged fluoroscopy with a cumulative dose greater than or equal to 1500 rads in a single field, or any delivery of radiotherapy to the wrong body region or greater than 25% over the planned radiotherapy dose.

n. **Patient Safety Advisories** are developed and disseminated to raise the level of awareness of an identified vulnerability when specific actions do not exist to immediately mitigate the hazard; however, suggestions may be offered to assist in addressing the vulnerability.

o. **Patient Safety Alerts** are notices sent from Central Office to the field that require action to be taken or eliminate or mitigate known vulnerabilities that can adversely impact the patients' life or health.

p. **Title 38 United States Code (USC) 5705** is the federal law and its implementing regulations that offers protection from disclosure of confidential documents that are developed with the intent of obtaining information for quality assurance purposes.

5. **RESPONSIBILITIES**:

a. **Director** is ultimately responsible for fostering a proactive "culture of safety" and for assuring processes are in place and resources are allocated appropriately to ensure an integrated proactive patient safety program. Additionally, the Director ensures that the medical center develops, implements, and maintains patient safety improvement and risk management programs that meet the requirements set forth by NCPS and TJC and are consistent with the goals and philosophy of the VISN and Veterans Health Administration (VHA). The ultimate goal of this program is to continuously provide a high quality of care and a safe environment for patients, visitors, and employees.

b. **Chief of Staff, Associate Director, and Associate Director for Patient/Nursing Services** are responsible for promoting an atmosphere where high quality of care, provided in a safe environment, is the norm. They also set the stage, along with the Director, in fostering a positive and proactive "culture of safety" throughout the medical center. The Chief of Staff is responsible for assuring that patients are informed of all outcomes of care, including negative outcomes, and that all appropriate clinical interventions have been offered to the patient and/or their family following an adverse event, according to medical center policy.

c. **Service chiefs and supervisors** are responsible for the ongoing evaluation of their respective areas for risk hazards and for taking action to correct them. They are responsible for fostering an environment in which their employees can respond quickly to unsafe or potentially unsafe processes in the environment. They are also responsible

for implementation of corrective actions resulting from event reports, safety and sentinel event alerts and RCAs, and for assuring expected outcomes are achieved.

d. **Risk Manager** collaborates in establishing and coordinating an integrated Patient Safety Program. Additionally, the Risk Manager is responsible for maintaining an integrated Risk Management Program and coordinates medical center risk-related activity including tort claims, peer reviews, etc.

e. **Patient Safety Manager** is responsible for the overall coordination and oversight of the Patient Safety Improvement Program. Additionally, the Patient Safety Manager is responsible for maintaining an integrated program of patient safety including:

(1) Utilizing, processing, and maintaining the Electronic Patient Event Reporting System and SPOT data base.

(2) Reporting adverse events as outlined in this policy.

(3) Actively advising and/or conducting appropriate event reviews and reporting to the VISN Patient Safety Officer (PSO) and National Center for Patient Safety (NCPS) within 45 days of the identification of events requiring an RCA.

(4) Actively advising and/or conducting aggregate reviews on medication errors, falls, missing patients, and other Wild Card aggregated events, as mandated by NCPS and the VHA National Patient Safety Handbook.

(5) Routinely analyzing care delivery systems to identify redesigns, which will improve patient safety, while trending events to identify opportunities for improvement.

(6) Supplying reports to the PSO when indicated.

(7) Adopting strategies to motivate and facilitate an employee, which enhances a culture of safety.

f. **Employees** are responsible for individual work practices which provide for a safe therapeutic environment and for prompt and accurate reporting of witnessed/discovered incidents or potential hazards. All employees will report any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call to the Patient Safety Manager (PSM). Adverse events must be reported within the facility to the PSM. All employees are responsible for encouraging patients' active involvement in their own care as a patient safety strategy. Patients, family members, or visitors can report concerns through any employee. All employees will take action to remedy patient safety concerns that are within each employee's control. All employees can direct patients, family members, or visitors wishing to report patient safety concerns to the close call form or directly to the Patient Safety Program Manager.

6. **PROCEDURES**:

a. **Event reporting**:

(1) An Electronic Patient Event Report (ePER) will be initiated without delay when a patient is involved in an event that either has harmed or has the potential of causing harm to the individual. The event may be an illness, adverse event, or injury resulting from either omission(s) or commission(s) by health care providers, the direct result of medical intervention, imprudent behavior on the part of the patient, or a close call/near miss situation.

(2) The employee who witnesses or discovers an event or “close call”/ “near miss”, will first ensure that the Veteran is rendered all appropriate care and then will promptly initiate an Event Report. This will be done by entering the event into the Electronic Patient Event Reporting (ePER) web based system using the most appropriate category; i.e., falls, medication errors, and close calls (Attachment A). Instructions for completing close call forms are attached (Attachment B). These forms are located at all patient care areas throughout the facility. This form can be completed anonymously or may be signed by the reporter. At a minimum, this reporting will include:

(a) **Sentinel events**

1. Death or major permanent loss of function not related to the natural course of the patient’s illness or underlying condition (i.e., acts of commission or omission). These include deaths related to medication errors, falls, or associated with unauthorized departure from an around-the-clock treatment setting (missing patient), or results of an assault or other crime.

2. Suicide of any patient receiving care, treatment, or services in a staffed around-the-clock setting or within 72 hours of discharge.

3. Surgery on the wrong patient or body part regardless of the magnitude of the operation.

4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure.

5. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

6. Abduction of any individual receiving care, treatment, or services.

7. Sexual abuse/assault (including rape)/

(b) **Adverse events that are non-sentinel events**

1. Suicide of a patient in the community who is under the care of a VA provider and not discharged from this facility within the last 72 hours.

2. Unexpected deaths

3. Missing patients

4. Assault – all types; patient on patient, patient on staff, or sexual assault

5. Allegations of patient abuse

6. Reaction to blood or blood products

7. Homicide

8. Falls

9. Adverse drug event

10. Transfusion error

11. Patients involved in fire

12. Diagnostic error

(c) **Other**: Any event not previously listed

(3) The physician or physician extender at the time of the event should be notified immediately for events involving patients. The physician or extender will examine and evaluate the patient, document findings electronically in the Computerized Patient Record System (CPRS). During other than normal operating hours, this will be completed by the Medical Officer of the Day (MOD). The Director and Chief of Staff will be informed immediately by the Administrative Officer of the Day (AOD), MOD, or Nursing Officer of the Day (NOD) of all patients that have a major injury or who fall into the category of a “sentinel event”.

(4) Patient Safety Manager will screen all patient event reports and submit to services for follow-up if required. Only reportable or problematic events (severity level 2 or 3, Safety Assessment Code (SAC) 2 and 3 or potential 3s) will be forwarded to the Chief of Staff and Director for signature (Attachment C). The Patient Safety Manager is delegated authority for signing off on all other lesser events (severity level 0 or level 1, SAC 1). Additionally, the Patient Safety Manager will take appropriate action to convert the event severity level to a higher level with appropriate documentation and reporting

when an injury is detected at a later date via x-ray or exam and is believed to have been caused by the original incident (fall or procedure, etc.).

(5) Chief of Staff and Director will review all problematic events and severity level 2 and 3, SAC 2 and 3 or potential 3 events and may request further review of the events with recommendations to the Director for initiating a focused review, Root Cause Analysis, or Administrative Investigation Boards (AIB).

(6) The Director acts upon and makes final determinations on Root Cause Analysis reports, focused reviews, and Administrative Investigation Boards (AIB).

b. **Other reporting requirements internal to Veterans Health Administration (VHA)**

(1) **Reporting allegations of patient abuse**: Allegations of mental, physical, sexual, or verbal abuse, including mistreatment or neglect of patients, may be made by the patient, family, or employee. All allegations must be documented on an ePER, given priority follow-up, and reviewed by the service chief in collaboration with the Patient Safety Manager. An Administrative Investigation Board (AIB) shall be conducted if there is a reasonable likelihood that the findings will be used as the basis for disciplinary actions and in other situations where testimony under oath is appropriate and confidential under 38 U.S.C. 5705 is not necessary. Allegations of patient abuse, unless found in a preliminary review by the Chief of Staff, or designee, to be clearly false, require an Administrative Investigation Board; however, if the employee admits to abuse, an Administrative Investigation Board is discretionary. The Director will initiate an Administrative Investigation Board within ten days of receipt of the allegation.

Patient abuse includes:

(a) Intentional omission of care

(b) Willful violation of a patient's privacy

(c) Willful physical injury

(d) Intimidation, harassment, or ridicule of a patient.

1. Incidents of alleged patient abuse will be documented in the computerized patient record.

2. Alleged patient abuse of residents and inpatients will be reported to the nursing staff.

(2) **Reporting medical device-related incidents**:

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(a) Any medical device that malfunctions while being used on a patient, or is in the process of being used on the patient, even if the patient is not harmed, must have an event report completed. The device will be taken out of service and the Biomedical Technician, Risk Manager, Patient Safety Manager, and Safety Manager will be notified.

(b) Medical Device Related (MDR) events that are reportable to the Food and Drug Administration (FDA) include events that involve the failure of a diagnostic device if information reasonably suggests that there is a probability that a misdiagnosis or lack of diagnosis resulting from the failure would/could cause or contribute to a death, serious illness, or serious injury if it were to occur. MDR reportable events also include events that are similar or identical to previously-reported events (i.e., if a reportable event occurs a second time with a device, such as an infusion pump, the event must be reported even though the first adverse event was reported in the past.) Reportable events caused by user errors or the failure to service or maintain devices must also be sent to the manufacturer or to the FDA, depending upon the event type.

(3) As stated in section 5a, all medical centers are required to report adverse events using the Electronic Patient Event Reporting System, and the automated data base developed by the National Center for Patient Safety (NCPS), known as SPOT.

(4) The Patient Safety Improvement (PSI) Program encompasses information from other “surveillance type” activities. In an effort not to duplicate these other activities’ reporting mechanisms that follow adverse event will not be reported through the PSI Program unless the patient experiences a major injury (injuries which require medical or surgical intervention, increased hospital stay, or are disabling and/or disfiguring to a degree that the patient will have permanently lessened function or require surgical repair) or death. This adverse event not reported through the PSI program is adverse drug events that are reported through the pharmacy package.

(5) If an event is an actual adverse event meeting The Joint Commission’s (TJC) definition of a “Reviewable Sentinel Event”, the Director will make the determination to report to the TJC or not. If it is determined that the event will be reported to TJC, this must occur within five days of awareness of the event. Prior to notifying the TJC, the medical center must notify the VISN Chief Medical Officer and VISN Patient Safety Officer of their intent to notify the TJC and provide a copy of the information that will be transmitted. Whether the event is transmitted to the TJC or not, the event must undergo an RCA. Feedback provided by TJC regarding the RCA must be shared with the VISN Chief Medical Officer and VISN Patient Safety Officer.

(6) Formal Reviews - If intentional unsafe acts are identified, an Administrative Investigation Board or other reviews instituted by outside regulatory agencies may be used to analyze the situation. Administrative investigations involve testimony under oath, and their documents are not considered to be confidential quality assurance documents under Title 38 U.S.C. 5705 and its implementing regulations. The medical center will use guidance provided for the AIB unless the event is under review by the Federal Bureau of Investigation, Office of Inspector General, or law enforcement

authorities. In such cases, medical centers should not conduct additional reviews until such criminal review is completed. Additional review is at the discretion of the Director or at the request of the Network Director.

c. **Acting upon the adverse event**

(1) The medical center employees will assure that the immediate needs of the patient are addressed to minimize injury. The employee witnessing the event will preserve all evidence and provide a factual description of the event to the Chief of Staff and Patient Safety Manager. In addition to providing timely clinical care recovery, the primary care provider or covering physician will make appropriate entries into the medical record.

(2) If the patient does experience an adverse event/outcome, the Chief of Staff will assure that appropriate procedures are followed as outlined in MCM 11-04, Disclosure of Adverse Events.

(3) As previously stated, once the patient and family are safe, the Patient Safety Manager will review the adverse event and assign a SAC score of 1 through 3 using the Safety Assessment Code matrix. Action will be initiated based on the assigned SAC score.

(a) Root cause analysis will be conducted for adverse events resulting in an actual SAC score of 3.

(b) Aggregate reviews will be conducted for falls, medication errors, missing patients, and events with a potential SAC score of 3.

(4) Only the Director, or his/her designee, may direct the appointment of an RCA team. Recommendations for the team appointment process include:

(a) The team will be advised of their role in writing and will be provided training in the RCA process.

(b) The written communication indicates that the team is functioning under the authority of the Director and that the confidentiality of the document is derived from Title 38 USC section 5705.

(c) The written communication also advises the team members prior to the onset of any review activity that the information they are viewing, collecting, and analyzing is confidential and privileged.

(d) The team will have a designated leader and facilitator.

(e) The team will receive advisory support from the Patient Safety Manager.

(f) The team will be provided with the resources necessary to complete their assigned task. (i.e., work space, time, and equipment).

(5) Once the team is appointed, they follow the RCA process (Attachment D) as outlined by the NCPS and guided by the automated SPOT software. The team meets the parameters discussed earlier in this policy regarding the characteristics, guidelines, credibility, and thoroughness of an RCA.

(a) If, during the course of conducting an RCA, it appears that the event under review is the result of an intentionally unsafe act, the RCA team will refer the event to the Director for appropriate further consideration as is noted under 3(f), Intentional Unsafe Acts. In such a situation, the RCA team discontinues their efforts, since the Director has assumed the responsibility for any further fact-finding or investigation.

1. The information already collected by the RCA team must remain confidential as per 38 USC 5705. This means that the members of the RCA team in question could not serve on an Administrative Investigation Board regarding this particular issue.

2. If an RCA is discontinued for any reason, the reason and final disposition of the case must be recorded and entered into the SPOT software program.

(b) The team members will provide and obtain feedback from the individual who submitted the report of the adverse event or close call. The feedback should focus on the actions resulting from the RCA.

(c) Prior to completing the RCA process, the team should consult with appropriate service chiefs and services to discuss the team's findings and the rationale and viability of potential recommendations to eliminate, control, or accept the root causes of the event as identified.

(d) The team must then obtain the concurrence of the Chief of Staff and Director on the action plan.

(e) Once Leadership concurrence is complete, the RCA is transmitted to the NCPS via SPOT software.

(6) Aggregate reviews will be completed according to the NCPS schedule for falls, medication errors, and missing patient events that have been rated as a "potential 3" based on the SAC matrix. Collection and collation of information for aggregate reviews is the primary responsibility of the Patient Safety Manager.

(a) Reviews are completed by a chartered RCA team.

(b) Upon receipt of the patient event reports an aggregate review log will be compiled by the Patient Safety Manager for the events identified above and provided to the team as the initial data base when they are convened.

(c) The aggregate review log is based on real time minimum data sets that are captured during each quarter.

(d) The team will complete the aggregate review log and add information as is necessary and will complete the Root Cause Analysis Form contained in SPOT.

(e) Once Leadership concurrence is complete, the aggregate RCA is transmitted to NCPS via SPOT software.

(7) The Patient Safety Manager will ensure that RCAs and other related reviews are completed and submitted according to established timeframes, as follows:

(a) Individual RCAs are due to the NCPS within 45 days of the facility's awareness date.

(b) Aggregate RCAs are due to the NCPS at these established times:

- Falls: Monitoring period October through September - due December 1
- Missing Patients: Monitoring period January through December - due March 1
- Drug Events: Monitoring period April through March - due June 1

(c) RCAs for sentinel events reported to the TJC are due to the VISN office within 40 calendar days following the initiation of the event report. This will allow time for consultation with the VISN Chief Medical Officer and approval of the Network Director prior to the final submission to TJC.

(d) Administrative Investigation Boards are due to the VISN within 45 calendar days following the initiation of the charter memo from the Director. The document submitted should be a summary document. Testimony and exhibits should not be forwarded to the VISN. The Director's concurrence and comments must be included with the submission.

d. **Reporting requirements external to VHA**. Use of Safety Alert and Advisory Information (discussion of Safety Alerts, Employee Alerts, and Safety Advisories will be referred to as Safety Alerts in the following procedure):

(1) Response to safety alerts:

(a) Safety alerts are developed and forwarded to all VHA facilities to prevent adverse outcomes based on current experiences. These safety alerts may be generated by the VISN, VHA Headquarters, TJC, or other agencies such as Institute for Safe Medical Practices (ISMP), etc.

(b) The Patient Safety Manager will advise the individuals “who need to know” about the alert as soon as possible via e-mail, develop a plan of action, and implement the plan.

(2) Generation of safety alerts and identification of other internal safety issues:

(a) Employees are encouraged to provide input on improvements that will enhance patient safety, as well as sharing significant issues that place patients at risk so that this information can be analyzed and acted upon. This may be done through a variety of methods including discussion at service staff meetings, presenting issues to the supervisor, talking directly to the Patient Safety Manager or Risk Manager, presenting to the Patient Safety Committee through one of its members, or reporting via the close call system. Periodically, surveys will be done of both employees and patients to gather information regarding their perception of risks.

(b) The Patient Safety Manager will report through electronic mail to the VISN Chief Medical Officer or VISN Patient Safety Officer any information that is felt to have broader implications in regards to patient safety.

(c) The VISN Chief Medical Officer will determine if this information should be shared VISN wide. If a determination is made to share the information, an “expert” will be identified from within the reporting medical center to answer questions regarding the information shared.

(d) The VISN PSO will notify NCPS of any information shared by a medical center so they may investigate the issue and use the information nationally, as appropriate.

e. **Proactive Risk Assessment**

(1) The medical center will use the Healthcare Failure Effects and Analysis (HCFMEA) Model to identify high-risk processes for proactive risk assessment each year. The number of HCFMEAs performed will be based on the medical center’s needs and will meet, at a minimum, the number of HCFMEAs required by regulating agencies. The selection of high risk processes will be based on:

(a) Information published periodically by the TJC that identifies the most common occurring types of sentinel events.

(b) Safety events and high-risk processes identified and recommended for annual review by the NCPS.

(c) Information gleaned from the VISN 4 PSO annual patient safety report.

(d) Individual medical center information obtained from completed root cause analyses, administrative investigation boards, tort claims, and management input, etc.

(2) Above topics will be collected by the Patient Safety Manager. Then, utilizing a standardized prioritization grid, a hazard vulnerability analysis team will identify high risk processes to evaluate. Results will be presented to the Patient Safety Committee and to Leadership Staff Council with recommendations on high risk processes to evaluate.

(3) A HCFMEA team will then be selected and appointed by the Director to complete the HCFMEA. To complete the HCFMEA, the NCPS guidelines will be followed. The steps to this process include:

(a) Defining the topic

(b) Assembling the team

(c) Graphically describing the process

(d) Conducting a hazard analysis

(e) Developing actions and outcome measures

7. **REFERENCES**:

a. VISN 4 Policy Memorandum 10N4-04, Patient Safety Improvement Program, dated 5/8/12

b. VISN 4 Policy Memorandum 10N4-23, Risk Management Program, dated 8/20/10

c. VHA Handbook 1050.1, VHA National Patient Safety Improvement Handbook, date 3/4/11

d. The Joint Commission Comprehensive Accreditation Manual

e. MCM 11-04, Disclosure of Adverse Events, dated October 2011.

8. **RECISSIONS**: MCM 00Q-28, Patient Safety Improvement Program (PSIP), dated November 2009.

9. **REISSUE DATE**: Three years from date of MCM

10. **FOLLOW-UP RESPONSIBILITY**: Patient Safety Manager

/s/
William H. Mills
Director

17. MCM 00Q-28, Patient Safety Improvement Program (PSIP)

Attachments A-D

Distribution: E

ATTACHMENT A

Events that Require Completion of an event report.

Inpatient Suicide – An act of intentionally killing oneself (All enrollees).
Sexual Assault – Includes sexual assault with or without penetration regardless of gender.
Alleged Patient Abuse - Acts against a patient, which involves physical, psychological, sexual, 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. Allegations of patient abuse may include any of the following: (a) Any action or behavior that conflicts with patient's rights as outlined in 38 CFR, section 17.34a; (b) Intentional omission of patient care; (c) Willful violation of the privacy of the patient(s); (d) Intimidation, harassment, or ridicule of the patient(s); (e) Willful physical injury of a patient. **Patient Abuse** – Allegation deemed valid by investigation.
Fall – An event, witnessed or not witnessed, 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 include blood or blood products. The reports are also to be included in the blood usage review process. **NOTE**: Idiosyncratic reactions to blood or blood products are not a reportable incident unless an error as previously described, was involved.
Adverse Drug Event (ADE) – The use or nonuse of a drug that causes injury to a patient.
Adverse Reaction to Drug/Anesthesia – Anaphylaxis or other adverse reactions seriously affecting the well being of the patient. (Level 2 and 3 adverse reaction to drug only; Level 0 and Level 1 reactions are reported through the Pharmacy ADE system. All reactions to anesthesia).
Incident Not Otherwise Listed – Any incident involving a patient not specifically addressed in other categories. It should be noted that acts of self-mutilation or abuse inflicted by a patient when not considered suicidal behavior would be included. This includes procedural complications.
Patients Involved in Fire - 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 the injury scale should only be applied to the patient that was assaulted. The severity of injury scale. (If the assaulter is injured, data for that patient should be entered as #12 - Incident not otherwise listed. There is no data entry for the assaulter otherwise). Regardless of the number of patients involved, an electronic patient event report is to be completed for each patient assaulted. This will allow a severity of injury assessment to be assigned to each patient assaulted. Rape or homicide should be reported only in those categories.
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 a patient or an outpatient (within 30 days of treatment) which is not attributable to the course of the patient's disease or a therapeutic misadventure. Reportable deaths are those which occur in the procedure clinic in the recovery room, during induction of anesthesia or conscious sedation (including in procedure rooms), within 48 hours of surgery, due to, during or within 24 hours of a procedure, due to equipment malfunction or during use of a medical device; reportable to and accepted by the medical examiner; of patients who are on the medical center grounds but not necessarily being treated at the time. Do Not Resuscitate (DNR), Do Not Intubate (DNI), and Comfort Measures Only (CMO) is not reportable unless death is due to something other than the patient's diagnosis/illness as described.
Missing Patient – Any patient who is considered absent whose location is not known. High risk patients (those who are legally committed, have a court appointed legal guardian, are considered to be a danger to themselves or others, lack the cognitive ability to make decisions, or have a history of escape or elopement) are considered to be missing as soon as their absence is noted. Low risk patients (patients who have been clinically assessed to have intact decision making ability and are minimal risk for harm due to cognitive and physical abilities) are considered to be missing if their location is not known within timeframes established at the local facility.
Reaction to Blood/Blood Products – 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.
Device Related - An adverse event to the patient due to malfunction of any medical device (medical device is defined as any instrument, apparatus or other article that is used to prevent, diagnose, mitigate or treat a disease or to affect the structure or function of the body excluding drugs).
Miscellaneous – Individual medical center determination for events not meeting above definitions and useful to track.

LEVEL OF INJURIES FOR PATIENT INCIDENT REPORTS

Level 0 - No injury or disability

Level 1 - Minor (injuries are minor in nature, and do not require any medical intervention or do not extend the patient's hospital stay except for observation to obtain diagnostic results). Examples are: (a) fractures of fingers and toes (i.e., phalanges, carpals, metacarpals, tarsals, and metatarsals); (b) bruises; (c) abrasions; (d) lacerations not requiring more than 12 sutures; (e) choking; (f) bites/stings; (g) burns (one cigarette; those less that 1% of body surface and 3rd degree smaller than ½" x ½").

Level 2 – Major (injuries which require medical or surgical intervention, increase hospital stay or are disabling/disfiguring to a degree that the patient will have any degree of permanently lessened function or require surgical intervention). Examples are: (a) laceration – those that require more than 12 sutures or with damage to vital structures(s); (b) fractures of: large bones (femur, tibia, fibula, humerus, radius, ulna); pelvis, vertebrae; ribs (multiple or a single rib where there is a significant problem such as pneumothorax or significant hemothorax); (c) burns – those that are more than 1% of body surface (i.e., size of the palm) or 3rd degree burns that are more than ½" x ½" (excludes one cigarette burn); (d) other – injuries requiring medical intervention (does not include minor injuries, as listed above).

Level 3 – Death

ATTACHMENT B

IDENTIFICATION AND REPORTING OF CLOSE CALLS

The best way to **prevent** accidents is to correct hazardous conditions before they result in injury, illness, or damage. Studies have shown that for every serious injury, there are 300 close calls. Reporting close calls gives us a chance to correct hazardous situations.

A **Close Call** is an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Such events have also been referred to as **Near Miss** incidents. Close Calls can involve patients, staff, or visitors. Close Calls can occur in patient care settings and **anywhere** else in a VA facility.

EXAMPLES OF CLOSE CALLS:

A nurse almost gives an overdose of insulin, but recognizes and prevents the error when double-checking the order. (During the double check, they realize that they had confused the “U” for units, with a “0”).

A day care worker notices a jug of industrial strength cleaner mistakenly left in the bathroom of a restroom in the Day Care Center. The day care worker returns it to the proper storage area before a child could open it and use it inappropriately.

On the way to the parking lot, a motor pool employee notices that a barricade, preventing anyone from using a sidewalk under repair, has fallen down, and been shoved aside. The employee replaces the barricade and then notifies Facilities Service of the hazardous situation before anyone trips and falls (Emergency Work Order Program).

WHAT A CLOSE CALL IS NOT:

Events or situations that are handled through administrative review or investigation.

These excluded events or situations are:

1. intentionally unsafe acts;

2. criminal acts;

3. acts related to alcohol or substance abuse, impaired provider/staff; and

4. events involving alleged or sustained patient abuse.

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HOW TO REPORT A CLOSE CALL:

If the close call happens in a patient care area, you have the option to report a Close Call through the Electronic Patient Event Reporting System and/or a Close Call Form.

If it is an emergency situation that needs **immediate** attention, you may call the appropriate supervisor, Facilities emergency number (extension 7314), Risk Manager, Patient Safety Manager, Safety Manager, or VA Police.

You may also use the Close Call Reporting Form available on all patient care areas and workstations.

You will be asked to:

1. describe what happened;

2. where and when it happened; and

3. how to fix or prevent it from happening in the future.

You may submit the form anonymously or if you sign your name and telephone number. This will assure that you will receive “direct” feedback on action to be taken, from the Risk Manager, Patient Safety Manager, or Safety Manager.

ATTACHMENT C

SAFETY ASSESSMENT CODE (SAC) MATRIX

Probability		Severity			
		Catastrophic	**Major**	**Moderate**	**Minor**
	Frequent	3	3	2	1
	Occasional	3	2	1	1
	Uncommon	3	2	1	1
	Remote	3	2	1	1

How the SAC Matrix Works
When you pair a severity category with a probability category for either an actual event or close call, you will get a ranked matrix score; highest risk = 3, intermediate risk = 2, and lowest risk = 1.

These ranks, or Safety Assessment Codes (SAC), can then be used for doing comparative analysis.

Severity Categories: Key factors for the severity categories are: extent of injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs. These categories apply to actual adverse events and potential events (close calls). For actual adverse events, assign severity based on the patient's actual condition. If the event is a close call, assign severity based on the most likely "worst case", systems level scenario.

Catastrophic	Major
Patients with Actual or Potential: 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) • Suicide (inpatient or outpatient) • Rape • Hemolytic transfusion reaction • Surgery/Procedure on the wrong patient or wrong body part • Infant abduction or infant discharge to the wrong family Death or major permanent loss of function that is 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 **Visitors and Staff** Death; or hospitalization of three or more (includes outpatients) **Fire** Any fire that grows larger than an incipient stage	**Patients with Actual or Potential:** 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) • Disfigurement Surgical intervention required • Increased length of stay of more than three patients • Increased level of care for more than three patients **Visitors** Hospitalization of one or more visitors requiring evaluation and treatment **Staff** More than three lost time or restricted duty injuries or illnesses **Equipment or facility** Damage more than $100,000
Moderate	**Minor**
Patients with Actual or Potential: Increased length of stay for one or two patients; or increased level of care for one or two patients **Visitors** Evaluation and treatment for one or two visitors **Staff** Medical expenses, lost time or restricted duty injuries or illnesses for one or two staff **Equipment or facility** Damage more than $10,000 but less than 100,000 **Fire** Incipient stage or smaller (incipient fire is smaller than burning waste paper basket)	**Patients with Actual or Potential:** No injury, increased length of stay, or increased level of care **Visitors** Evaluated and no treatment required or refused treatment **Staff** No lost time or restricted duty injuries or illnesses **Equipment or facility** Damage less than $10,000

Probability: In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs at the facility. Sometimes the data will be easily available because it is routinely tracked. Sometimes getting a feel for the probability of events which are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

- **Frequent** – Likely to occur immediately or within a short period of time (may happen several times in one year)
- **Occasional** – Probably will occur in time (may happen several times in one to two years).
- **Uncommon** – Possible to occur in time (may happen sometime in two to five years).
- **Remote** – Unlikely to occur (may happen sometime in 5 to 30 years).

ATTACHMENT D

Simplified View of the Root Cause Analysis (RCA) Process