DEPARTMENT OF VETERANS AFFAIRS
Office of the General Counsel
Washington DC 20420

JUL 12 2010

In Reply Refer To:

William E. Reukauf
Acting Special Counsel
U.S. Office of Special Counsel
1730 M Street NW
Suite 300
Washington, D.C. 20036-4505
Attn: Catherine A. McMullen, Chief, Disclosure Unit

RE: OSC File No. DI-09-3272

Dear Mr. Reukauf:

This is in response to the July 6, 2010, request by Ms. Siobhan Smith and Ms. Catherine McMullen of your staff that the Department of Veterans Affairs (VA) provide additional information to supplement the report on allegations of improper cleaning and sterilization of reusable medical instruments and failure of management officials to initiate actions to address the practice at the G.V. Sonny Montgomery Medical Center, Jackson, Mississippi (OSC File No. DI-09-3272). Specifically, we were asked to provide more information on how and why the determination was made by the Pre-Clinical Risk Assessment Advisory Board (Pre-CRAAB) that the risk of patient exposure to blood-borne pathogens was negligible and that veterans do not need to be notified of possible exposure in this case. We also were asked to provide the particular metric, if any, which was used for the Pre-CRAAB assessment.

Enclosed is a copy of the minutes for the Pre-CRAAB meeting, dated February 5, 2010. Also enclosed is a copy of VHA Directive 2008-002 (January 18, 2008), Disclosure of Adverse Events to Patients.

Please let us know if we can be of further assistance.

Sincerely yours,

Walter A. Hall
Assistant General Counsel

Enclosures

MEMORANDUM FOR RECORD

Date: February 5, 2010

Issue: Pre-CRAAB Meeting – Report of Investigation to the US Office of Special Counsel
Jackson VAMC, MS – VISN 16

Participants:
Robert Jesse, MD, Acting PDUSH (10A)
William Duncan, MD, PhD, 10G
Patricia Murray, RN, MSN (representing L. O'Grady, 10A)
Gary Roselle, MD, National Program Director, Infectious Disease (111)
Ronald Valdeserri, MD, Public Health & Environmental Hazards (113)
Jeffrey Robbins, DPM, National Program Director, Podiatry
Rosie Fardo, RN, Infectious Disease Program Office
Tommy Stewart, Patient Care Services
Lori King, Biomedical Engineer, NCPS (10X)
Oyweda Moore, 10G
Yuri Walker, 10Q
Odette Levesque, 10N

VISN/Medical Center Participants
VISN 16
Gregg Parker, MD, CMO
Mary Jones, EA to the CMO, VISN 16

Sonny Montgomery VA Medical Center, Jackson, MS:
Linda Watson, Medical Center Director
Kent Kirchner, MD, Chief of Staff
Shannon Novotny, Associate Director
Dr. Dorothy White-Taylor, Associate Director of Patient Care Services
Rathel Nolan, MD Hospital Epidemiologist.
Nirmala Rozario, MD Associate Chief, Performance, Productivity, Efficiency
Chad Butler, Quality Management Program Analyst
Leola Kirsh, Deputy Associate Director of Patient Care Services
Risa Webb, MD, Infection Control Physician
Mimi Spruill, Infection Control Nurse
Ava Abney, Chief, Quality Management

Summary of Discussion:
The Pre-CRAAB was called to discuss the VHA investigation findings triggered by an anonymous complaint to the Office of Special Counsel. The following areas from the investigation were scheduled for discussion:

- OR-PACU
- Radiology/Vascular Procedure Suite

- Podiatry
- SPD

Facility Medical Center Director provided an overview of events leading to the pre-CRAAB.
OR-PACU – The OR has had issues with dirty instruments about once a month. There is no evidence that the quality control measures in the OR failed to identify the soiled instruments before they were used on a patient. This issue is being tracked in the facility OR Committee. There were no patients at risk; Acting PDUSH stated that no disclosure was required.

Radiology/Vascular Procedure Suite – NCPS reported that the facility is following manufacturer instructions for the Ultrasound vaginal probe but that it was not properly documenting. There were no patients at risk; Acting PDUSH stated that no disclosure was required.

Podiatry – The VHA investigation team had concerns about the podiatry reprocessing standards that were used in the facility from December 1999 – June 2006. During that period, nail clippers (nippers) were reused between patients after being wiped off with a germicidal wipe rather than sterilization. The facility podiatrists stated that the podiatry nippers were checked after each use and were sent for sterilization if contaminated with blood. The facility reported that 1,129 patients were examined during this period and that in the range of 1-2% had observable blood. Approximately 91% of the patients were being seen for nail debridement. Ninety-five percent of the patients in the cohort are still being followed at the medical center or are deceased.

Dr. Robbins stated that it has been VA policy since the early 2000's to reprocess instruments between patient uses. He said that he was unable to find any reported outbreaks of clusters of infections from podiatry procedures in the medical literature. Dr. Roselle and Dr. Robbins agreed that the risk to patients for bloodborne pathogen exposure was negligible. Acting PDUSH concurred that no disclosure was required.

SPD – There have been long standing issues with SPD and the reprocessing of RME at the facility. However, the facility has been implementing an action plan to address the problems such as inadequate staff training, quality and quantity instruments, etc. There was no evidence of patients being at risk that would necessitate a large scale disclosure.

Pre-CRAAB Decision:

- Acting PDUSH decided that a CRAAB will not need to be convened regarding the events at the Jackson VAMC
- The Jackson VAMC does not need to conduct a large scale disclosure regarding this event

- Continue implementation of Actions Plan initiated in response to investigation triggered by OSC complaint

Recorder
Yuri N. Walker, RN, JD, MPH
Director, Risk Management Program (10Q)

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 2008-002

January 18, 2008

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy pertaining exclusively to the disclosure of adverse events, related to clinical care, to patients or their personal representatives. ***NOTE:*** *Information pertaining to adverse events in research can be found in VHA Handbook 1200.5 and VHA Handbook 1058.01.*

2. BACKGROUND

a. VHA facilities and individual VHA providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future.

(1) The patient is free to involve family members in the disclosure process.

(2) If the patient is deceased, incapacitated, or otherwise unable to take part in a process of adverse event disclosure, the process needs to involve the patient's personal representative and anyone who is designated by the personal representative.

b. Disclosure of adverse events to patients or their personal representatives is consistent with VHA core values of trust, respect, excellence, commitment, and compassion. Providers have an ethical obligation to be honest with their patients. Honestly discussing the difficult truth that an adverse event has occurred demonstrates respect for the patient, professionalism, and a commitment to improving care.

c. Clinicians and organizational leaders are to work together to ensure that appropriate disclosure to patients or their personal representatives is a routine part of the response to a harmful or potentially harmful adverse event. Telling patients or their personal representatives about adverse events, or potentially harmful adverse events, is never easy, however, it needs to be done and with skill and tact.

d. Disclosure of adverse events and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients according to this Directive in no way obviate the need to report adverse events (and close calls) as required under VHA Handbook 1050.01. Internal reporting through the adverse event and close call reports are protected from disclosure under Title 38 United States Code (U.S.C.) Section 5705. Records protected under 38 U.S.C. Section 5705, that is, quality management and safety activities records, may not be subsequently used as the source of information communicated in the disclosure of an adverse event.

THIS VHA DIRECTIVE EXPIRES JANUARY 31, 2013

NOTE: *This Directive is consistent with The Joint Commission requirement that patients and, when appropriate, their families be told of "unanticipated outcomes" of care (Standard - Ethics, Rights, and Responsibilities (RI) 2.90, 2006).*

e. Despite the general obligation to disclose adverse events to patients, there are legal restrictions on the information that can be shared. The information communicated to the patient comes from those involved in the adverse event and from factual information in the patient's medical record.

(1) Confidentiality statutes and regulations, such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, limit disclosure of any record containing a patient's personal information to others without the patient's authorization or other legal authority. ***NOTE:*** *The patient's personal representative is authorized to have access to the patient's protected health information except as noted in this subparagraph and subparagraph 2e(2) (see VHA Handbook 1605.1).*

(2) Under 38 U.S.C. Section 7332, VHA may not disclose information related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, or infection with the Human Immunodeficiency Virus (HIV) to others, even after a patient's death without a "special authorization" or other exception. Questions about release of such information in the case of an adverse event are to be referred to the facility's Privacy Officer. ***NOTE:*** *Consultation with VHA's Privacy Officer may also be necessary.*

(3) Under 38 U.S.C. Section 5705, VHA may not communicate to patients, or their personal representatives, information that is obtained from documentation of certain quality management activities, such as root cause analyses or patient safety registry records. Rather, the information communicated must come from those involved in the adverse event and from factual information in the patient's medical record. ***NOTE:*** *Specific questions regarding sources of information that may not be disclosed or released to the patient or representative may be found in VHA Handbook 1605.1. Other guidance is available from VHA's Privacy Officer.*

f. **Definitions**

(1) **Adverse Event.** 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. ***NOTE:*** *To determine which incidents need to be considered for Root Cause Analysis, the definition of adverse event in the VHA Handbook 1050.01 is be used.*

(2) **Disclosure of Adverse Events.** For the purpose of this Directive, the phrase "disclosure of adverse events" refers to the forthright and empathetic discussion of clinically significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. VA recognizes three types of disclosure of adverse events:

(a) Clinical Disclosure of Adverse Events. Clinical Disclosure of Adverse Events is an informal process for informing patients or their personal representatives of harmful adverse events related to the patient's care. In a clinical disclosure, one or more members of the clinical team provides factual information to the extent it is known, expresses concern for the patient's welfare, and reassures the patient or personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. The clinical disclosure of adverse events is considered a routine part of clinical care, and needs to be made by the attending or senior practitioner, or designee. Additional guidance on what must be disclosed, when, and how is provided in Attachment A.

(b) Institutional Disclosure of Adverse Events. In cases resulting in serious injury or death, or those involving reasonably expected serious injury, or potential legal liability, a formal process is needed; this process is called institutional disclosure of adverse events. Institutional disclosure of adverse events should not take place until organizational leaders, including, as appropriate, the facility Director, Chief of Staff, Nurse Executive, and members of the treatment team, have conferred with Regional Counsel and addressed what is to be communicated, by whom and how. In an institutional disclosure the patient(s) or personal representative(s) and any family member(s) designated by the patient or personal representative are invited to meet with institutional leaders and others, as appropriate. An apology is made, and information about compensation and procedures available to request compensation is provided, when appropriate. Additional guidance on what must be disclosed, when, and how is provided in Attachment A. Documentation of institutional disclosure using the Computerized Patient Record System (CPRS) template is mandatory (see Att. B).

(c) Large Scale Disclosure of Adverse Events. "Large scale" is defined as involving a large number of patients, even if at a single facility. For large scale disclosures of adverse events, collaboration with Department of Veterans Affairs (VA) Central Office is required for evaluation and planning. Decisions regarding large scale disclosure of adverse events will be made by the Principal Deputy Under Secretary for Health and may include consultation with the Clinical Risk Assessment Advisory Board (CRAAB). ***NOTE:*** *Additional guidance on large scale disclosure is provided in Attachment C.*

(3) **Patient's Personal Representative.** A personal representative of the individual is any person(s) who, under applicable law, has the authority to act on behalf of the individual when making decisions related to health care or to act on behalf of a deceased individual. The personal representative of an individual has the ability to exercise the individual's rights. A personal representative for the purposes of this Handbook does not necessarily equate to a surrogate for the informed consent process (see Title 38 Code of Federal Regulations (CFR) §17.32(e) for authorized surrogates for informed consent; see VHA Handbook 1605.1 for details on personal representatives).

(4) **The Clinical Risk Assessment Advisory Board (CRAAB).** The CRAAB is a VA Central Office board which will be convened at the request of the Deputy Under Secretary for Health for Operations and Management (10N) in response to actual or potential adverse events which may not be limited to a small number of patients, especially "large-scale" disclosures as defined in subparagraph 2f(2)(c). Notification of VA regarding the potential need for large scale

disclosure does not eliminate the requirement for adverse event reporting and follow-up as described in VHA Handbook 1050.01.

3. POLICY: It is VHA Policy that disclosure of adverse events that cause harm to patients to be routine practice.

4. ACTION

a. **Facility Director.** The facility Director is responsible for:

(1) Ensuring that VHA health care providers communicate, as appropriate, harmful adverse events openly and promptly with patients and/or patients' personal representatives and that, when necessary, the process for large scale adverse event disclosure is appropriately initiated.

(2) Ensuring the facility policy on disclosure of adverse events to patients is in alignment with this Directive by September 30, 2008.

(3) Promoting a ethical health care environment in which appropriate disclosure of adverse events becomes routine practice.

(4) Ensuring that clinical staff are aware of this Directive and the local facility policy, and implementing them. ***NOTE:*** *Practitioners are encouraged to confer with the local ethics consultation service, their Service Chief, Chief of Staff, Nurse Executive, Regional Counsel, Risk Manager, or Patient Safety Manager to clarify any concerns about how best to communicate this information and what adverse events are applicable to the disclosure of adverse event process.*

(5) Ensuring that staff members involved in adverse events and subsequent disclosure processes are provided with adequate support systems and ensuring that staff members are aware of them.

(6) Ensuring that adverse events are appropriately disclosed in collaboration with the Chief of Staff, Risk Manager, Nurse Executive and the treatment team. Appropriate disclosure includes the following:

(a) Ensuring that as part of the disclosure process, patients or their personal representatives are offered appropriate options, such as arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the adverse event.

(b) Ensuring that veteran patients or their personal representatives are made aware of their rights under 38 U.S.C. Section 1151, made aware of the Tort Claim process, and provided information concerning the necessary forms.

(c) Ensuring that adverse events that may require large scale patient disclosures are thoroughly documented and communicated to the VISN Director.

(7) Ensuring that adverse events are documented in CPRS.

(a) Institutional disclosures must utilize the "Disclosure of Adverse Event Note" template (see Att. B). Specific documentation in CPRS is not required for all clinical disclosures, as some clinical disclosures may be considered a part of routine care; however, for significant adverse events, it is appropriate to document the clinical disclosure of an adverse event, in a progress note or using the "Disclosure of Adverse Event Note" template.

(8) Ensuring the VISN Director and the Deputy Under Secretary for Health for Operations and Management are informed of any significant, critical, urgent adverse events.

b. **Risk Manager or Patient Safety Manager.** The Risk Manager or Patient Safety Manager is responsible for:

(1) Immediately notifying the Nurse Executive, Chief of Staff, or Facility Director about the discovery of a significant adverse event that is brought to their attention, especially those that may require institutional disclosure or a decision regarding a large scale disclosure of adverse events.

(2) Establishing a regular dialogue with Regional Counsel and requesting that Regional Counsel educate providers as needed about the legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.

c. **Chief of Staff and Nurse Executive.** The Chief of Staff and Nurse Executive are responsible for:

(1) Immediately notifying the Facility Director about the discovery of a significant adverse event that is brought to their attention.

(2) Participating in discussions with others, e.g., clinicians, facility top management team, Regional Counsel, VISN staff, patients, or personal representatives, as appropriate, concerning the adverse event.

d. **The Veterans Integrated Service Network (VISN) Director.** The VISN Director, or designee, is responsible for:

(1) Promoting an ethical health care environment in which appropriate disclosure of adverse events becomes routine practice.

(2) Ensuring that a collaborative relationship between Regional Counsel and VA medical center staff is established to ensure appropriate and timely disclosure of adverse events to patients.

(3) Ensuring that adverse events that may require large scale patient disclosures are thoroughly documented and communicated to the Office of the Deputy Under Secretary for Health for Operations and Management.

e. **Deputy Under Secretary for Health for Operations and Management (10N).** The Deputy Under Secretary for Health for Operations and Management is responsible for reviewing those adverse events that may require large scale adverse event disclosures to determine if the adverse event needs to be sent to the CRAAB for its review and recommendations. If there are clinical issues, consultation with the Chief Consultant, Medical-Surgical Service of Patient Care Services and other senior officials may be necessary to assist in the decision making process.

f. **The Clinical Risk Assessment Advisory Board (CRAAB)**

(1) The CRAAB is made up of appropriate representatives from the Office of the Deputy Under Secretary for Health for Operations and Management, National Center for Ethics in Health Care, Office of Nursing Services, Office of Quality and Performance, National Center for Patient Safety, Office of Patient Care Services, and Office of Public Health and Environmental Hazards, as well as subject matter experts from VHA or non-VA experts as needed.

(a) The CRAAB is chaired by the Chief Officer for Public Health and Environmental Hazards, or designee, with close collaboration with the Office of Patient Care Services' Chief Consultant, Primary Care, or the Chief Consultant for Pharmacy Benefits Management, as appropriate to the particular event.

(b) The board is convened at the request of the Deputy Under Secretary for Health for Operations and Management as needed. The Chief Officer for Public Health and Environmental Hazards is responsible for leading, organizing, and implementing any required VHA "lookback" program performed as part of, or following, a large-scale disclosure to patients.

(2) The CRAAB is responsible for:

(a) Conducting, for each request by the Deputy Under Secretary for Health for Operations and Management, a decision process based on organizational, ethical, and clinical risk considerations outlined in Attachment C.

(b) Establishing and communicating the evaluation factors to be used to determine population risk. ***NOTE:*** *One example for the Clinical Risk Assessment Advisory Board to use as a starting point is provided in the Matrix and Flow Chart in Attachment C.* Depending on the event, factors may include evaluation and estimation of:

1. The population at risk of the adverse event or a potential adverse event,

2. The potential severity of the outcomes,

3. The probability of these outcomes, and

4. How to integrate other factors germane to the impact on the population at risk.

(c) Providing recommendations and documentation to the Principal Deputy Under Secretary for Health regarding the necessity of a large scale disclosure.

(d) Providing recommendations and documentation to the Principal Deputy Under Secretary for Health, if a large scale disclosure is approved, on how it should conducted and serve in an advisory role to the individual or group assigned to conduct the actual disclosure.

g. **The Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health makes the decision concerning large scale adverse event disclosures and communicates that decision to the Deputy Under Secretary for Health for Operations and Management with a copy to the Chair, CRAAB.

5. REFERENCES

a. American Society for Healthcare Risk Management of the American Hospital Association. "Disclosure of Unanticipated Events: The Next Step In Better Communication With Patients," May 2003.

b. American Society for Healthcare Risk Management of the American Hospital Association. "Disclosure of Unanticipated Events: Creating An Effective Patient Communication Policy," November 2003.

c. American Society for Healthcare Risk Management of the American Hospital Association. "Communication: What Works Now and What Can Work Even Better," February 2004.

d. JCAHO Accreditation Manual for Hospitals, Ethics, Rights and Responsibilities, RI 2.90, 2006.

e. JCAHO Accreditation Manual for Hospitals, Leadership Standards, LD 4.40, 2006.

f. VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act.

g. VHA Handbook 1050.01.

h VHA Handbook 1004.1.

j. VHA Handbook 1605.1.

k. VHA National Ethics Committee Report, "Disclosing Adverse Events to Patients," March 2003. http://vaww1.va.gov/vhaethics/download/AdverseEventsReport.doc

6. FOLLOW-UP RESPONSIBILITY: The Deputy Under Secretary for Health for Operations and Management (10N), the National Center for Ethics in Health Care (10E), and Patient Care Services (11) are jointly responsible for this Directive. Questions about operational issues may

be addressed to (202) 273-5852. Questions about the ethical content may be addressed to (202) 501-0364.

7. **RESCISSION:** VHA Directive 2005-049 is rescinded. This Directive expires January 31, 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 1/23/08
FLD: VISN, MA, DO, OC, OCRO, and 200 E-mailed 1/23/08

ATTACHMENT A

WHAT ADVERSE EVENTS WARRANT DISCLOSURE? WHEN SHOULD DISCLOSURE OF AN ADVERSE EVENT OCCUR? HOW SHOULD ADVERSE EVENTS BE COMMUNICATED?

1. WHAT ADVERSE EVENTS WARRANT DISCLOSURE?

a. 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 Veterans Health Administration (VHA) facility. For an adverse event that has the apparent potential to affect, or may have already affected patients at more than one VHA field facility, or affects a significant number of patients, or involves significant actual or potential severity the process for large scale disclosure must be followed. The process is based on ethical and clinical considerations as outlined in Attachment C.

b. For all other adverse events, patients or their personal representatives must be informed of the occurrence of any adverse event that has resulted in, or can be expected to result in, harm to the patient, including the following:

(1) Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output), disclosure is required because a perceptible effect is anticipated to occur.

(2) Adverse events that necessitate a change in the patient's care. For example, a medication error that necessitates extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or a surgical procedure that necessitates further (corrective) surgery.

(3) Adverse events with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small. For example, a known, accidental exposure of a patient to ionizing radiation, a toxin, an organism, or infectious entity associated with a rare, but recognized serious short-term or long-term effect (e.g., bloodborne pathogen infection or increased incidence of cancer). In some cases, however, no definite exposure of this type can be determined. Only an increased risk of exposure is known or thought to exist. In such cases, disclosure should be decided on a case by case basis considering the best interests of the patient, weighing the risks and benefits of disclosure relative to the probability of serious future health consequences.

(4) Adverse events that require providing a treatment or procedure without the patient's consent. For example, if an adverse event occurs while a patient is under anesthesia, necessitating a deviation from the procedure the patient expected, the adverse event needs to be disclosed. Patients have a fundamental right to be informed about what is done to them and why.

c. Disclosure of other adverse events is optional and at the discretion of the providers involved. Cases need to be considered individually and in relation to the specific circumstances.

d. Disclosure of "close calls" to patients is also discretionary, but is advisable at times, such as when the patient or family becomes aware that something out of the ordinary has occurred. For example, a nurse sets a patient up for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, abruptly stops the transfusion just before the blood enters the patient's vein. The patient deserves an explanation, even if this is not considered a clinical disclosure of adverse events. ***NOTE:*** *Although the disclosure of a close call to the patient is optional, reporting it is required under VHA Handbook 1050.01*

2. WHEN SHOULD DISCLOSURE OF AN ADVERSE EVENT OCCUR?

Optimal timing of disclosure of adverse events varies with the specific circumstances of the case. If a patient needs urgent treatment to minimize injuries resulting from an adverse event, clinical disclosure must occur quickly. If immediate corrective action is not required, disclosure may be delayed, but only long enough to give staff members time to collect preliminary information and plan the best way to disclose. For patients who are aware of, or suspect, an adverse event, more time prior to disclosure may increase the chance for patients to have anxiety and suspicion, and decrease the patient's trust of VHA health care providers and management.

a. Clinical disclosure of an adverse event must occur within 24 hours of a practitioner's discovery of the adverse event if adequate information is available.

b. Institutional disclosure of an adverse event must take place as soon as possible (generally within 24 hours, but no more than 72 hours if adequate information is available) after a practitioner's discovery of the adverse event.

c. For large scale adverse event disclosure, adequate time is necessary for evaluation and planning in collaboration with the Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Operations and Management, and the Clinical Risk Assessment Advisory Board (CRAAB). In these cases the disclosure process should start within 30 days after the Chairperson, Clinical Risk Assessment Advisory Board has accepted the adverse event(s) for review, unless extension is granted by the Principal Deputy Under Secretary for Health.

3. HOW SHOULD ADVERSE EVENTS BE COMMUNICATED?

a. **Clinical Disclosure of Adverse Events.** In general, communication about an adverse event done as a clinical disclosure of an adverse events proceeds as follows:

(1) One or more members of the clinical team provides preliminary factual information to the extent it is known, expresses concern for the patient's welfare, and reassures the patient or

personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm.

(2) A social worker, chaplain, patient advocate, or other staff may be present to help the patient or personal representative cope with the news and to offer support, if needed.

(3) The patient's treating practitioner is responsible for determining who shall communicate this information. Such disclosure needs to occur in an appropriate setting and be done face-to-face. ***NOTE:*** *The location needs to be a quiet, private place and adequate time needs to be set aside, with no interruptions.*

b. **Institutional Disclosure of Adverse Events.** Sometimes, given the nature, likelihood, and severity of injury, and the degree of risk for legal liability, there is a need for institutional disclosure of adverse events either instead of, or in addition to, clinical disclosure. Like clinical disclosure, institutional disclosure needs to occur in an appropriate setting and be done face-to-face. The location needs to be a quiet, private place and adequate time needs to be set aside, with no interruptions. Institutional disclosure includes the following elements:

(1) Institutional Leaders (e.g., the Nurse Executive, Chief of Staff or facility Director) invite the patient or personal representative to meet for an Institutional Disclosure of Adverse Event Conference. Institutional leaders may only invite the personal representative if he or she is involved in the patient's care (and the patient does not object), or is acting as a personal representative as outlined in VHA Handbook 1605.1. ***NOTE:*** *The facility Risk Manager or Patient Safety Manager, treating physician, or other VHA personnel deemed appropriate, may be included in this conference at the discretion of facility leadership.*

(2) Institutional disclosure of adverse events should not take place until organizational leaders, including, as appropriate, the facility Director, Chief of Staff, Nurse Executive and members of the treatment team, have conferred with Regional Counsel and addressed what is to be communicated, by whom, and how.

(3) Any request by a patient or personal representative to bring an attorney must be honored, but may influence whether providers will participate.

(4) The Risk Manager or Patient Safety Manager or organizational leaders need to engage in ongoing communication with the patient or personal representative to keep them apprised, as appropriate, of information that emerges from investigation of the facts related to the adverse event. Documents considered confidential under Title 38 United States Code (U.S.C.) Section 5705, such as root cause analyses and peer reviews, cannot be disclosed to attorneys, patients, or the personal representatives of patients, and may only be used for patient safety and quality improvement.

(5) If the patient is not capable of understanding the disclosure of adverse event, and the patient does not have a personal representative as defined in VHA Handbook 1605.1, the facility may make the institutional disclosure to a family member involved in the patient's care. Consult the facility's or VHA's Privacy Office for additional guidance.

(6) Documentation such as reports of contact or incident reports may be kept in some other file at the facility's discretion and entitled "Adverse Event and Close Call Report." This information must not be retrieved by patient identifier and must be identified by a case number. ***NOTE:*** *The Adverse Event and Close Call Report is protected under 38 U.S.C. Section 5705.*

(7) Documenting information in records protected under 38 U.S.C. Section 5705 is never to be done to shield information to which a patient is entitled. Likewise, the fact that information may be documented in records protected under 38 U.S.C. Section 5705 does not mean that the identical information, documented in CPRS, cannot be retrieved by patients.

(8) Institutional disclosure must be documented using the template in Attachment B.

(9) Institutional disclosure of adverse events must include:

(a) An apology including a complete explanation of the facts.

(b) An outline of treatment options.

(c) Arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the adverse event.

(d) Notification that the patient or personal representative has the option of obtaining outside legal advice for further guidance.

(10) After complete investigation of the facts, the veteran patient or personal representative is to be given information about compensation under 38 U.S.C. Section 1151 and the Federal Tort Claims Act claims processes, including information about procedures available to request compensation and where and how to obtain assistance in filing forms. In the event that the investigation is not complete, information about compensation may be given based on the current understanding of the facts or information may be deferred until the investigation is competed. There should be no assurance that compensation will be granted, as the adverse event may not give rise to and meet legal criteria for compensation under 38 U.S.C. Section 1151 and the Federal Tort Claims Act.

(11) If a patient or the patient's personal representative asks whether an investigation will be conducted and whether the patient or the patient's personal representative will be told of the results of an investigation, the patient or personal representative is to be informed that only the results of an administrative board of investigation (AIB) may be released.

c. **Large Scale Disclosure of Adverse Events.**

(1) Large scale disclosure will be done in alignment with the plan for disclosure as developed by the Department of Veterans Affairs (VA) CRAAB with adequate time for

evaluation and planning at the VA Central Office level. Depending on the nature of the event, disclosure to veterans may entail any or all of the following:

(a) Institutional disclosure to affected veterans.

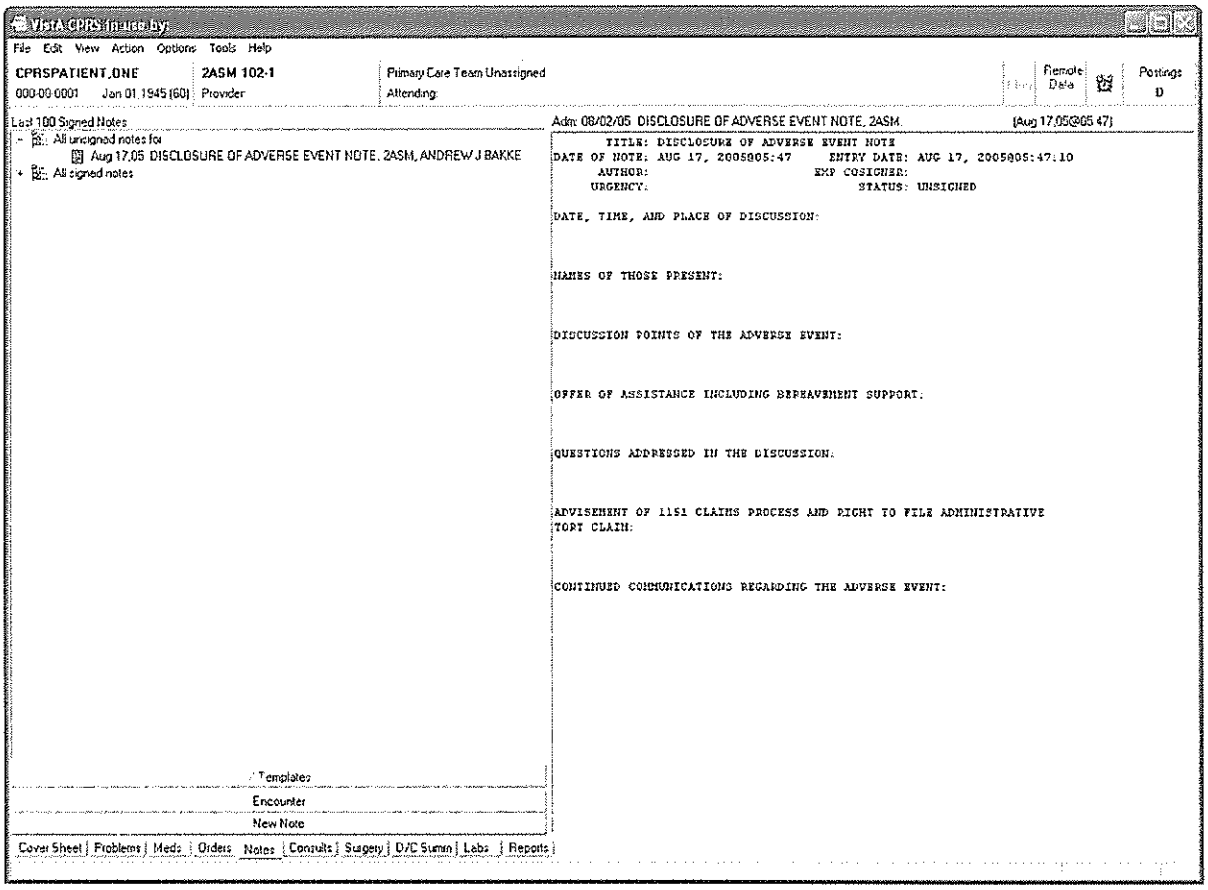
(b) Notification by mail or telephone to potentially affected veterans.

(c) Notification to facilities for required follow up with potentially affected veterans.

(2) In addition, the disclosure plan may include public affairs strategies such as announcement through the media, information and support to clinical providers, and/or establishment of call centers or web sites.

ATTACHMENT B

DISCLOSURE OF ADVERSE EVENT NOTE TEMPLATE FOUND IN THE VETERANS HEALTH INFORMATION SYSTEM AND TECHNOLOGY ARCHITECTURE (VISTA) COMPUTERIZED PATIENT RECORD SYSTEM



ATTACHMENT C

LEADERSHIP DECISION PROCESS FOR LARGE SCALE DISCLOSURE OF ADVERSE EVENTS

NOTE: *This guidance is based on the Veterans Health Administration (VHA), VHA National Center for Ethics Report on Ethical Leadership: Fostering an Ethical Environment and Culture. 2007, p. 34.*

1. Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and magnitude of harm resulting from the adverse event as well as a weighing of additional factors, including, but not limited to salient ethical principles; risk of harm to veterans and identifiable third parties; benefit and burden of disclosure to veterans including medical, psychological, social or economic, impact on the institution's perceived integrity and its capacity to provide care and treatment for all veterans; as well as applicable policy and relevant precedent. The Clinical Risk Assessment Advisory Board (CRAAB) needs to include the following considerations in its decision process:

1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION?

a. How many veterans exposed or potentially exposed?

b. What is the probability that a given veteran was exposed to the adverse event?

c. What is the probability that the adverse event will cause a particular veteran harm?

d. What is the nature of the potential harm?

e. What is the expected magnitude of the harm?

f. What is the expected duration of the harm?

g. Is there treatment available to prevent or ameliorate the harm?

h. Does the harm have the potential to extend beyond the identified patient, to third parties and what is the probability that the extension of harm would occur?

NOTE: *On a case-by-case basis, additional questions may be relevant. Consult the matrix and flow chart in this Attachment C to analyze relevant facts.*

2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS DECISION?

a. Membership in the CRAAB includes the following offices:

(1) Deputy Under Secretary for Health for Operations and Management;

(2) Office of Patient Care Services (e.g., Infectious Diseases Program Office and/or Primary Care or Pharmacy Benefits Management, as appropriate to the event);

(3) National Center for Ethics in Health Care;

(4) National Center for Patient Safety;

(5) Office of Public Health and Environmental Hazards;

(6) Office of Nursing Services; and

(7) Office of Quality and Performance.

NOTE: *Consideration is to be given on a case-by-case basis to including other individuals or groups to ensure that the perspectives of all relevant subject matter experts and stakeholders affected by the decision have an opportunity for input.*

3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?

a. Does the decision reflect VHA core values such as trust, respect, excellence and commitment? For example, would the decision inspire a high degree of confidence in our honesty, integrity, reliability and sincere good intent? Would the decision demonstrate an understanding of, sensitivity to, and concern for each person's individuality and importance? Would the decision indicate that we are taking responsibility for our collective action? That we are preserving the organization's reputation and exercising appropriate stewardship of public resources?

b. Does the decision reflect values central to health care provider professionalism? For example, does the decision hold in high regard the dignity and worth of our patients?

c. Does the decision reflect values central to public health practice? For example, does the decision reflect and make use of the best epidemiological evidence to improve population health?

NOTE: *On a case-by-case basis, additional values may be relevant.*

4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY POTENTIAL HARMS?

Although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large scale disclosure of adverse events likely involves the following considerations:

a. Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?

b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?

c. What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that veterans and Congress would have in VHA?

NOTE: *On a case-by-case basis, additional questions may be relevant.*

5. WILL THIS DECISION KEEP THE PROBLEM FROM RECURRING OR ESTABLISH A GOOD PRECEDENT?

a. Is this a good model for how similar questions should be handled in the future?

b. Has the decision process been followed and documented in a way that can be easily referenced for any similar future cases?

6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION?

a. Does this decision reflect similar decisions by other large health care systems?

b. Will the decision be understood and accepted by veterans, the public?

c. Was the process used to make the decision systematic, examining the question from all angles?

d. Was the process used to make the decision transparent, that is, was the reasoning made clear to all involved?

2. In any particular large scale case, the answers to these questions should assist in the assessment of the benefits and burdens of disclosure. After these issues are considered, the Matrix and Flow Charts in Attachments D and E are examples of aids for the Clinical Risk Assessment Advisory Board to use as a starting point for making disclosure decisions for large scale adverse events. Based on the nature of the adverse event, the Clinical Risk Assessment Advisory Board may also seek other sources or develop additional aids to assist with this patient centered decision making. ***NOTE:*** *The content in both the Matrix and Flow Chart is the same, but is presented in two different formats for the reader's benefit.*

ATTACHEMENT D

CLINICAL CONSIDERATIONS

The following Matrix is an example of an aid for the Clinical Risk Assessment Advisory Board (CRABB) to use as a starting point for making disclosure decisions for large scale adverse events. Based on the nature of the adverse event, the Clinical Risk Assessment Advisory Board may also seek out other sources and/or develop additional aids to assist with this patient-centered decision making.

MATRIX TO AID IN ADVERSE EVENT DISCLOSURE DECISIONS FOR LARGE SCALE EVENTS

		Severity	
		Effect Would be Clinically Significant, i.e., Clinically Significant means a condition that causes harm or illness and/or that requires testing, monitoring, or short-term or long-term treatment.	Effect Would Not be Clinically Significant, i.e., Not Clinically Significant means a condition that causes no perceptible harm or illness and does not require any testing, monitoring, or short-term or long-term treatment.
Probability The probability is determined based on a review of the literature, or, if inadequate literature, by the expert opinion of the Department of Veterans Affairs (VA) CRAAB. Previous VA and non-VA experience with similar adverse events or exposures may be appropriate for consideration, even if not available in the published literature.	Less than one patient in 10,000 patients subject to the event or exposure are expected to have any short-term or long-term health effect that would require any treatment or cause serious illness if untreated.*	*No presumption in favor of disclosure of event or exposure; however disclosure or notification may be warranted on the basis of ethical, clinical, or other considerations.*	*No requirement to disclose event or exposure*

		Clinically Significant	Not Clinically Significant
Probability: The probability will be determined based on a review of the literature, or, if inadequate literature, by the expert opinion of the VA CRAAB. Previous VA and non-VA experience with similar adverse events or exposures may be appropriate for consideration, even if not available in the published literature.	One patient or more in 10,000 patients subject to the event or exposure is expected to have a short-term or long-term health effect that would require treatment or cause serious illness if untreated.	*Presumption in favor of disclosure of event or exposure; however, a decision not to disclose or notify may be warranted on the basis of ethical, clinical, or other considerations.*	*No requirement to disclose event or exposure*

ATTACHMENT E

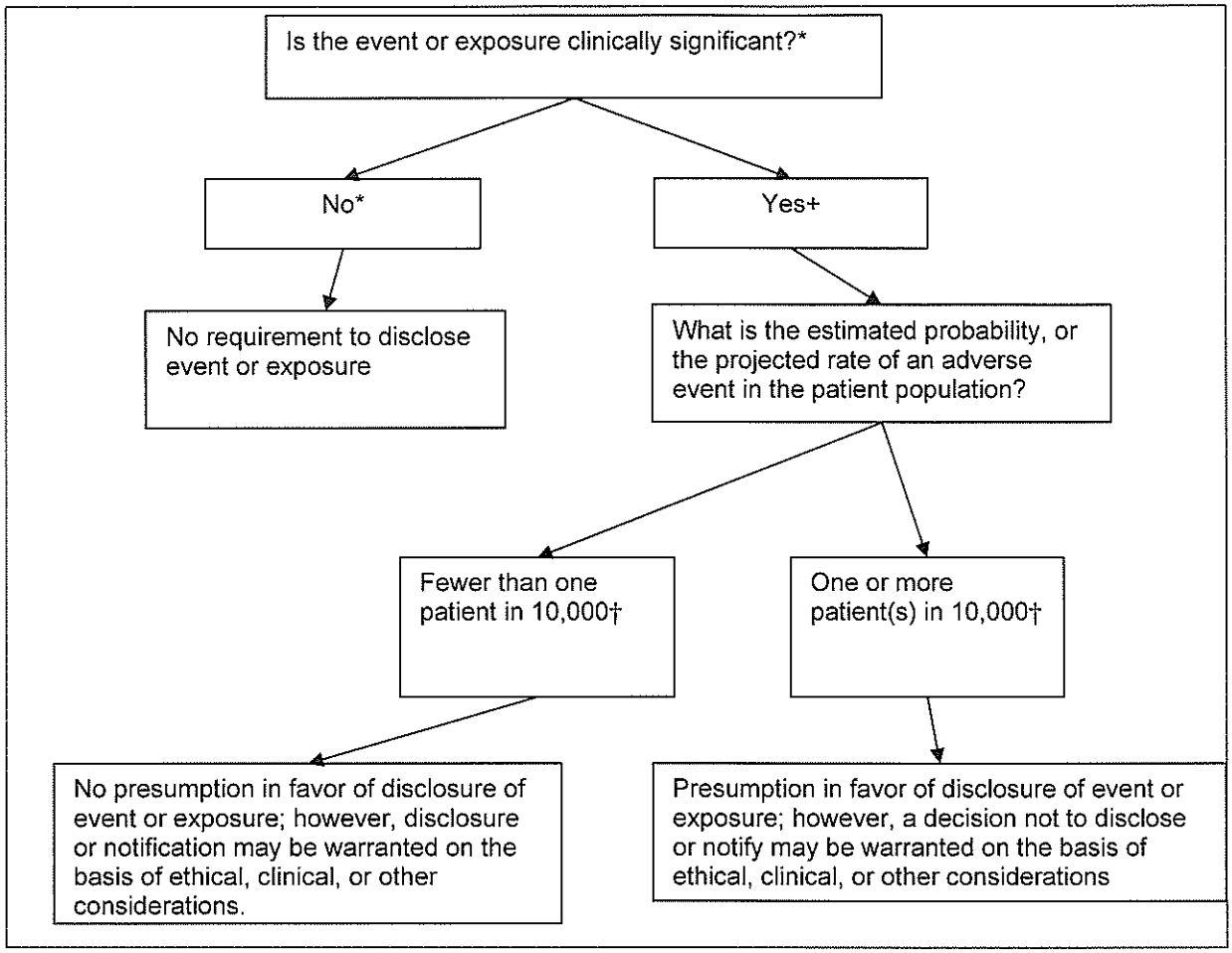
FLOW CHART TO AID IN ADVERSE EVENT DISCLOSURE DECISIONS FOR LARGE SCALE EVENTS

The following Flow Chart is an example of an aid for the Clinical Risk Assessment Advisory Board to use as a starting point for making disclosure decisions for large scale adverse events. Based on the nature of the adverse event, the Clinical Risk Assessment Advisory Board may also seek out other sources and/or develop additional aids to assist with this patient-centered decision making.

*Clinically Significant: A condition causes harm or illness and/or requires testing, monitoring, or short-term or long-term treatment.

+Not Clinically Significant: A condition that causes no perceptible harm or illness and requires no testing, monitoring, or short-term or long-term treatment.

† Probability The probability is determined based on a review of the literature, or, if inadequate literature, by the expert opinion of the VA Central Office Clinical Risk Assessment Advisory Board. Previous VA and non-VA experience with similar adverse events or exposures may be appropriate for consideration, even if not available in the published literature.


Is the event or exposure clinically significant?*
No*
Yes+
No requirement to disclose event or exposure
What is the estimated probability, or the projected rate of an adverse event in the patient population?
Fewer than one patient in 10,000†
One or more patient(s) in 10,000†
No presumption in favor of disclosure of event or exposure; however, disclosure or notification may be warranted on the basis of ethical, clinical, or other considerations.
Presumption in favor of disclosure of event or exposure; however, a decision not to disclose or notify may be warranted on the basis of ethical, clinical, or other considerations