
From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz <[REDACTED]@mac.com>
Cc: Ike Perlmutter <[REDACTED]@frenchangel59.com>; mbsherman <[REDACTED]gmail.com>
Bcc:
Subject: Updates
Date: Tue Mar 27 2018 10:43:42 CDT
Attachments:

I spoke to Dr Hoyt this morning and I wanted to share the plan as he sees it now- to make sure that we are all comfortable with this- This is how we described the plan to me-

VA will get him a list of 15 potential sites for a site visit -

All 15 sites will complete the pre- survey assessment

The College will then select 2-3 sites to visit to start

The earliest he sees a site visit is late June or early July.

I've let him know I want to do this asap so to ask for any help if there is a way to speed this up

On the governance side we are working hard on a plan to restructure governance and incorporate assistance from our academic partners

Please let me know if you have any feedback or suggestions at this time

Thanks

David

Sent with Good (www.good.com)

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz <(b) (6)@mac.com>
Cc:
Bcc:
Subject: FW: NSO Survey Response and Appendix
Date: Wed Mar 07 2018 20:03:11 CST
Attachments:

FYI

Sent with Good (www.good.com)

From: Gunnar, William
Sent: Wednesday, March 07, 2018 5:57:21 PM
To: DJS
Cc: (b) (6); Clancy, Carolyn
Subject: RE: NSO Survey Response and Appendix

Dr. Shulkin,

Dave Hoyt responded that he is ready to move forward. He requested a conference call to discuss. I can arrange but wanted to know who from OGC should join to coordinate contract, etc.

Bill

From: DJS
Sent: Wednesday, March 07, 2018 3:42 PM
To: Gunnar, William
Cc: (b) (6); Clancy, Carolyn
Subject: RE: NSO Survey Response and Appendix

Yes please do - we want to start asap

Sent with Good (www.good.com)

From: Gunnar, William
Sent: Wednesday, March 07, 2018 12:41:11 PM
To: DJS
Cc: (b) (6); Clancy, Carolyn
Subject: FW: NSO Survey Response and Appendix

Dr. Shulkin,

(b) (6) requested an update. I have not heard back from the ACS (email receipt attached).

Let me know if you would like me to follow-up with Dr. Hoyt.

Bill

From: Gunnar, William
Sent: Monday, February 26, 2018 2:46 PM
To: DJS
Cc: Clancy, Carolyn
Subject: FW: NSO Survey Response and Appendix

Sec Shulkin,

I am forwarding the survey response provided today to the American College of Surgeons and the appendix list of references. I can forward the additional 7 emails with referenced documents if you wish.

Sincerely,

Bill

From: Gunnar, William
Sent: Monday, February 26, 2018 2:12 PM
To: Clancy, Carolyn; David Hoyt
Cc: Clifford Ko
Subject: NSO Survey Response and Appendix

Dave,

I have attached the VHA National Surgery Office response to the ACS "Red Book" Survey and the Appendix index of attached documents.

The attached documents will be sent in a series of emails given document size.

As discussed, Carolyn look forward to meeting following your review.

Regards,

Bill

William Gunnar, MD, JD, FACHE

National Director of Surgery

810 Vermont Ave NW

Washington, DC 20420

202-461-7148

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: FW: NSO Survey Response and Appendix
Date: Mon Feb 26 2018 15:50:00 CST
Attachments: Appendix02.26.18.pdf
NSO Response.ACS Standards QM 02.26.18.pdf

FYI

Sent with Good (www.good.com)

From: Gunnar, William
Sent: Monday, February 26, 2018 11:45:59 AM
To: DJS
Cc: Clancy, Carolyn
Subject: FW: NSO Survey Response and Appendix

Sec Shulkin,

I am forwarding the survey response provided today to the American College of Surgeons and the appendix list of references. I can forward the additional 7 emails with referenced documents if you wish.

Sincerely,

Bill

From: Gunnar, William
Sent: Monday, February 26, 2018 2:12 PM
To: Clancy, Carolyn; David Hoyt
Cc: Clifford Ko
Subject: NSO Survey Response and Appendix

Dave,

I have attached the VHA National Surgery Office response to the ACS "Red Book" Survey and the Appendix index of attached documents.

The attached documents will be sent in a series of emails given document size.

As discussed, Carolyn look forward to meeting following your review.

Regards,

Bill

William Gunnar, MD, JD, FACHE

National Director of Surgery

810 Vermont Ave NW

Washington, DC 20420

202-461-7148

Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: Appendix02.26.18.pdf
Last Modified: Mon Feb 26 15:50:00 CST 2018

Appendix

VHA Directives

VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value

VHA Directive 1039, Ensuring Correct Surgery and Invasive Procedures

VHA Directive 1043, Restructuring of VHA Clinical Programs

VHA Directive 1063, Utilization of Physician Assistants (PA)

VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs

VHA Directive 1103, Prevention of Retained Surgical Items

VHA Directive 1124, Equal Employment Opportunity Policy

VHA Directive 1128, Timeline Scheduling of Surgical Procedures in the Operating Room

VHA Directive 1139, Palliative Care Consult Teams (PCCT) and VISN Leads

VHA Directive 1350, Advanced Practice Registered Nurse Full Practice Authority

VHA Directive 1605.01, Privacy and Release of Information

VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities That Can Generate Confidential Documents

VHA Directive 2009-053, Pain Management

VHA Directive 2010-018, Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures

VHA Directive 2010-025, Peer Review for Quality Management

VHA Directive 2011-012, Medication Reconciliation

VHA Directive 2011-037, Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center

VHA Directive 2012-018, Solid Organ and Bone Marrow Transplantation

VHA Directive 2012-033, Heart Failure Treatment Utilizing a Ventricular Assist Device or Total Artificial Heart: Patient Selection and Funding.

VHA Handbooks

VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures

VHA Handbook 1004.05, iMedConsent

VHA Handbook 1004.08, Disclosure of Adverse Events to Patients

VHA Handbook 1050.01, VHA National Patient Safety Improvement VHA Handbook

VHA Handbook 1100.19, Credentialing and Privileging

VHA Handbook 1101.03, Organ, Tissue, and Eye Donation Process

VHA Handbook 1102.01, National Surgery Office

VHA Handbook 1109.02, Clinical Nutrition Management

VHA Handbook 1110.04, Case Management Standards of Practice

VHA Handbook 1170.03, Physical Medicine and Rehabilitation Service (PM&RS) Procedures

VHA Handbook 1400.01, Resident Supervision

Guides

Healthcare Failure Mode and Effect Analysis (HFMEA™)

National Surgery Office Reports

VHA National Surgery Office Annual Surgery Report, FY2016

VHA National Surgery Office Quarterly Report, Q4 FY17 (redacted)

VHA National Surgery Office Quarterly Report Interpretation Document

VHA National Surgery Office Transplant Program Quarterly Report, Q4 FY17

VHA National Surgery Office Transplant Program Quarterly Report Interpretation Document

Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: NSO Response.ACS Standards QM 02.26.18.pdf
Last Modified: Mon Feb 26 15:50:00 CST 2018

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Standard 1.1: Commitment to a Surgical Quality and Safety Program

There is an identifiable “Program” for surgical quality and safety supported by the hospital

Reference Chapter 1: Optimal Resources for surgical quality and safety: An introduction (pg. 17)

Compliance Assessment Questions:

1. Provide a written document from hospital leadership demonstrating their commitment to the “Program”.

Response: Veterans Health Administration (VHA) Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value. All referenced documents, including VHA Directives and VHA Handbooks, can be found in the attached Appendix.

2. How do you define the Surgical Quality and Safety Program in your hospital?

Response: It is VHA policy that an enterprise-wide framework be established for each organizational level that: integrates the functions of quality, safety, and high reliability to achieve value for Veterans; recognizes current and emerging Veteran needs; is aligned with VHA strategic guidance and resource allocation; and is consistent with Department of Veterans Affairs (VA) Core Values of Integrity, Commitment, Advocacy, Respect, and Excellence (VHA Directive 1026). Additional information regarding VA ICARE core values can be found at <https://www.va.gov/icare/>.

3. How does your hospital leadership demonstrate commitment to the Surgical Quality and Safety Program?

Response: VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value assigns duties and responsibilities to all levels of the VHA organization.

VHA Handbook 1102.01, National Surgery Office establishes the structure, process and outcomes reporting schedule that supports the VHA Enterprise Framework for Quality, Safety, and Value.

4. Describe each of the quality efforts related to surgical care at your hospital (for example, committees, staff reporting structure, databases for tracking surgical outcomes, process for loop closure - analogous to those found in a “high-reliability” organization)?

Response: The following VHA policy describes the structure, process, and outcomes reporting that support quality and safety efforts related to surgical care:

VHA Handbook 1102.01, National Surgery Office

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

VHA Directive 2010-018, Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures

VHA Directive 2011-037, Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center

VHA Directive 1039, Ensuring Correct Surgery and Invasive Procedures

VHA Directive 1103, Prevention of Retained Surgical Items

VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook

VHA Directive 2010-025, Peer Review for Quality Management

VHA Handbook 1004.08, Disclosure of Adverse Events to Patients

5. How does your hospital staff and measure the surgical quality and safety operations at your hospital? Include any roles within your organization which have been created to support these operations including leadership, administrative support (i.e. program coordinator), and data abstraction-type personnel.

Response: Quality metrics and safety events are captured through a number of mechanisms facilitated by the VA electronic health record and the Facility medical staff including the Chief of Surgery and the Facility Surgical Quality Nurse. The National Surgery Office (NSO) publishes a detailed NSO Quarterly Report with detailed data for outcomes, quality including VA Surgical Quality Improvement Program (VASQIP), access, safety, productivity, satisfaction, operating room efficiency, and policy compliance for the established 137 VHA Surgery Programs. The NSO also publishes the NSO Transplant Quarterly Report with detailed data for VA Transplant Program's 13 VA Transplant Centers including transplant workload, transplant event tracking, and transplant outcomes. Examples of the Annual Surgery Report, the NSO Quarterly Report, the NSO Transplant Quarterly Report, and the associated Report Interpretation Documents identifying data sources and methodology can be found in the attached Appendix. In addition, the NSO has established a number of online resources and technical tools to support the quality improvement activities and VASQIP data collection of the VHA surgical services including:

- Risk Calculator - Based on preoperative VASQIP specialty-specific data, calculates the risk-adjusted probability of mortality within 30 days and 180 days of surgery, as well as morbidity within 30 days of surgery, for VASQIP-eligible procedures.
- Operative Complexity & CPT Lookup - Lets users query Common Procedure Terminology (CPT) codes by number or description to display Operative Complexity categories, VASQIP eligibility, and national median operative times.
- Operative Complexity Beyond Designation Case Review Form - Template which facilitates reporting cases indicated as occurring beyond the facility's operative

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

complexity level, upon completion the form is routed to the Veterans Integrated Service Network (VISN) Chief Surgical Consultant for evaluation.

- Data Definition Lookup - Provides search options and categorization queries of all Surgical Quality Nurse collected and reviewed VASQIP data points.
- Surgical Audit Forms - Template provided for standardized review of surgical deaths for quality reviews and level of concern audits.
- Critical Incident Tracking Notification (CITN) - Notification system to alert select key personnel of critical events in surgery when they occur.
- Clinic & Operating Room Resources - The NSO's Clinic & Operating Room Resources system collects data from each facility with an approved VHA surgical program, including (1) Clinic Resources, (2) Operating Room Resources, (3) Operating Room Staffing Resources, (4) Intensive Care Unit Resources, (5) and Operating Room Closures. These data supplement other VHA data sources to provide reporting on surgical program Access and Operating Room Efficiency.
- The Enhancing Surgical Access Tool - ESAT allows VA provider staff the ability to enhance access and evaluate barriers to surgical care by monitoring the "third next available" appointment clinic metric and compliance with timely scheduling of OR procedures by identifying needs with staffing, space, equipment, and IT. These metrics support policy requirements of VHA Directive 1128.
- Mechanical Circulatory Assist Device (MCAD) Tracker – MCAD Tracker provides a platform for VHA approved programs to report Ventricular Assist Device (VAD) and Total Artificial Heart (TAH) workload activity. The tracker facilitates reimbursement to approved programs to cover additional expenses associated with surgical implantation of VADs and TAHs, per VHA Directive 2012-033.
- NSO Data Viewer - The NSO Data Viewer consists of an interactive user interface that generates myriad reports for a single medical center's facility-level and patient-level data that relate to the content of the NSO Quarterly Report.
- OPO|DCD Verification - Each VA medical facility must have at least one Agreement with an Organ Procurement Organization (OPO), tissue bank, and eye bank, and per VHA policy must verify compliance annually with the Food and Drug Administration (FDA) registration requirement. Further, each facility is required to establish local policy regarding organ donation after circulatory death (DCD). The NSO hosts a secure web-based application to support compliance with OPO and DCD annual verification requirements.
- Surgical Infrastructure Inventory Tool (SIIT) – Per VHA Directives 2010-018 and 2011-037, surgical procedures performed shall not exceed the supportive infrastructure of the surgical program's designated complexity. To facilitate compliance, the NSO provides

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

the SIIT for VHA facilities to annually certify maintenance of infrastructure requirements for surgical programs.

- The Transplant Referral and Cost Evaluation/Reimbursement (TRACER) – TRACER application facilitates the receipt, processing, approval, and archiving of transplant referrals nationwide by tracking activities and providing reporting/reimbursement data for transplant-related activity. Developed by the NSO, TRACER securely manages transplant information among VA referring hospitals, VA Transplant Centers, and the NSO. Dashboard modules serve to provide at-a-glance status of patients in real time; and standardized business rules allow the application to accumulate cost data for transplant related activities and provide accurate reimbursement totals to VA Transplant Centers.

Standard 1.2: Commitment to Team Based Care

There is a commitment to demonstrable, surgeon-led team-based care for the surgical patient in each of the five phases of care, where applicable.

Reference Chapter 2: Team-based care: The surgeon as leader in each phase of surgical care (pg. 25)

Compliance Assessment Questions:

1. What is your hospital's definition of team-based care as it relates to the surgical patient? Please include:
 - Who is part of the team?
 - How is the surgeon involved in leading team?
 - How the members of the team and surgical leadership span across all five phases or care?
 - How consistent and reliable is this model across the different surgical specialties?

Response: VHA Handbook 1102.01 identifies in detail the qualifications, duties, and responsibilities of the VISN Chief Surgical Consultant, VISN Lead Surgical Nurse, VISN Surgical Workgroup, and the Facility Surgical Workgroup (refer to section 5).

2. Define the roles and responsibilities of the team and how the various disciplines are adequately represented (including anesthesia, nursing, techs, and others depending on the magnitude and type of procedure)?

Response: VHA Handbook 1102.01 requires the Facility Chief of Surgery to chair the Facility Surgical Workgroup with membership to include but not be limited to the Chief of Staff, Surgical Quality Nurse, and Operating Room Manager.

3. Describe the surgeon's role as the leader of the surgical team and his/her involvement in the various aspects of care across the five phases. Include any circumstances where certain providers/specialties may not ascribe to this model and how this is addressed within your hospital.

Response: The duties and responsibilities of the Chief of Surgery as chair of the Facility Surgical Workgroup are identified in section 5 of VHA Handbook 1102.01.

4. What are the institutional authorities vested in the primary surgeon as he/she leads the team?

Response: The primary surgeon is required by VHA policy to schedule the surgical procedure in standard process (VHA Directive 1128), perform written and informed consent (VHA Handbook 1004.01), and provides appropriate resident supervision (VHA Handbook 1400.01).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

5. Is there documentation by the institution affirming its commitment to the surgical team as defined above?

Response: Yes, please reference VHA Handbook 1102.01 for Facility structure, process, and outcomes reporting requirements that support the surgical team.

6. How are surgical appropriateness (including any non-surgical alternatives), risk-stratification, and evidence-based practice guidelines presented to the patient by the surgeon as part of the consent process and how is this documented in the medical record?

Response: VHA has established policy and guidance regarding the infrastructure requirements for VHA facilities providing surgical services in relationship to the complexity of surgical procedures being performed as well as the method for monitoring compliance (VHA Directive 2010-018, VHA Directive 2011-037). The informed consent process is guided by VHA Handbook 1004.01; requiring the surgeon as part of the informed consent process to do the following: describe the name, nature, and details of the recommended treatment or procedure, and the indications for that course of action, including the likelihood of success of the recommended treatment or procedure for that particular patient; describe the expected benefits and known risks associated with the recommended treatment or procedure, including problems that might occur during recuperation; and describe reasonable alternative treatments and procedures.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Standard 2.1: Five Phases of Care

The “Program” includes standardized processes to ensure surgical quality, safety, and reliability in all of the following five of phases of care

1. Surgical preoperative evaluation and preparation phase of care
2. Immediate preoperative readiness phase of care
3. Intraoperative phase of care
4. Postoperative phase of care
5. Post-discharge phase of care

Reference Chapter 2: Team-based care: The surgeon as leader in each phase of surgical care (pg. 25)

Response: VHA has established policy and guidance regarding the infrastructure requirements for VHA facilities providing surgical services in relationship to the complexity of surgical procedures being performed as well as the method for monitoring compliance (VHA Directive 2010-018, VHA Directive 2011-037). This policy provides in specifics the infrastructure requirements that must be in place to address the five phases of care.

Compliance Assessment Questions:**Across All Five Phases**

1. Describe how the hospital implements these processes, including how the surgeon is an active team member and leads in each of the five phases of care (PRQ and onsite).

Requested Documentation:

- a. For each of the phases of care, provide the policies that have been adopted at your institution?

For example: cancellations as a response to preoperative readiness, discharge process, etc.

Response: VHA Handbook 1102.01 defines the lead role the Chief of Surgery in the Facility Surgery Workgroup. The policy defines the duties and responsibilities of the Facility Surgery Workgroup in addressing oversight and quality improvement across the continuum of care.

2. How standardized is the care across all surgical specialties at your hospital?

Response: VHA policy establishes a standardized structure and process across all 137 VHA Surgery Programs with oversight by the VISN Chief Surgical Consultant, the VISN Lead Surgical Nurse, the VISN Surgical Workgroup, and the NSO (VHA Handbook 1102.01). Furthermore, VHA Directive 2010-018 and VHA Directive 2011-037 collectively referred to as the VHA Operative Complexity policy, establishes the infrastructure requirements for Facilities providing in-house surgical services in relationship to the complexity of surgical procedures being performed as well as the method for monitoring compliance.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

3. How does your hospital internally assess for compliance with these policies?

Response: The NSO and the VISN Surgical Workgroups provide oversight to policy compliance at each of the 137 VHA Surgery Programs. The NSO publishes a detailed NSO Quarterly Report with detailed outcomes, quality (including VASQIP), access, safety, productivity, satisfaction, operating room efficiency, and policy compliance data. The Facility Surgical Workgroup and the VISN Surgical Workgroup meet on a monthly basis to address all relevant issues and concerns as they arise as described in VHA Handbook 1102.01. The NSO participates in the monthly VISN Surgical Workgroups, holds monthly conference calls with the VISN Chief Surgical Consultants and VISN Lead Surgical Nurses, and participates in a face to face VISN Surgical Workgroup meeting with each VISN on an annual basis. In addition, the NSO holds an annual NSO Conference with VISN Chief Surgical Consultants and VISN Lead Surgical Nurses to address emerging topics and issues.

4. How does your hospital incorporate the generalizable focus areas, such as palliative care, geriatrics, etc.?

For example: geriatric care pathways that address delirium, nutrition, pain management, medication reconciliation, and active ambulation

Response: VHA policy requires each VHA Facility to have a Palliative Care Consult Team (VHA Directive 1139) and providers to perform medication reconciliation (VHA Directive 2011-012), nutrition (VHA Handbook 1109.02) and pain management (VHA Directive 2009-053). In addition, the NSO has established the surgery outcomes Risk Calculator that allows the provider to calculate the risk-adjusted probability of mortality within 30 days and 180 days of surgery, as well as morbidity within 30 days of surgery, for surgical procedures that are eligible for VASQIP assessment.

Surgical Pre-op Evaluation and Preparation Phase

5. Does your hospital have a consistent process for pre-op evaluation and patient education prior to the day of surgery?

Response: VHA policy requires a standardized infrastructure (VHA Directive 2010-018, VHA Directive 2011-037), scheduling of surgical procedures (VHA Directive 1128), and informed consent (VHA Handbook 1004.01) to support a consistent process for pre-op evaluation and patient education.

6. Is review of prior operative notes on a re-operative case included in the surgical workup discussion?

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: VHA providers utilize the Veterans Information Systems and Technology Architecture (Vista), a common patient electronic medical record, which allows for readily available access to operative notes from prior surgical procedures.

7. How is risk established, mitigated, and communicated to the patient?

Response: Risk is established, mitigated, and communicated to the patient through written informed consent (VHA Directive 1004.01) and IMedConsent, a commercial software solution with imbedded known procedural risks (see VHA Handbook 1004.05). The NSO supports pre-op risk assessment with the Risk Calculator that allows the provider to calculate the risk-adjusted probability of mortality within 30 days and 180 days of surgery, as well as morbidity within 30 days of surgery, for surgical procedures that are eligible for VASQIP assessment.

Immediate Pre-op Readiness Phase

8. For each surgical specialty, how is pre-op readiness performed at your hospital?

Response: VHA policy (VHA Directive 2010-018, VHA Directive 2011-037) requires medical, anesthesia, and surgery consultation be available for pre-operative consultation and patient assessment.

9. Does this change across different surgical specialties? If yes, how so?

For example: orthopedics vs. general surgery

Response: VHA policy (VHA Directive 2010-018, VHA Directive 2011-037) applies to all surgical specialties.

10. How are Advance Practice Clinicians incorporated into your hospital's workflow?

Response: VHA policy establishes Advanced Practice Clinicians the scope of practice and supervisory requirements for Advanced Nurse Practitioners (VHA Handbook 1100.19) and Physician Assistants (VHA Directive 1063). Recently, the VHA has established regulations allowing Advanced Nurse Practitioners full practice authority (VHA Directive 1350).

Intra-op Phase

11. Given existing standards, such as The Joint Commission, how is care standardized at your hospital during the intra-op phase of care?

Response: VHA Directive 1039 establishes a universal protocol for ensuring that all surgery and invasive procedures performed in the clinical setting are performed on the correct patient, at the correct site, and if applicable, with the correct implant. This policy applies to all specialties. The NSO reports universal protocol compliance in the NSO Quarterly Report as the components of

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

the universal protocol (patient identification, informed consent, etc.) are documented in VistA. Furthermore, the NSO collaborates with the VHA National Center for Patient Safety in the CITN process that alerts the VHA Surgery Program, VISN, and national program offices of safety events including wrong site surgery, retained surgical items, operating room deaths, operating room burns and fires. These CITN safety events are then examined in detail through peer review (VHA Directive 2010-025) and root cause analysis process (VHA Handbook 1050.01).

Post-op Phase

12. How is care provided and coordinated in the ICU, elevated care unit(s), and the surgical floor between the individual surgeon and the surgical team?

Response: VHA Operative Complexity policy (VHA Directive 2010-018, VHA Directive 2011-037) establishes the Facility infrastructure requirements based on the VHA Surgery Program Operative Complexity designation and thereby the complexity of surgical procedures performed. Specifically, this policy establishes requirements for critical care including staffing, multi-disciplinary care coordination, call coverage, and nursing competencies based on the complexity and types of surgical procedures being performed.

Post-discharge Phase

13. How is care coordinated for post-op care following discharge including timely receipt of medications, managing and triaging patient questions, etc.?

Response: The VHA is the largest integrated health care system in the US supported by a common electronic medical record, an award winning Pharmacy Benefits Management including a mail-order process, telehealth services, secure messaging, and a patient health information platform called MyHealthVet (see <https://www.myhealth.va.gov/>). The NSO tracks Veteran access to outpatient surgery appointments by Facility and surgical specialty, reporting the following metrics in the NSO Quarterly Report: percent new patients seen within 30 days, missed opportunities, percent stat consults completed with 48 hours, and clinic room utilization.

Standard 3.1: Surgical Quality Officer

There is an appointed a Surgical Quality Officer (SQO) that is a surgeon serving as the hospital's surgical champion for quality and safety. Depending on the hospital's size and infrastructure, this role may be shared by more than one qualified surgeon.

Reference Chapter 3: Surgical Quality Officer (pg. 37)

Compliance Assessment Questions:

1. Provide the following for the individual(s) at your center that serve as the SQO:
 - a. Provide a formal job description that details the responsibilities, reporting relationships, programmatic authority, and experience required of the individual(s) serving as the SQO?

Response: VHA Handbook 1102-01 establishes that the Chief of Surgery functions as the SQO supported by the Surgical Quality Nurse and Operating Room Nurse Manager. The Facility Chief of Surgery reports to the Facility Chief of Staff and sits on the Medical Executive Committee.

- b. Enumerate the qualifications of the individual(s) currently serving in the SQO role, including:
 - i. Education (graduate of ACGME approved surgical or surgical specialty residency/fellowship)
 - ii. Active State License
 - iii. Specialty board certification
 - iv. CME

Response: The Facility Medical Center Director authorizes the hiring, credentialing, privileging, and assignment of the Facility Chief of Surgery based on a standardized policy that requires an active state license and accordingly CME (VHA Handbook 1100.19). VHA Operative Complexity policy (VHA Directive 2010-018, VHA Directive 2011-037) requires board eligibility/certification for specific surgical provider staff (ex. Cardiothoracic surgeons) and attending surgeons providing call coverage.

- c. Describe how these specific individual(s) are appropriate for the SQO role in terms of their experience, leadership, and personal attributes.

Response: The duties and responsibilities of the Chief of Surgery as SQO and the Facility Surgical Workgroup are defined by VHA Handbook 1102.01.

- d. Describe how the individual(s) in this role are qualified and enabled to perform the role as described.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: The Facility Medical Center Director authorizes the hiring, credentialing, privileging, and assignment of the Facility Chief of Surgery based on a standardized policy. The hiring process is supported by the Chief of Staff, Medical Executive Committee, and the Professional Standards Board at the Facility (VHA Handbook 1100.19).

2. Describe how job performance is measured and success is defined for the individual(s) in the SQO role.

Response: Per VHA Handbook 1102.01, the NSO publishes the NSO Quarterly Report with detailed data for each of the established 137 VHA Surgery Programs (111 Inpatient VHA Surgery Programs, 26 VHA Ambulatory Surgery Centers). The NSO Quarterly Report addresses surgical outcomes; quality of services; access, safety, productivity, satisfaction, operating room efficiency, and policy compliance. The NSO publishes the Annual Surgery Report with a fiscal year summary of NSO Quarterly Report data rolled up at the Veterans Integrated Service Network (VISN) and national level. VHA Handbook 1102.01 also requires the Facility Chief of Staff and direct supervisor to the Chief of Surgery to be engaged in the Facility Surgical Workgroup.

3. Does the SQO have formal quality training related to their role as SQO and, if yes, to what extent?

Response: The NSO through the NSO website homepage makes available on the VA intranet (not publicly available) the necessary information and resources for the Facility Chief of Surgery to perform the role of SQO; including relevant policies and communications, guidance, on-line tools, and reports. Annually, the NSO requires the Facility Chief of Surgery to review all established and available infrastructure and enter this information into the SIIT in accordance with the VHA Operative Complexity policy (VHA Directive 2010-018, VHA Directive 2011-037).

4. What are the internal and external resources, including but not limited to budget support, available to the SQO that support their job functions?

Response: Federal funding of the Facility Surgery Program is facilitated by the Veterans Equitable Resource Allocation (VERA) system and distributed in relationship to workload. Budget support to any given Facility is overseen and authorized by the VISN Network Director. Additional information regarding VERA can be found at <https://catalog.data.gov/dataset/decision-support-system-dss>.

5. Please describe any barriers that may hinder the SQO from being effective in this role.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: The role of the Facility Chief of Surgery and SQO may be hindered by local hiring practices, delays in contracting, resource allocation, conflict or issues with the academic affiliation, and negative media attention either locally or nationally.

6. How does the SQO interact with the various quality-related committees and programs and measurement tools (such as NSQIP, TQIP, MBSAQIP, etc.) in place at the institution? Please provide an organizational chart illustrating these relationships, including reporting relationships to hospital leadership.

Response: Each of the 137 VHA Surgery Programs reports outcomes data including VASQIP data to the NSO in support of the NSO Quarterly Report and Annual Surgery Report. The Facility Surgical Workgroup reports directly to the Chief of Staff due in part to the Chief of Staff's membership on the Workgroup. The Facility Chief of Surgery and Chief of Staff participate on the VISN Surgical Workgroup with membership including the VISN Chief Medical Office. The VISN Surgical Workgroup reports (dotted line) to the NSO through the VISN Chief Surgical Consultant and VISN Lead Surgical Nurse, both appointed by the VISN Director (VHA Handbook 1102.01).

In addition, the VA has established the Strategic Analytics for Improvement and Learning (SAIL) for summarizing hospital system performance within the VHA. SAIL is published quarterly and designed to measure, evaluate, and benchmark quality and efficiency at medical centers. The SAIL model highlights successful strategies of VA's top performing facilities in order to promote high quality, safety, and value-based health care across all of its medical centers. A fact sheet summarizing SAIL can be found at <http://www.blogs.va.gov/VAntage/wp-content/uploads/2014/11/SAILFactSheet.pdf>.

7. What is the role of the SQO in analyzing outcomes of various quality programs to detect trends and formulate actions required to correct deficiencies?

Response: The Facility Chief of Surgery and SQO as chair of the Facility Surgical Workgroup has duties and responsibilities to detect trends and formulate actions to correct deficiencies. The VISN Chief Surgical Consultant and VISN Lead Surgical Nurse provide oversight to quality improvement activities. The NSO provides consultative site visits to Facilities by request or level of concern site visits as required by VASQIP when causes or concerns persist beyond Facility and VISN corrective actions (VHA Handbook 1102.01).

8. Does the SQO also play a leadership role in various external quality organizational entities, such as Joint Commission, Leapfrog Group, etc.?

Response: The VHA National Director of Surgery currently serves as Co-Chair for the National Quality Forum Standing Surgery Committee.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

9. Participation in ACS NSQIP is encouraged but not required. Please list the data sources utilized by the SQO to assess surgical quality at the hospital.

Response: All 137 VHA Surgery Programs participate in NSO reporting and the VASQIP (VHA Handbook 1102.01).

Standard 4.1: Case Review Process

The hospital has established detailed, organized, and protected process(es) for multi-disciplinary case review, separate from individual case review, including how the center:

1. Monitors for quality and safety issues to identify possible cases for review (e.g. individual reporting, reporting system, registry)
2. Selects cases for review based on standardized criteria
3. Uses a standardized process for case reviews/evaluation
4. Documents reviews and resolution
5. Integrates resolutions/findings with quality improvement activities in clinical care
6. Maintains surveillance of the issue

Reference Chapter 4: Case review and peer review: Forums for quality improvement (pg. 51)

Compliance Assessment Questions:

1. Demonstrate how the hospital monitors for quality and safety issues to identify possible cases for review.

For example: individual reporting, reporting system, registry, etc.

- a. Describe how objective data (ACS NSQIP, NHSN, etc.) is used to benchmark, track, and trend performance.

Response: The Facility monitors for quality and safety issues through the peer review process (VHA Directive 2010-025), the CITN process, and the NSO Quarterly Report providing detailed data for surgical outcomes, quality including VASQIP, access, safety, productivity, satisfaction, operating room efficiency, and policy compliance (VHA Directive Handbook 1102.01).

- b. Demonstrate the use of tools to identify individual versus system failure.

Response: The VHA peer review process establishes two separate processes to identify individual versus system failure (VHA Directive 2010-025). The protected peer review process assesses system failure for quality improvement whereas non-protected peer review assesses individual performance in support of focused and on-going professional practice evaluation. In addition, individual events may be mandated by outcome or selectively referred for root cause analysis to provide a detailed analysis of individual or system failure to identify corrective actions and lessons learned in support of quality improvement (VHA Handbook 1050.01). The process for protected peer review and root cause analysis generate confidential documents as protected under 38 USC §5705 and it's implementing regulations (VHA Directive 2008-077).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

- c. Who (what hospital department or division) is responsible for pulling and/or accumulating this data?

Response: VHA Directive 2010-025 requires that each VISN and health care facility establish and maintain a program of peer review for quality management purposes (including resource utilization) relevant to the care provided by individual health care providers, in support of clinical care programs and professional services; and must comply with the requirements of those accrediting and oversight agencies that periodically review VHA health care facilities, including, but not limited to The Joint Commission. The Facility Director is ultimately responsible for ensuring the Peer Review Committee has appropriate membership and performing duties and responsibilities in accordance with VHA Directive 2010-025 and as a component of the VHA Enterprise Framework for Quality, Safety and Value (VHA Directive 1026).

- d. Describe how this is conducted specific to surgical specialty or across all surgery.

Response: The peer review process is described in VHA Directive 2010-025. Per VHA Handbook 1102.01, systems issues and lessons learned from protected peer reviews are discussed at the Facility and VISN Surgical Workgroup monthly meetings. The root cause analysis process is directed and performed by the National Center for Patient Safety through the Facility Patient Safety Manager and VISN Patient Safety Officers to the national program office (VHA Handbook 1050.01). On a quarterly basis, the NSO and the National Center for Patient Safety review all surgery related root cause analysis reports including those that generated a CITN, then publish a redacted synopsis with systems issues and lessons learned to the VISN Surgical Workgroups for review and discussion.

- e. How does the case review process fit into the overall infrastructure of the “Program”, as described in Standard 1.1?

Response: The peer review process and root cause analysis process support the VHA Enterprise Framework for Quality, Safety, and Value (VHA Directive 1026).

2. Demonstrate how the hospital selects cases for review based on standardized criteria.

Response: The cases selected for peer review and root cause analysis are either mandated (triggered) by policy or individually selected by the Chief of Surgery or supervisory leadership chain including the Chief of Staff and Facility Director (VHA Directive 2010-025, VHA Handbook 1050.01).

3. Demonstrate how the hospital uses a standardized process for case reviews/evaluations.

- a. Describe how evidence-based medicine or best practices are used when assessing performance.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: The hospital uses a standardized process for case reviews/evaluations selected for peer review and root cause analysis as described in VHA Directive 2010-025 and VHA Handbook 1050.01, respectively.

- b. Provide committee meeting minutes and attendance as evidence of this process.

Response: VHA Directive 2010-025 requires the hospital Peer Review Committee, chaired by the Chief of Staff, to maintain a record of meeting minutes and attendance. Root cause analysis documents are maintained by the National Center of Patient Safety in a central repository named WebSPOT.

4. Demonstrate how the hospital documents the review and evaluation.

- a. How does the hospital categorize the outcomes of the review?

- 1) System error
- 2) Physician error
- 3) Quality concern

For example: preventable/non-preventable complication, etc.

Response: Per VHA Directive 2010-025, the peer review of any individual case, whether for protected (system error, quality concern) or non-protected purpose (physician error), will result in level determination as follows: (a) Level 1 is the Level at which the most experienced, competent practitioners would have managed the case in a similar manner; (b) Level 2 is the Level at which the most experienced, competent practitioners might have managed the case differently; or (c) Level 3 is the Level at which the most experienced, competent practitioners would have managed the case differently.

5. Demonstrate how the hospital integrates resolutions/findings with quality improvement activities in clinical care.

- a. Describe your hospital's process for linking case review to performance improvement and loop closure.

For example: follow-up, refer to peer review committee, refer to other department, refer to M+M for educational purposes, defer to Medical Executive Committee, no further action required, etc.

Response: In accordance with VHA Directive 2010-025, the Chief of Surgery, or Chief of Staff if applicable, is responsible for ensuring appropriate action is taken in response to findings from peer review evaluations where issues or concerns regarding an individual provider are raised or systems issues are identified (peer review level 2 and 3 determinations). System issues and lessons learned from a root cause analysis are coordinated through the Facility Director who provides signature concurrence on the report (VHA Handbook 1050.01).

6. Demonstrate how the hospital maintains surveillance of identified quality issues.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: In accordance with VHA Directive 1026, the Facility Director must chair or co-chair a committee which maintains surveillance of identified quality issues, meets quarterly or more often as warranted, and ensures aggregated data collected for the Enterprise Framework for Quality, Safety, and Value functions are analyzed and reviewed.

7. Demonstrate how your hospital provides education to empower its residents, nurses, and staff to report adverse outcomes and protects them from retaliation.

Response: The NSO and National Center for Patient Safety encourage timely reporting of adverse outcomes without blame by any staff member or trainee through policy, structure, and a reporting structure that includes multiple levels of the organization (VHA Directive 1026, VHA Handbook 1050.01). The VHA has established strict guidance regarding retaliation (VHA Directive 1124)

8. If a teaching hospital, provide evidence of how residents are incorporated into the process for adverse outcome reporting and peer review as mandated by ACGME/CLER.

Response: VHA Handbook 1400.1 requires the Facility Director to, among other responsibilities, monitor resident supervision including involvement in adverse events and peer review.

9. Demonstrate your hospital's typical process for mortality review.

Response: VHA Directive 2010-025 requires that all deaths occurring within the medical center and those occurring in the community setting that are brought to the attention of the medical center and have identified concerns (including all suicides) must be screened against death review criteria.

10. Define the role of hospital leadership in this process.

- a. How are reviewers selected and what qualifications are considered?

For example: chief of surgery, senior surgeons, specialty leaders, etc.

Response: Per VHA Directive 2010-025, the Facility Director selects Peer Review Committee membership, and the Facility Chief of Staff is responsible for chairing the Peer Review Committee and coordinating selection of the appropriate peer reviewer of any given case. Each Peer Reviewer must possess the relevant clinical expertise necessary to make accurate judgments about the decisions being reviewed, be able to make a fair and credible assessment of the actions taken by a provider relative to the episode of care under review, possess knowledge of current evidence based standards of care relevant to the case under review, and be knowledgeable of the peer review process, responsibilities, and the associated legal and ethical requirements.

11. How does multi-disciplinary involvement in the review process occur, when the case is specific to an individual discipline?

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: Per VHA Directive 2010-025, the term “peer reviewer” is defined as a health care professional who can make a fair and credible assessment of the actions taken by the provider relative to the episode of care under review. Factors to consider when selecting a peer reviewer include, but are not limited to, whether the individual has similar or more advanced education, training, experience, licensure, clinical privileges, or scope of practice. Examples include: a general surgeon and a neurosurgeon performing the same procedure can peer review each other; an orthopedic surgeon can peer review a physician’s assistant assigned to the Orthopedic Clinic; a nurse practitioner working as a primary care provider can be peer reviewed by a physician who works in Primary Care.

12. When the case is multi-disciplinary, how are reviewers from other disciplines chosen?

For example: surgery alone, surgery and anesthesia/other specialties, etc.

Response: Per VHA Directive 2010-025, the Facility Director has ultimate responsibility for peer reviews that are performed within the facility and requesting an external peer review when appropriate, the Facility Chief of Staff ensures the appropriate peer reviewers are selected for any given case, and the Service Chiefs actively participate in the peer review committee as appropriate.

13. Describe the process for how summary results are communicated back to leadership at the end of the review process to inform general quality improvement efforts, resource allocation, etc.?

Response: Per VHA Directive VHA 2010-025, the summary results of the Peer Review Committee, chaired by the Facility Chief of Staff with membership including Service Chiefs, is communicated to the Medical Executive Committee, the Facility Director, the VISN Chief Medical Officer, and the VISN Director for notification and action as necessary. The VISN Director is responsible for ensuring that VISN peer review summary data is collected, analyzed, and acted upon, as appropriate; and when significant variance is noted, each facility has a process in place to monitor until closure.

14. How is documentation of case reviews managed and protected?

Response: Per VHA Directive 2008-077, peer reviews for quality management are protected under federal statute, 38 USC §5705 and its implementing regulations. Per VHA Directive 2010-025, the Facility Chief of Staff is responsible for compliance with confidentiality statutes and associated regulations, and the Service Chief is responsible for assisting the training and mentoring of peer reviewers.

Standard 4.2 Peer Review Process for the Individual Surgeon

The hospital has established process(es) to monitor and address quality and safety issues with the individual surgeon through a formal peer review process that respects both the institution and the individual surgeon, and is detailed, organized, and protected.

Reference Chapter 4: Case review and peer review: Forums for quality improvement (pg. 51)

Compliance Assessment Questions:

1. Describe the process for how individual surgeons are monitored for:

- a. Sentinel events

Response: Sentinel events must undergo peer review (VHA Directive 2010-025) and root cause analysis (VHA Handbook 1050.01).

- b. Patterns of adverse outcomes

Response: Per Directive 2010-025, a pattern of adverse outcomes of an individual surgeon will be examined in the process of a Focused Professional Practice Evaluation (FPPE) or Ongoing Professional Practice Evaluation (OPPE). FPPE refers to an evaluation of privilege-specific competence of a practitioner or provider who does not have current documented evidence of competently performing requested privileges. FPPE occurs at the time of initial appointment and prior to granting new or additional privileges. OPPE is the ongoing monitoring of privileged practitioners and providers to confirm the quality of care delivered and ensure patient safety. Activities such as direct observation, clinical discussions, and clinical pertinence reviews, if documented, can be incorporated into this process. FPPE and OPPE information and data must be considered during the provider credentialing and privileging process (VHA Handbook 1100.19).

2. Describe how the peer review process for individual surgeons is separate from multi-disciplinary case review.

Response: Morbidity and Mortality conferences involve multi-disciplinary case review for the purpose of quality management and may include VA practitioners and non-VA practitioners from affiliated academic facilities (VHA Directive 2008-077). Although multiple disciplines may engage in the review of any individual case, the peer review process is an internal VA process, performed by an assigned peer reviewer in isolation with responsibility to provide the Peer Review Committee with a report and peer review level of care assignment (VHA Directive 2010-025).

3. Describe how an individual is identified for needing peer review.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: VHA Directive 2010-025 specifies the circumstances in which an adverse event must be referred for peer review, including but not limited to post-op deaths, major morbidity, suicides, unexpected or negative outcomes including unplanned returns to the operating room, and events that rise to a quality of care concern from executive leadership (VHA Directive 2010-025).

4. Describe how the process by which individual peer review is accomplished.

For example: chart review by internal committee, external consultant, use of external benchmark data, etc.

- a. Describe the tools used for this process and how the reviews are managed.

Response: The Peer Review Committee assigns the case to the appropriate peer reviewer who then reviews the case and provides a report and level of care assignment to the Peer Review Committee within a defined timeframe. The peer reviewer is responsible for conducting the case review through application of current standards of care, accepted evidence based practice guidelines (as available), and analysis of peer reviewed professional literature. The Peer Review Committee then reviews the peer reviewer documents and provides a final level of care assignment. The Facility Chief of Staff is responsible for coordinating an external peer review in collaboration with the VISN Chief Medical Officer when the Facility does not have the appropriate peer review. The external peer review may be performed by another Facility provider or through established contract with an outside business associate (VHA Directive 2010-025).

5. How do you ensure an objective evaluation of adverse outcomes?

Response: The Chief of Staff, Peer Review Committee, and the peer reviewer have responsibility to ensure that peer review is performed objectively and without a conflict of interest. An external peer review will be performed as coordinated by the Facility Chief of Staff and VISN Chief Medical Officer if for any reason the peer review cannot be performed objectively at the Facility (VHA Directive 2010-025).

6. Describe how you tailor individual surgeon peer review to newly appointed surgeons through onboarding and mentorship programs.

Response: The credentialing and privileging process is defined in VHA Handbook 1100.19. Each Service Chief must establish criteria for granting of clinical privileges within the service consistent with the needs of the service and the Facility as well as within the available resources to provide these services. Clinical privileges must be based on evidence of an individual's current competence. When privilege delineation is based primarily on experience, the individual's credentials record must reflect that experience, and the documentation must include the numbers, types, and outcomes of related cases, when available. FPPE is required for practitioners new to the facility, as well as practitioners already appointed at the facility who are

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

requesting new privileges. FPPE is not a restriction or limitation on the practitioner to independently practice, but rather an oversight process to be employed by the facility when a practitioner does not have the documented evidence of competent performance of the privileges requested. It is a process whereby the facility evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility. The criteria for the FPPE process are to be defined in advance, using objective criteria accepted by the practitioner, recommended by the Service Chief and Executive Committee of the Medical Staff as part of the privileging process and approved by the Director. The process may include periodic chart review, direct observation, monitoring of diagnostic and treatment techniques, or discussion with other individuals involved in the care of patients.

Standard 5.1: The Surgical Quality and Safety Committee

The hospital has established process(es) for monitoring administrative and operational aspects of surgical quality and safety (particularly how aspects are surveyed, managed, and implemented) through a Surgical Quality and Safety Committee, led or co-led by the SQO.

Reference Chapter 5: The Surgical Quality and Safety Committee: Providing the operational infrastructure to ensure quality, safety, and reliability (pg. 61)

Compliance Assessment Questions:

1. Describe your hospital's committee responsible for overseeing surgical quality and safety at your hospital, including:
 - a. The committee's formal charter (provide copy).
 - b. The composition of the membership.
For example: Surgical and non-surgical disciplines represented (i.e. nursing, anesthesia, OBGYN, etc.), surgical specialties represented (i.e. ortho, thoracic, etc.), leadership, and process for appointments
 - c. The committee's position within the organizational framework of the hospital (provide organizational chart), including its relationship to other overall quality and safety efforts (peer-protected/non-protected distinction).
 - d. How often the committee meets and attendance requirements.
 - e. The institutional resources dedicated to supporting the leadership and efforts of this committee, including but not limited to salary-support for leadership and administrative duties.

Response: The Facility Surgical Work Group serves as the Surgical Quality and Safety Committee, is chaired by the Chief of Surgery (SQO), and has membership that includes but is not limited to the Chief of Staff, Operating Room Nurse Manager, and the Surgical Quality Nurse. The Facility Surgical Work Group meets at least monthly and functions to support the VISN Surgical Work Group to integrate surgical quality improvement data, improve practice and patient safety, and ensure communication at the VHA facility level to the NSO through the VISN Chief Surgical Consultant or VISN Lead Surgical Nurse when appropriate (VHA Handbook 1102.01).

2. Describe the day-to-day operations of this committee, including:
 - a. Meeting agendas and minutes
 - b. What drives the agenda items discussed at each committee meeting?

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

- c. The flow of information to and from this committee as it relates to surgical quality and safety efforts throughout the hospital.
- d. The data and information sources utilized by this committee and the responsibilities for information gathering.
- e. How the operations and quality initiatives of the committee are sustained in between committee meetings.

Response: Please refer to VHA Handbook 1102.01. The Facility Surgical Work Group meets monthly, or more frequently as necessary. Meeting minutes must be documented, stored on a secured VHA facility or VISN intranet site. The duties and responsibilities of the Facility Surgical Work Group include but are not limited to the following:

- Developing a strategic plan to improve surgical care that aligns with the VISN Surgical Work Group and the NSO;
 - Overseeing the VHA facility's surgical morbidity and mortality conference(s);
 - Reviewing surgical deaths monthly;
 - Analyzing efficiency and utilization metrics;
 - Implementing and monitoring surgery performance improvement activities;
 - Identifying gaps within surgical care and recommends actions;
 - Overseeing compliance with VHA facility surgical complexity infrastructure requirements;
 - Reviewing NSO surgical quality reports;
 - Overseeing and managing surgical outcome data;
 - Overseeing surgical complexity infrastructures; and
 - Evaluating critical surgical events.
3. Describe the committee's authority to take action to ensure surgical quality safety as it relates to the following:
 - a. Monitoring individual surgeon performance and enacting corrective action or mandatory practice guidelines when appropriate.
 - b. Surgeon credentialing process and review of surgeon privileges.

Response: The NSO, VISN Surgical Work Group, and Facility Surgical Work Group are intended and structured to support quality management and the VHA Framework for Quality, Safety, and Value (VHA Handbook 1102.01, VHA Directive 1026). The structure and process for credentialing and privileging, FPPE, OPPE, and non-protected peer review of individual surgeon performance is managed separately by the Facility under separate authority (VHA Handbook 1100.19, VHA Directive 2010-025).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

4. Please provide the hospital's written performance improvement (PI) plan and demonstrate how it has been implemented across the Department of Surgery, including:
 - a. How the quality and safety organizational structure is organized and speaks to appropriate lines of authority and responsibility.
 - b. The methodology(s) used for PI.
 - c. The mechanism for operationalizing PI
 - d. The process for loop closure

Response: It is VHA policy that an enterprise-wide framework be established for each organizational level that: integrates the functions of quality, safety, and high reliability to achieve value for Veterans; recognizes current and emerging Veteran needs; is aligned with VHA strategic guidance and resource allocation; and is consistent with Department of Veterans Affairs (VA) Core Values of Integrity, Commitment, Advocacy, Respect, and Excellence. Accordingly, the Facility Director is responsible for establishing a standing committee under an enterprise framework to review data, information, and risk intelligence and ensure that key quality, safety, and value functions are discussed and integrated on a regular basis. The committee is comprised of a multidisciplinary group working towards understanding the complex environment that results in adverse events, and loss of value and efficiency. The committee must develop prioritized recommendations to aid facility leadership. Medical facility leadership must charter improvement teams or initiate strategies to make changes to improve outcomes for Veterans (VHA Directive 1026).

5. Describe the relationship between this committee and the Multi-disciplinary Peer Review Committee (MPRC)?

Response: The Facility Surgical Work Group (i.e., SQSC) and the Peer Review Committee (i.e., MRPC) are established under separate authority and for separate purpose. The Chief of Staff and Chief of Surgery (SQO) participate in both activities.

6. How does one ensure that members of the SQSC are themselves practicing evidence-based medicine?

Response: The VA provides care and treatment to eligible and enrolled Veterans only if determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the Veteran and is in accordance with generally accepted standards of medical practice (38 CFR §17.38). The VHA process for credentialing and privileging is established to ensure that VA providers are practicing evidence-based medicine (VHA Handbook 1100.19). Furthermore, VHA policy ensures that the structure that supports quality management and peer review has participants that meet this standard (VHA Directive 1026 and VHA Directive 2010-025 assigning oversight responsibility to Facility Director).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

7. Does your hospital have a Surgical Quality Program Manager that reports to the SQO and assists the SQO in the overall development and administration of the Surgical Quality Program? If yes, please provide official job description.

Response: VHA Handbook 1102.01 requires each Facility with a VHA Surgery Program to have a Surgical Quality Nurse. The Surgical Quality Nurse is a VHA facility-designated Registered Nurse functioning as the VistA surgery package subject-matter expert for VASQIP data collection. The duties and responsibilities of the Surgical Quality Nurse include, but are not limited to:

- Collecting surgical quality data;
- Ensuring accurate VASQIP data submission process (data entry, interpretation, and timely transmission of the data to the NSO);
- Managing programmatic issues related to surgical data;
- Maintaining competency in VASQIP definitions and chart review processes;
- Participating in VHA facility mortality and morbidity reviews;
- Collaborating regularly with the Chief of Surgery regarding surgical data and programs, regardless of the specific department to which he/she organizationally reports (e.g., Surgery, Quality Management, or Nursing);
- Participating in surgical performance improvement activities; and
- Providing ongoing educational activities regarding VASQIP to relevant personnel at the VHA facility.

8. Is there a hospital administrative leader that is appointed to the committee to serve as a liaison with senior hospital leadership? If yes, please describe.

Response: Per VHA Handbook 1102.01, the Facility Chief of Surgery, and chair of the Facility Surgical Work Group, serves as a liaison with senior hospital leadership; providing oversight to clinical outcomes, surgical standards of care, and coordination of surgical care within the VHA facility; and ensuring dissemination of information provided by NSO or the VISN leadership to Facility Surgical Work Group members and others as appropriate.

9. What, if any, barriers exist that prevent this committee from effectively meeting the goals outlined in the committee's charter?

Response: VHA Handbook 1102.01 establishes a Facility Surgical Work Group at all Facilities with a VHA Surgery Program, defines the Facility Surgery Work Group chair and membership duties and responsibilities, as well as the duties and responsibilities of the Facility Chief of Surgery and the Surgical Quality Nurse. Any barriers that prevent the Facility Surgical Work

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Group from effectively meeting the goals as described in VHA Handbook 1102.01 can be addressed with the Chief of Staff who sits as member. If barriers are not resolved at the Facility level the Chief of Surgery is responsible for addressing issues and concerns with the VISN Chief Surgical Consultant and the VISN Surgical Work Group. Barriers that cannot be resolved at the VISN level can be brought to the NSO by the VISN Chief Surgical Consultant or VISN leadership.

Standard 6.1: Surgical Credentialing and Privileging

The hospital has established credentialing and privileging process(es) that ensure their surgeons are qualified to provide optimal care within the framework of a just culture. The process is informed by the Quality and Safety Program.

Reference Chapter 6: Surgical credentialing and privileging: Ensuring that surgeons are capable of providing optimal care (pg. 69)

Compliance Assessment Questions:

1. Describe roles and responsibilities of the surgical credentialing committee at your hospital, including:
 - a. Who leads and serves on the credentialing committee.
 - b. A detailed description of the credentialing process for initial and maintenance of credentials.
 - i. Describe how you monitor maintenance of board certification ?
 - c. The relationship of the Surgical Quality Officer to the credentialing committee.

Response: VHA Handbook 1100.19 describes in detail the credentialing process. The Facility Chief of Staff is responsible for maintaining the Facility credentialing and privileging system. The credentialing process includes verification, through the appropriate primary sources, of the individual's professional education; training; licensure; certification and review of health status; previous experience, including any gaps (greater than 30 days) in training and employment; clinical privileges; professional references; malpractice history and adverse actions; or criminal violations, as appropriate. Except as identified in subparagraph 13a., medical staff and employment commitments must not be made until the credentialing process is completed, including screening through the appropriate State Licensing Board, Federation State Medical Boards, and the National Practitioner Data Bank. All information obtained through the credentialing process must be carefully considered before appointment and privileging decision actions are made. The applicable Service Chief reviews the credentialing file and requested privileges and makes recommendations regarding the appointment. The folder and recommendations are reviewed by the credentialing committee (Professional Standards Board) and then submitted with recommendations to the medical staff's Executive Committee.

2. Describe the privileging process, including:
 - a. The core privileges for each specialty
 - b. Provide the lists of special privileges for each specialty
 - c. Describe how competency is demonstrated for each of these.

Response: Per VHA Handbook 1100.19, the Facility Chief of Surgery is responsible for recommending the criteria for clinical privileges that are relevant to the care provided in the

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

service; reviewing all credentials and requested clinical privileges, and for making recommendations regarding appointment and privileging action; and monitoring and surveillance of the professional competency and performance of those who provide patient care services with delineated clinical privileges.

3. For ongoing privileging, provide documentation demonstrating:
 - a. How early review of performance is conducted, including who is responsible.
 - b. How ongoing review of performance is conducted, including:
 - i. How often ongoing review is conducted.
 - ii. Who is responsible for conducting reviews.

Response: Per VHA Handbook 1100.19, the on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE) is essential to confirm the quality of care delivered. This allows the facility to identify professional practice trends that impact the quality of care and patient safety. Such identification may require intervention by the medical staff leadership. Criteria-based privileges make the on-going monitoring of privileges easier for medical staff leadership. Each Service Chief should consider what medical facility, regional, state, national, and specialty standards, activities, and data are available to meet these needs. The maintenance of certification is not sufficient in and of itself. There are a number of activities such as direct observation, clinical discussions, and clinical pertinence reviews that, if documented, can also be incorporated into the on-going monitoring process. Data must be practitioner specific, reliable, easily retrievable, timely, justifiable, comparable, and risk adjusted where appropriate. OPPE is supported by the peer review process (VHA Directive 2010-025).

4. Describe how privileges are granted including a detailed description of the review process in each of the following circumstances:
 - a. New surgeons requesting privileges, including how you verify competence for performance of procedures.
 - b. Established surgeons renewing existing privileges, particularly evaluating how an experienced surgeon is keeping up with evolutions in practice and standards of care. Please describe the mechanism used to monitor this. If not monitored, please provide rationale for continuance of privileges.
 - c. Established surgeons requesting new privileges.
 - d. Safe introduction of innovative procedures and technologies, such as robotic operations, POEM, etc. (see ACS-CESTE principles on pg. 80).

Response: The privileging process is defined in VHA Handbook 1100.19. Each Service Chief must establish criteria for granting of clinical privileges within the service consistent with the needs of the service and the Facility as well as within the available resources to provide these services. Clinical privileges must be based on evidence of an individual's current competence.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

When privilege delineation is based primarily on experience, the individual's credentials record must reflect that experience, and the documentation must include the numbers, types, and outcomes of related cases, when available. FPPE is required for practitioners new to the facility, as well as practitioners already appointed at the facility who are requesting new privileges. FPPE is not a restriction or limitation on the practitioner to independently practice, but rather an oversight process to be employed by the facility when a practitioner does not have the documented evidence of competent performance of the privileges requested. It is a process whereby the facility evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility. The criteria for the FPPE process are to be defined in advance, using objective criteria accepted by the practitioner, recommended by the Service Chief and Executive Committee of the Medical Staff as part of the privileging process, and approved by the Director. The process may include periodic chart review, direct observation, monitoring of diagnostic and treatment techniques, or discussion with other individuals involved in the care of patients.

VHA Directive 1043, Restructuring of VHA Clinical Programs, establishes the process for VHA leadership approval of new clinical program or service that involves a significant increase in complexity or volume of clinical workload (ex. Robotics). The Facility submits a business proposal through the VISN to VA Central Office which then directs the NSO to perform a business plan review and site visit to ensure appropriateness of implementation and that all necessary infrastructure and support is available. The NSO performs surgical program restructuring site visits using relevant subject matter experts from established Surgical Advisory Boards (VHA Handbook 1102.01).

5. Describe how the principles of a just culture are used to maintain a fair process for reviewing credentials and privileging for the impaired or failing surgeon.

Response: VHA Handbook 1100.19 defines the process for reviewing credentials and privileging for the impaired or failing surgeon. In support of this process, the Facility leadership has the option to proctor the individual when appropriate. Proctoring is the activity by which a practitioner is assigned to observe the practice of another practitioner performing specified activities and to provide required reports on those observations. The proctor must have clinical privileges for the activity being performed, but must not be directly involved in the care the observed practitioner is delivering. Proctoring that requires a proctor to do more than just observe, i.e., exercise control or impart knowledge, skill, or attitude to another practitioner to ensure appropriate, timely, and effective patient care, constitutes supervision which may constitute a reduction in privileges. When a reduction in surgeon privileges is recommended by the Executive Committee of the Medical Staff, appropriate notice, examination of documentation, and due process is required.

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

6. Provide bylaws and policies for disciplinary steps for surgeons exhibiting unethical conduct, disruptive or unprofessional behavior in addition to a detailed description of this process including a real-life example.

Response: In accordance with VHA Handbook 1100.19, the Facility Director, designated by the Under Secretary for Health as the Governing Body of the facility, is responsible for ensuring that local facility policy, including Medical Staff Bylaws, Rules, and Regulations, is consistent with this handbook.

7. How does the surgeon credentialing and privileging committee at your hospital define scope of practice, appropriate procedural training (both for surgeons and non-surgeons) and how do they delineate criteria across specialties (for example across vascular, interventional radiology, and radiology)? Include a description of how the SQO and Chief of Surgery are involved in evaluating procedures for practitioners when new disciplines are considering training.

Response: VHA Handbook 1100.19 defines the roles and responsibility of the Facility Director, Chief of Staff, Medical Executive Committee, Credentialing Committee, Professional Standards Board, and Service Chief in the process for credentialing and privileging any single provider. Accordingly, the Medical Executive Committee, Chaired by the Chief of Staff, would delineate criteria across specialties for scope of practice. The Chief of Surgery is Service Chief and SQO and thereby sits on the Medical Executive Committee.

Standard 7.1: Culture of Patient Safety and High Reliability

The hospital has established a hospital-wide culture of high reliability, safety, and accountability through team-based care.

Reference Chapter 7: Creating a culture that is focused on safety and high reliability (pg. 85)

Chapter 8: Patient safety and high reliability: Establishing the infrastructure (pg. 97)

Compliance Assessment Questions:

1. Describe how your institution incorporates the following:
 - a. High reliability, including the following:
 - i. How engagement in the concept of high reliability is established at all levels of the institution.
 - ii. The specific technique(s) applied to establish a high reliability culture.
 - iii. How data is used for performance benchmarking.
 - iv. How accountability is established.
 - b. Culture of safety and accountability
 - c. Team-based care
 - d. How it is measured? How often?

Response: It is VHA policy that an enterprise-wide framework be established for each organizational level that: integrates the functions of quality, safety, and high reliability to achieve value for Veterans; recognizes current and emerging Veteran needs; is aligned with VHA strategic guidance and resource allocation; and is consistent with Department of Veterans Affairs (VA) Core Values of Integrity, Commitment, Advocacy, Respect, and Excellence (VHA Directive 1026). In support of this policy, the VA has established the Strategic Analytics for Improvement and Learning (SAIL) for summarizing hospital system performance within the VHA. SAIL is published quarterly and designed to measure, evaluate, and benchmark quality and efficiency at medical centers. The SAIL model highlights successful strategies of VA's top performing facilities in order to promote high quality, safety, and value-based health care across all of its medical centers. A fact sheet summarizing SAIL can be found at <http://www.blogs.va.gov/VAntage/wp-content/uploads/2014/11/SAILFactSheet.pdf>

In addition, the NSO publishes the NSO Quarterly Report with detailed data for surgical outcomes, quality including VASQIP, access, safety, productivity, satisfaction, operating room efficiency, and policy compliance. A Facility site visit process is established to perform an external mortality review and site visit when triggered by a VASQIP level of concern for high outlier status in a 30-day mortality observed to expected ratio for all surgical procedures performed in a rolling 12 month period (see VHA Handbook 1102.01, NSO Quarterly Report, and Report Interpretation Document for additional details).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

2. Describe your hospital's serious surgical safety event classification system to identify and track undesirable events.

Response: The NSO in collaboration with the National Center for Patient Safety developed and implemented the CITN process for alerting leadership of the VHA Surgery Program, VISN, and national program offices of safety events including wrong site surgery, retained surgical items, operating room deaths, operating room burns and fires. These CITN safety events are then examined in detail through peer review and root cause analysis process. On a quarterly basis, the NSO and the National Center for Patient Safety review all surgery related root cause analysis reports that were generated by a CITN event then publish a redacted synopsis with systems issues and lessons learned to the VISN Surgical Workgroups for review and discussion.

3. Describe the self-assessment tool(s) adopted at your hospital to develop benchmarks, against which culture change can be measured for resiliency.

Response: The NSO publishes the NSO Quarterly Report with detailed data for surgical outcomes, quality including VASQIP, access, safety, productivity, satisfaction, operating room efficiency, and policy compliance (VHA Handbook 1102.01, refer to NSO Quarterly Report and Report Interpretation Document). The NSO publishes the Annual Surgery Report with a fiscal year summary of NSO Quarterly Report data rolled up at the Veterans Integrated Service Network (VISN) and national level. In addition, the NSO publishes the NSO Transplant Quarterly Report with detailed data for VA Transplant Program's 13 VA Transplant Centers including transplant workload, transplant event tracking, and transplant outcomes. Please refer to the NSO reports provided in the attachments.

4. Describe your hospital's efforts to maintain transparency surrounding surgical quality, including:
 - a. Does your center have a surgical quality dashboard? If so, please provide.
 - b. How do employees access this report?

Response: The NSO Annual Surgery Report, Quarterly Transplant Reports, and SAIL Reports are available to all VA employees. The NSO Quarterly Report is a confidential document, protected by 38 USC §5705, and is accessible to the VISN Surgical Work Group, Facility, and VISN leadership. The VA participates in Medicare Hospital Compare and publically reports a SAIL star rating for each Facility.

5. Describe education provided to staff on the culture of safety and high reliability and how information is disseminated (grand rounds, committee meeting minutes, online courses, etc.).

Response: VHA Handbook 1100.19 requires that all VA employees complete mandatory training upon hiring and determined by the VA Office of Quality, Safety, and Value. The NSO in collaboration with the National Center for Patient Safety and the Employee Education System

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

developed a mandatory training module for providers upon hiring to ensure understanding of VHA Directive 1039, Ensuring Correct Surgery and Invasive Procedures. Patient safety alerts and patient safety advisories are disseminated to the medical staff through the Patient Safety Manager (VHA Handbook 1050.01). The Facility Chief of Surgery is responsible for ensuring dissemination of information provided by the NSO or the VISN leadership, and the Facility Surgical Quality Nurse is responsible for providing ongoing educational activities regarding VASQIP to relevant personnel at the Facility (VHA Handbook 1102.01).

6. Does your hospital use the SAQ (Safety Attitudes Questionnaire) or HSOPS (Hospital Survey on Patient Safety Culture)? If so,
- a. When and how often is this conducted?
 - b. How is this information utilized?
Demonstrate evidence of a culture initiative carried out as a consequence of the SAQ or HSOPS.

Response: The VA utilizes the Healthcare Failure Mode and Effect Analysis (HFMEA) to identify and prevent product and process problems before they occur. The National Center for Patient Safety provides guidance and toolkits to allow the Facility to perform HFMEAs independently and is available to perform the HFMEA as indicated. A HFMEA guide is provided as an attachment and additional information regarding HFMEA process is available at <https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp>.

Alternatively, the Facility can request the National Center for Patient Safety to conduct Clinical Team Training. The Clinical Team Training program offers an opportunity for clinicians to improve patient safety and job satisfaction by facilitating clear and timely communication through collaborative teamwork in the clinical workplace. Principles of aviation's Crew Resource Management (CRM) are introduced in a clinical context to model specific applications in the healthcare environment.

7. Provide your hospital's code of conduct policy.

Response: The VA code of conduct is grounded in mission, "to care for him who shall have borne the battle, and for his widow, and his orphan," and I CARE values. Additional information regarding I CARE can be found at <https://www.va.gov/icare/>.

8. Does your hospital have a separate, established process for anonymous reporting of unsafe behavior and patient safety issues? If so, please describe:

Response: Yes. The VA employee may file a complaint with the Office of the Inspector General, the Office of the Medical Inspector, the US Office of Special Counsel, or Congress (VHA Directive 1605.01). The employee is protected in this activity by VHA policy (VHA Directive 1124) and federal statute; 5 U.S.C. §2301 et seq., The Notification and Federal Employee

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Antidiscrimination and Retaliation Act (NoFEAR Act) of 2002 and the Whistleblower Protection Enhancement Act of 2017.

9. How do you ensure that high reliability culture is pervasive at your hospital? Please describe:
- a. The process for scaling it across the hospital (for example, what resources are available to lead it with the appropriate authority to ensure it is widely adopted)
 - b. The education plan for ensuring ongoing education and adherence.
 - c. Provide an example demonstrating the pervasiveness of high reliability culture at your center.

Response: The VHA enterprise framework for quality, safety, and value establishes the foundation for a high reliable culture (VHA Directive 1026). The NSO supports this framework and culture through structure, process, and regular reporting of outcomes (VHA Handbook 1102.01).

Standard 8.1: Disease-based Management

The hospital has established programmatic disease management and specialty-specific/multidisciplinary standards related to the surgical patient, and measures compliance with these standards.

Reference Chapter 9: Disease management and multidisciplinary patient care (pg. 107)

Compliance Assessment Questions:

1. Please list any and all disease or specialty-specific standards-based surgical quality programs (for example, MBSAQIP, Trauma Verification, Cancer, etc.) your hospital participates in and provide a detailed description of your center's participation in each. For each:
 - a. Describe current participation status, list staff involved/responsible for maintaining participation (for example, Trauma Program Manager), describe how standards are monitored and integrated into hospital/surgeon practice, recent report findings, and any activities or action taken at the hospital as a result of your participation or report findings.
 - b. Describe the SQO's involvement and relationship to staff charged with managing participation.
 - c. Describe how the program is integrated into overall hospital infrastructure, including any executive oversight provided at the hospital board or C-suite level (for example, are hospital standings in these programs regularly reviewed at this level?).
 - d. If relevant, describe how these programs are used for service-line development.

Response: VHA Handbook 1102.01 mandates that the Facility with a VHA Surgery Program participate in NSO surgery outcomes reporting and VASQIP. The Facility Chief of Surgery ensures participation and data submission through the Surgical Quality Nurse to the NSO for publication of the NSO Quarterly Report. The NSO Quarterly Report provides foundational information to support service-line development. In addition, the VA has a business associate agreement with the American College of Surgeons (ACS) to allow Facilities to elect participation in the Cancer Care Registry (CCR). Approximately 45 Facilities currently participate in the ACS CCR.

2. When care is being managed by multiple specialists (for example, cardiac surgeon, cardiologist, and radiologist), describe how joint decision-making is managed? Who is ultimately responsible?

Response: The VHA Operative Complexity policy (VHA Directive 2010-018, VHA directive 2011-037) establishes the following requirements for VHA Surgery Programs: 1) availability of multiple specialists on site and on-call for consultation and bedside care; and 2) written policy or plan for medical co-management of surgical patients in the Intensive Care Unit of VHA Inpatient Surgery Programs with an Intermediate and Complex designation. The VHA

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

promotes case management of the highly complex patient requiring longitudinal care coordination that emphasizes nursing and social work involvement (VHA Handbook 1110.04). Ultimately, the assigned clinical service and supervising attending staff member is responsible for care coordination of the patient (VHA Handbook 1400.01).

Standard 9.1: External Regulations in Patient Safety

The hospital has established compliance with external regulations and maintains appropriate accreditation(s).

Reference Chapter 10: External regulation of quality and patient safety (pg. 197)

Compliance Assessment Questions

1. Please list all of the external regulatory bodies that designate your hospital (for example, governmental agencies at the national, state, and county level, CMS Conditions of Participation, The Joint Commission or equivalent, payer-based designations, etc.) and describe your participation and status with each.

Response: VHA has federal authority to provide a complete medical and hospital service for the medical care and treatment of Veterans (38 USC §7301(b)). VHA policy mandates that all Facilities obtain and retain accreditation from The Joint Commission (VHA Directive 1100.16). In addition, all Inpatient rehabilitation units must obtain and retain accreditation from the Commission on Accreditation for Rehabilitation Facilities (VHA Handbook 1170.03). The VA is not subject to the laws, regulations, and policies of the Department of Health and Human Services (HHS), Centers of Medicare and Medicaid (CMS), as they relate to transplant services; as explained in paragraph 2.b. of VHA Handbook 1101.03. CMS requirements are essentially conditions of participation for purposes of receiving Medicare payment, which do not apply to VA. Nonetheless, VA as a matter of policy adopts CMS requirements related to organ donation and transplant services to the extent possible under law. VA Transplant Centers are thus United Network of Organ Sharing (UNOS) certified and fully comply with Organ Procurement and Transplant Network (OPTN) Policy as established by HHS. In addition, VA Transplant Centers, as a matter of VHA policy, fully comply with OPTN public reporting requirements to the Scientific Registry for Transplant Recipients (VHA Directive 2012-018).

2. Please describe the SQO's involvement with external regulatory bodies.

Response: The Facility Medical Director is responsible for ensuring the VA medical facility is accredited and for oversight of continual compliance with The Joint Commission standards and accreditation procedures including coordinating the professional activities required by The Joint Commission (VHA Directive 1100.16). The Facility Chief of Surgery (SQO) supports the accreditation process by meeting patient safety goals, overseeing surgical patient care and treatment, providing organizational leadership, and participating in performance measurement.

3. When there are known problems identified, who is made aware of them (for example leadership, frontline providers, etc.) and how is it managed?

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Response: Facility problems or concerns identified by The Joint Commission are communicated throughout the VHA organization for notification and corrective actions as required. Ultimately the Principle Deputy Under Secretary for Health collaborates with the Associate Deputy Under Secretary for Health for Quality, Safety, and Value and the Deputy Under Secretary for Health for Operations and Management to ensure all VA medical facilities are accredited by The Joint Commission (VHA Directive 1100.16).

Standard 10.1 Data Surveillance

The hospital has established process(es) for how it uses objective, externally benchmarked, risk-adjusted data to provide surveillance and identify surgical quality and safety issues.

Standard 10.2 Data to promote a culture of high reliability and safety

The hospital has established a track record of using data to affirm the goal of high reliability and culture of safety.

Standard 10.3 Data for Improvement

The hospital has established process(es) for using data thoughtfully and responsibly to support surgical quality improvement within a framework of a just culture.

Reference Chapter 11: Data analytics: An overview of systems used to improve health care quality and safety (pg. 211)

Chapter 12: Putting the data to work: Using databases for quality improvement and patient safety (pg. 237)

Compliance Assessment Questions

1. Please list databases, registries, and other data sources used to monitor surgical quality at your hospital. For example (ACS NSQIP, UHC, TQIP, administrative data, etc.).

Response: Per VHA Handbook 1102.01, the NSO publishes the NSO Quarterly Report with detailed data for each of the established 137 VHA Surgery Programs (111 Inpatient VHA Surgery Programs, 26 VHA Ambulatory Surgery Centers) performing approximately 420,000 surgical procedures per year. The NSO Quarterly Report addresses surgical outcomes; quality of services including VASQIP; access, safety, productivity, satisfaction, operating room efficiency, and policy compliance in reference to VHA national benchmarks. The NSO also publishes the Annual Surgery Report with a fiscal year summary of NSO Quarterly Report data rolled up at the Veterans Integrated Service Network (VISN) and national level for comparisons. In addition, the NSO publishes the NSO Transplant Quarterly Report with detailed data for VA Transplant Program's 13 VA Transplant Centers including transplant workload, transplant event tracking, and transplant outcomes referenced to OPTN outcomes as publically reported by the Scientific Registry for Transplant Recipients (SRTR).

2. How do you maintain appropriate knowledge and expertise, for data analyses and measure development? Please include who manages the data sources, how they are resourced, and provide their qualifications.

Response: The NSO publishes the NSO Reports, including the NSO Quarterly Report and the NSO Quarterly Transplant Report. Detailed report interpretation documents and other educational material are available to the user on the NSO intranet website (VHA Handbook 1102.01, VHA Directive 2012-018). The Facility Chief of Surgery and Surgical Quality Nurse are

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

local subject matter experts regarding NSO reports and VASQIP and can reach out to the VISN Chief Surgical Consultant, VISN Lead Surgical Nurse, or the NSO if needed to respond to a concern or question.

3. Please describe how your hospital uses the data (for example reports, dashboards, quality in peer review meeting agenda, etc.) in a meaningful way.

Response: The NSO reports are utilized by the Chief of Surgery, the Facility Surgical Work Group, and Facility leadership to track and monitor the quality and safety of the VHA Surgical Program (VHA Handbook 1102.01). The Facility Surgical Work Group supports the VHA enterprise framework for quality, safety, and value (VHA Directive 1026).

4. How do you use data discovery of issues to inform surgical quality improvement?

Response: Issues that inform surgical quality improvement are discovered through the NSO reports, the Critical Incident Tracking and Notification process, the peer review process, the root cause analysis process, and other quality reporting including SAIL.

5. Included, but not limited to data, what are your hospital's surveillance tools used for monitoring surgical quality? *For example, rounds, open door policy, dashboard monitoring, M&M conference, etc.*

Response: The Facility Surgical Work Group provides oversight to the M&M conference(s), and ensures dissemination of the NSO Quarterly Report (VHA Handbook 1102.01). The Facility Chief of Staff chairs the Peer Review Committee which informs the Medical Executive Committee and the Facility Director regarding quality and safety events (VHA Directive 2010-025). The Facility Director maintains and chairs a standing committee under an enterprise framework to review data, information, and risk intelligence and ensure that key quality, safety, and value functions are discussed and integrated on a regular basis. The committee is comprised of a multidisciplinary group working towards understanding the complex environment that results in adverse events, and loss of value and efficiency. The committee must develop prioritized recommendations to aid facility leadership. Medical facility leadership must charter improvement teams or initiate strategies to make changes to improve outcomes for Veterans (VHA Directive 1026).

6. If using administrative data, how do you know it's accurate and account for deficiencies in the data quality?

Response: NSO report data is collected from the VA electronic health record and reviewed for accuracy by the Facility Surgical Work Group, the VISN Surgical Work Group, and the NSO. The Facility Surgical Quality Nurse has individual patient data for VASQIP assessed procedures for review if needed. Furthermore, the NSO has an established methodology for performing inter-rater reliability assessment of VASQIP risk assessment data upon request or when

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

calculated expected morbidity and/or mortality rates are deemed suspect with regard to the patient population and other risk characteristics (ASA classification, complexity of procedures performed, etc).

7. How does your hospital use data to achieve high reliability?

Response: Data is used to achieve high reliability and improved outcomes for Veterans through improvement teams or other strategies based on the issues or concerns identified (VHA Directive 1026).

Optimal Resources for Surgical Quality and Safety Standards

CONFIDENTIAL: NSO Response 01/26/2018

Additional Questions:

In addition to meeting Standards 1-10 outlined above, demonstrate how your hospital does the following, if applicable:

1. Does your hospital participate in any surgical quality collaboratives? If yes, please list and describe each.

Reference Chapter 13: The essentials of surgical quality improvement collaboratives (pg. 251)

Response: The VA's Strategic Analytics for Improvement and Learning (SAIL) examines many of the same metrics tracked by surgical quality collaboratives such as the Partnership for Patients established by the National Quality Forum. Additional information regarding SAIL can be found at <https://sail.vssc.med.va.gov/>. In addition, the VA's Office of Strategic Integration (OSI)/Veterans Engineering Resource Center (VERC) established under the Principle Deputy Under Secretary for Health serves Veterans by improving organizational efficiency and successfully implementing health and business programs. Staffed by clinical and administrative professionals with subject matter, project management, contracting, training, and organizational expertise, OSI|VERC utilizes a combination of government staff and contractor staff to comprehensively meet stakeholder needs. As VHA's Enterprise Program Management Office, OSI|VERC specializes in: rapid execution of large, complex, multi-stakeholder projects; providing customized consulting services that improve the performance of VA offices, programs, processes, and initiatives; and training of VHA staff and the next generation of professional in improvement methods as they apply to healthcare.

2. How does your hospital use practice guidelines to improve patient care and how are they incorporated into the patient-care workflow?

Reference Chapter 14: Using practice guidelines to improve patient care (pg. 263)

Response: The VHA, in collaborations with the Department of Defense (DoD) and other leading professional organizations, has been developing clinical practice guidelines since the early 1990s. In 2010 the Institute of Medicine identified VA/DoD as leaders in clinical practice guideline development. VA/DoD clinical practice guidelines can be found at <https://www.healthquality.va.gov>.

From: Bruce Moskowitz
<(b) (6)@mac.com>
To: DJS </o=va/ou=exchange administrative
group (fydibohf23spdl)/cn=recipients/cn= < >
Cc:
Bcc:
Subject: [EXTERNAL] Re: NSO Survey Response and Appendix
Date: Mon Feb 26 2018 16:25:21 CST
Attachments:

Excellent

Sent from my iPad
Bruce Moskowitz M.D.

> On Feb 26, 2018, at 4:50 PM, DJS <vacodjs1@va.gov> wrote:

>
> FYI
>
>
>
> Sent with Good (www.good.com)
>
> _____
> From: Gunnar, William
> Sent: Monday, February 26, 2018 11:45:59 AM
> To: DJS
> Cc: Clancy, Carolyn
> Subject: FW: NSO Survey Response and Appendix
>
> Sec Shulkin,
> I am forwarding the survey response provided today to the American College of Surgeons and the
> appendix list of references. I can forward the additional 7 emails with referenced documents if you
> wish.
> Sincerely,
> Bill
>
> From: Gunnar, William
> Sent: Monday, February 26, 2018 2:12 PM
> To: Clancy, Carolyn; David Hoyt
> Cc: Clifford Ko
> Subject: NSO Survey Response and Appendix
>
> Dave,
> I have attached the VHA National Surgery Office response to the ACS "Red Book" Survey and the
> Appendix index of attached documents.
> The attached documents will be sent in a series of emails given document size.
> As discussed, Carolyn look forward to meeting following your review.
> Regards,
> Bill
>
> William Gunnar, MD, JD, FACHE
> National Director of Surgery

> 810 Vermont Ave NW
> Washington, DC 20420
> 202-461-7148
>
>
>
>
>
>
> <NSO Response.ACS Standards QM 02.26.18.pdf>
> <Appendix02.26.18.pdf>

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: marcbsherman <(b) (6)@gmail.com>; Bruce Moskowitz <(b) (6)@mac.com>; Ike Perlmutter <[REDACTED]@frenchangel59.com>
Cc:
Bcc:
Subject: FW: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...
Date: Sat Feb 24 2018 14:26:02 CST
Attachments:

See below- may be worth discussing on Tuesday

David

Sent with Good (www.good.com)

From: (b) (6)
Sent: Saturday, February 24, 2018 11:56:47 AM
To: Shulkin, David J., MD
Cc: Blackburn, Scott R.; (b) (6)
Subject: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...

Secretary Shulkin,

I am writing to share some exciting feedback. Yesterday afternoon, (b) (6) and I had the pleasure of joining Scott and the team to review the status of some of our recommendations from the Jan 5th gathering, particularly around open APIs and the opportunity to better align with community providers.

We are pleased to report your team appears to have successfully designed a contract that will reap interop benefits far beyond the VA. Signing this agreement, and encouraging community providers to join you in a "standards acceleration" effort as previously noted as a "pledge", will:

- make care safer for vets who receive both community care and direct services from the VA;
- accelerate by years an open API-based data sharing network by inspiring community care providers and their EHR vendors to reciprocate what your team will do in making more EHR data accessible via APIs than are currently planned for production absent your intervention;
- unleash a true "apps economy" that will compete to delight veterans, clinicians, and care coordination service providers in the use of longitudinal health information for care decisions.

To complement the specific provisions your team has negotiated with Cerner, the standards acceleration initiative ("pledge") is critical to ensuring your trading partners in the private sector/community can reciprocate in data sharing at the pace the VA will set.

Launching this collaborative, in time for a possible HIMSS announcement, might warrant your personal

attention in recruiting CEOs to serve as charter members of what will be an open process.

I'll defer to [REDACTED] and Scott on the roster of CEOs you might wish to call, but I've circulated a DRAFT of the acceleration effort with CIOs and CEOs who have participated in the Jan 5th gathering and one of the White House EHR listening sessions I attended a week or two ago. I'm confident, if asked, they will join:

Mayo
Hopkins
Cleveland Clinic
Geisinger
Intermountain
Fairview (MN)

others to consider: U. Washington, Partners, Rush, UPMC (and anyone else Scott [REDACTED] suggest).

Congratulations on taking what I presume was a good contract, to something closer to great on account of the impact it will have in making open, standards-based interop a reality faster than if you hadn't made this a priority.

Regards,

[REDACTED]
President
(703) 672-[REDACTED]

This email is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential or otherwise protected from disclosure. Dissemination, distribution, or copying of this email or the information herein by anyone other than the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, is prohibited. If you have received this email in error, please immediately notify us.

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: RE: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...
Date: Sat Feb 24 2018 14:56:04 CST
Attachments:

Good- that's the reason we need to discuss- I'm still learning this stuff

Thanks

Sent with Good (www.good.com)

From: Bruce Moskowitz
Sent: Saturday, February 24, 2018 12:41:09 PM
To: DJS
Cc: marcbsherman; Ike Perlmutter
Subject: Re: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...

Will discuss with everyone. Open API does not depend on signing the Cerner contract. Also this term is being tossed around without a full understanding of what it accomplishes.

Sent from my iPad
Bruce Moskowitz M.D.

> On Feb 24, 2018, at 3:26 PM, DJS <vacodjs1@va.gov> wrote:

>
> See below- may be worth discussing on Tuesday

>
> David

>
>
>
>
> Sent with Good (www.good.com)

>
> _____
> From: (b) (6) [REDACTED]
> Sent: Saturday, February 24, 2018 11:56:47 AM
> To: Shulkin, David J., MD
> Cc: Blackburn, Scott R.; (b) (6) [REDACTED]
> Subject: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...

>
> Secretary Shulkin,
>

> I am writing to share some exciting feedback. Yesterday afternoon, (b) (6) and I had the pleasure of joining Scott and the team to review the status of some of our recommendations from the Jan 5th gathering, particularly around open APIs and the opportunity to better align with community providers.

>

> We are pleased to report your team appears to have successfully designed a contract that will reap interop benefits far beyond the VA. Signing this agreement, and encouraging community providers to join you in a "standards acceleration" effort as previously noted as a "pledge", will:

>

> -make care safer for vets who receive both community care and direct services from the VA;

>

> -accelerate by years an open API-based data sharing network by inspiring community care providers and their EHR vendors to reciprocate what your team will do in making more EHR data accessible via APIs than are currently planned for production absent your intervention;

>

> -unleash a true "apps economy" that will compete to delight veterans, clinicians, and care coordination service providers in the use of longitudinal health information for care decisions.

>

> To complement the specific provisions your team has negotiated with Cerner, the standards acceleration initiative ("pledge") is critical to ensuring your trading partners in the private sector/community can reciprocate in data sharing at the pace the VA will set.

>

> Launching this collaborative, in time for a possible HIMSS announcement, might warrant your personal attention in recruiting CEOs to serve as charter members of what will be an open process.

>

> I'll defer to (b) (6) and Scott on the roster of CEOs you might wish to call, but I've circulated a DRAFT of the acceleration effort with CIOs and CEOs who have participated in the Jan 5th gathering and one of the White House EHR listening sessions I attended a week or two ago. I'm confident, if asked, they will join:

>

> Mayo

> Hopkins

> Cleveland Clinic

> Geisinger

> Intermountain

> Fairview (MN)

>

> others to consider: U. Washington, Partners, Rush, UPMC (and anyone else Scott (b) (6) suggest).

>

> Congratulations on taking what I presume was a good contract, to something closer to great on account of the impact it will have in making open, standards-based interop a reality faster than if you hadn't made this a priority.

>

> Regards,

>

> (b) (6)

> President

> (703) 672-(b) (6)

>

>

> (b) (6)

>

> This email is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential or otherwise protected from disclosure. Dissemination, distribution, or copying of this email or the information herein by anyone other than the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, is prohibited. If you have received this email in error, please immediately notify us.



From: Bruce Moskowitz
(b) (6) @mac.com>
To: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn= >
Cc: marcbsherman (b) (6) @gmail.com>;
Ike Perlmutter (b) (6) @frenchangel59.com>
Bcc:
Subject: Re: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...
Date: Sat Feb 24 2018 14:41:09 CST
Attachments:

Will discuss with everyone. Open API does not depend on signing the Cerner contract. Also this term is being tossed around without a full understanding of what it accomplishes.

Sent from my iPad
Bruce Moskowitz M.D.

> On Feb 24, 2018, at 3:26 PM, DJS <vacodjs1@va.gov> wrote:

>
> See below- may be worth discussing on Tuesday

>
> David

>
>
>
>
> Sent with Good (www.good.com)

>
> _____
> From: (b) (6)
> Sent: Saturday, February 24, 2018 11:56:47 AM
> To: Shulkin, David J., MD
> Cc: Blackburn, Scott R.; (b) (6)
> Subject: [EXTERNAL] Closing the loop on Jan 5th MITRE recommendations...

>
> Secretary Shulkin,

>
> I am writing to share some exciting feedback. Yesterday afternoon, (b) (6) and I had the pleasure of joining Scott and the team to review the status of some of our recommendations from the Jan 5th gathering, particularly around open APIs and the opportunity to better align with community providers.

>
> We are pleased to report your team appears to have successfully designed a contract that will reap interop benefits far beyond the VA. Signing this agreement, and encouraging community providers to join you in a "standards acceleration" effort as previously noted as a "pledge", will:

>
> -make care safer for vets who receive both community care and direct services from the VA;

>
> -accelerate by years an open API-based data sharing network by inspiring community care providers and their EHR vendors to reciprocate what your team will do in making more EHR data accessible via APIs than are currently planned for production absent your intervention;

>
> -unleash a true "apps economy" that will compete to delight veterans, clinicians, and care coordination service providers in the use of longitudinal health information for care decisions.

>

> To complement the specific provisions your team has negotiated with Cerner, the standards acceleration initiative ("pledge") is critical to ensuring your trading partners in the private sector/community can reciprocate in data sharing at the pace the VA will set.

>

> Launching this collaborative, in time for a possible HIMSS announcement, might warrant your personal attention in recruiting CEOs to serve as charter members of what will be an open process.

>

> I'll defer to (b) (6) and Scott on the roster of CEOs you might wish to call, but I've circulated a DRAFT of the acceleration effort with CIOs and CEOs who have participated in the Jan 5th gathering and one of the White House EHR listening sessions I attended a week or two ago. I'm confident, if asked, they will join:

>

> Mayo

> Hopkins

> Cleveland Clinic

> Geisinger

> Intermountain

> Fairview (MN)

>

> others to consider: U. Washington, Partners, Rush, UPMC (and anyone else Scott (b) (6) suggest).

>

> Congratulations on taking what I presume was a good contract, to something closer to great on account of the impact it will have in making open, standards-based interop a reality faster than if you hadn't made this a priority.

>

> Regards,

>

> (b) (6)

> President

> (703) 672-(b) (6) >

>

>

> (b) (6)

>

> This email is intended only for the person or entity to which it is addressed and may contain information that is privileged, confidential or otherwise protected from disclosure. Dissemination, distribution, or copying of this email or the information herein by anyone other than the intended recipient, or an employee or agent responsible for delivering the message to the intended recipient, is prohibited. If you have received this email in error, please immediately notify us.

>

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Ike Perlmutter <[REDACTED]@frenchangel59.com>;
Bruce Moskowitz <[REDACTED]@mac.com>; [REDACTED] <[REDACTED]@gmail.com>
Cc:
Bcc:
Subject: FW: VA collaborates with ACS to review VA Surgical Program Quality
Date: Wed Feb 14 2018 13:56:39 CST
Attachments: Optimal Resources for Surgical Quality and Safety booklet.pdf

We're getting close

Sent with Good (www.good.com)

From: Gunnar, William
Sent: Wednesday, February 14, 2018 11:53:41 AM
To: [REDACTED]
Cc: DJS; Clancy, Carolyn
Subject: VA collaborates with ACS to review VA Surgical Program Quality

[REDACTED]

Sec Shulkin asked me to reach out to David Hoyt, MD, Executive Director of the American College of Surgeons (ACS) today regarding a collaboration between the VA and ACS that will analyze the quality of surgical services provided by VHA Surgery Programs. The ACS has a newly established process for reviewing the delivery of surgical services (see attached). The current plan is for ACS to examine the VHA surgery programs through data analysis and site visits to the VHA Surgery Programs located at Houston VAMC and Milwaukee VAMC.

Speaking with Dr. Hoyt today, he is committed to the project and will work with you and your staff to collaborate on a press release for as early as tomorrow. He asked that you contact him directly at [REDACTED]@facs.org. His office number is 312-202-[REDACTED]. Additional information regarding ACS can be found at www.facs.org and the ACS executive staff at <https://www.facs.org/about-acsgovernance/exec-staff>

Let me know if there is anything I can do to assist you. I will notify the MCD and Chief of Staff of the Houston VAMC and Milwaukee VAMC as a heads up.

Feel free to call me if you need additional information.

Bill



Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: Optimal Resources for Surgical Quality and Safety booklet.pdf
Last Modified: Wed Feb 14 13:56:39 CST 2018



AMERICAN COLLEGE OF SURGEONS

Inspiring Quality.
Highest Standards. Better Outcomes

100+ years

You have the passion
You have the drive
We have the road map

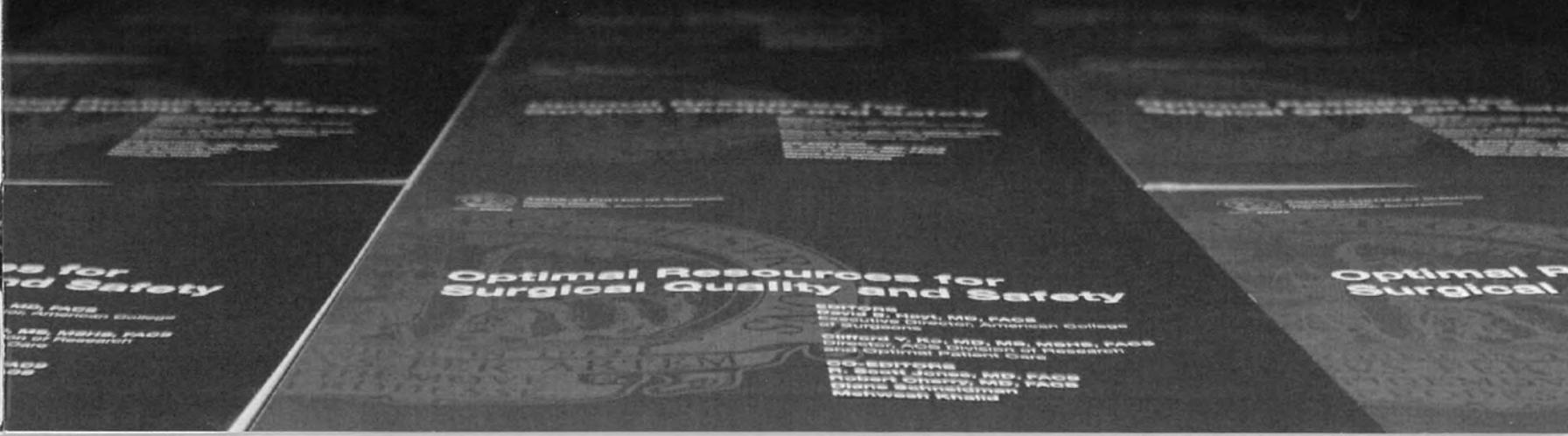
Optimal Resources for Surgical Quality and Safety

EDITORS

David B. Hoyt, MD, FACS, Executive Director,
American College of Surgeons
Clifford Y. Ko, MD, MS, MSHS, FACS, Director,
ACS Division of Research and Optimal Patient Care

CO-EDITORS

R. Scott Jones, MD, FACS
Robert Cherry, MD, FACS
Diane Schneidman
Mehwesh Khalid



"You have to know your own outcomes in order to improve them."

—Ernest A. Codman, MD, FACS, a founder of the American College of Surgeons

Your journey begins here

It begins with a mindset—a mindset that you, the surgeon, own the outcome. You are the leader. You are the one who is ultimately responsible for delivering safe, high-quality, high-reliability care. After all, patients put their trust in you.

But leading today looks much different than it did even a decade ago. Today, you cannot be out in front of the team, you must lead from within the team, working in concert with other health care professionals, the patient, and the patient's family. Today, your world is multidisciplinary, and the continuum of care is much longer and more complex than ever. The regulatory pressure you face is unprecedented. No one ever said that establishing a patient- and surgeon-driven culture was going to be easy, but the rewards will be there. Guaranteed.

Leading through the five phases of care

The operation may be "the main event," but when it comes to ensuring quality and safety in surgical care, it's important to think holistically and factor into the equation the five phases of care. The surgeon must lead the team through each phase:

1	2	3	4	5
Surgical preoperative evaluation and preparation phase of care	Immediate preoperative readiness phase of care	Intraoperative phase of care	Postoperative phase of care	Postdischarge phase of care

Depending on the phase, your team members will vary, and may include the patient/family, office staff, primary and consulting physicians, and nurses. The domains will vary from the clinic for preoperative evaluation to a skilled nursing center or at-home care postdischarge. No matter where surgical care is delivered, your patient will count on you for guidance and expert care.

The patient's safety is in your hands.



The Surgery Quality Officer

A dedicated Surgical Quality Officer (SQO) goes a long way toward ensuring that surgeons and their teams have the infrastructure, resources, and training needed to provide cost-effective and high-reliability care. If your organization does not have an SQO, perhaps your chief of surgery is functioning in this capacity.

The SQO is the individual who leads the department of surgery's quality improvement effort, and is your champion and ally.

The SQO is the key figure in building the quality and safety infrastructure and leads a key component of that framework—the hospital's Surgical Quality and Safety Committee (SQSC). Among other things, that committee should:

- ✓ **Monitor surgical mortality and adverse event rates**
- ✓ **Address clinical practice variations**
- ✓ **Establish quality and safety standards, guidelines, and surgery-related policies**
- ✓ **Monitor primary data and data reports to identify consistent, cross-cutting surgical issues**



AMERICAN COLLEGE OF SURGEONS
*Inspiring Quality:
Highest Standards, Better Outcomes*

100+ years

Case review and peer review

In addition to the SQSC, case review and peer review are essential to the quality improvement infrastructure. Hardly new concepts, peer and case review are rooted in a tradition started by one of the founders of the American College of Surgeons—Ernest A. Codman, MD, FACS, who advocated in the early 1900s his “end result idea.” The “idea” was simply the premise that hospital staffs would follow every patient they treat long enough to determine whether the treatment was successful, learn from any failures, and determine how to avoid those situations in the future. Dr. Codman’s passion to learn from past failures is very much the same as surgeons’ today—you want to do what is best for the patient, and case review and peer review are essential to that quest.

At the most basic level, case review and peer review refer to the formal processes that health care professionals use to evaluate their clinical work and ensure that prevailing standards of care are being met. Today, both standing and ad hoc committees perform these types of reviews.

The five types of clinical reviews are:

- ➔ **Case review (single discipline)**
- ➔ **Case review (multidiscipline)**
- ➔ **Peer review of individual surgeons**
- ➔ **Data/registry review**
- ➔ **Educational review conferences**

While the chief of surgery or the SQO must ensure adherence to and foster a commitment to these review processes, you, as a surgeon leader, also will want to lead the way when it comes to holding regular reviews. You must recognize and communicate to your team that not all adverse outcomes are attributable to systems problems; undisciplined or unsafe practices require principled action. You need to model the behavior that you expect of your team members. You are the surgeon leader.

Credentialing and privileging

You need to be an active participant in the credentialing and privileging processes. Why? Because as a surgeon of the best. Remember the goal of credentialing and privileging is to ensure that you and your colleagues are trained to provide safe, reliable care. It is not enough to put your efforts into building the team you work with day-to-day; as a surgeon leader, you want to contribute to your organization's culture of patient-centered care.

Culture of high reliability

Culture—that's what it's all about. Without a shared culture that places quality, safety, and high-reliability above all else, it will be extremely difficult to implement best practices and improve patient care. Fortunately, many health care organizations are working to establish cultures that incorporate the principles applied in high-reliability organizations (HROs), including emphasis on systems-based care, transparency, teamwork, nonpunitive analysis of errors, and best practices. But creating a culture of high-reliability requires you, as the surgeon leader, to show some "attitude." An attitude that says to the team, "we've got this." We know what we need to do to ensure high reliability.

Databases and registries

Databases and registries are the key components of health care data analytics and can be extremely helpful in your quest for high reliability. Numerous data and registry programs are available, and you will want to rely on the literature and trusted colleagues to identify those of most value to you.

If you aren't familiar with a data source or registry, here are some questions to consider:

- ➔ **Who sponsors and maintains the database or registry program?**
- ➔ **What is the aim of the program?**
- ➔ **What sets the program apart from others?**
- ➔ **What is the history of the program, and what is its track record for improving care?**

Practice guidelines

Clinical practice guidelines (CPG) are sets of evidence-based recommendations that help health care professionals make decisions regarding the care they deliver to individual patients and groups of patients with similar diseases. A critical element in implementing guidelines in health care institutions is physician buy-in. As a surgeon leader, you must participate in the development, implementation, and evolution of successful guidelines.



AMERICAN COLLEGE OF SURGEONS
*Inspiring Quality:
Highest Standards, Better Outcomes*

100+years

Key points and specifications

How do we measure quality and safety in surgical care? *Page 19*

KEY POINTS

Quality and safety are measured on the basis of the following:

- Outcomes
- Processes
- Structure

WHY YOU NEED TO KNOW IT

To understand what the surgeon can do as the leader of the surgical team to provide safe, high-quality, high-value care to every patient.

What occurs in each of the five phases of care, and what are the surgeon's responsibilities? *Pages 28-35*

KEY POINTS

The five phases of surgical care are:

- Preoperative evaluation and preparation
- Immediate preoperative readiness phase of care
- Intraoperative phase of care
- Postoperative phase of care
- Postdischarge phase of care

WHY YOU NEED TO KNOW IT

To understand the proven techniques for providing safe, high-quality, highly reliable team-based care.

Why does a surgical institution need a Surgical Quality Officer? *Pages 39-48*

KEY POINTS

The SQO:

- Leads efforts to establish and maintain the infrastructure and standards that lead to high reliability
- Ensures team members have the skills, tools, resources, and training needed to provide optimal care
- Identifies, acknowledges, and addresses factors that may contribute to suboptimal care

WHY YOU NEED TO KNOW IT

To take ownership of quality improvement in the surgeon's institution and practice.

What are the different types of case review and peer review in surgery? *Pages 53-56*

KEY POINTS

The five types of reviews commonly conducted in surgery are:

- Single-discipline case review (such as case review for morbidity and mortality conference)
- Multidisciplinary case review (case review centered on the actions of all specialists involved in patient care)
- Peer review of individual surgeons (review of an individual's performance issues)
- Data/registry review (reviews of reports from clinical databases)
- Educational case review (emphasis on creating a learning environment)

WHY YOU NEED TO KNOW IT

- To ensure that the profession can continue to regulate itself
- To identify outliers and process deviations
- To stimulate research and innovation

Why should surgical institutions have Surgical Quality and Safety Committees? *Pages 63-67*

KEY POINTS

The SQSC is an oversight committee, which conducts quality evaluations and leads quality assurance activities.

WHY YOU NEED TO KNOW IT

The effectiveness of the overall quality and safety program within a surgical department is dependent on the committee infrastructure through which that work is accomplished. Surgeon participation is critical.

How do credentialing and privileging processes affect the delivery of quality care? *Pages 71-72 and 81-82*

KEY POINTS

The credentialing process ensures that health care professionals are appropriately trained to deliver safe care, and the privileging process ensures that health care professionals deliver care within their scope of expertise.

WHY YOU NEED TO KNOW IT

The credentialing and privileging committees need input from an appropriate mix of specialties to ensure that team members have the skills and experience to deliver high quality health care providers.

What qualities define a health care culture focused on quality and safety? *Pages 87-89*

KEY POINTS

Health care should perpetuate a just culture, which takes a non-punitive, thoughtful approach to addressing errors. This culture should:

- Place patient safety above all else
- Reduce unwarranted variation
- Standardize best practices
- Encourage teamwork
- Promote effective communication

WHY YOU NEED TO KNOW IT

The individual surgeon must lead by example to create a culture rooted in the principles of high reliability, quality assurance, and patient-centered care.

What specific systems and processes need to be in place to ensure patient safety? *Pages 99-104*

KEY POINTS

Surgical institutions and practices should use the following systems and processes to ensure patient safety:

- Development of patient safety reports
- Open discussion of errors
- Root-cause analysis
- Participation in clinical registries

WHY YOU NEED TO KNOW IT

The surgeon and other surgical team members are responsible for ensuring consistent use of surgical strategies and tools.

What are the different requirements for the various disciplines involved in surgical patient care? *Chapter 9*

KEY POINTS

Each surgical discipline has its own scope of practice, clinical registries, practice guidelines, and regulatory requirements.

WHY YOU NEED TO KNOW IT

The surgeon leader needs to be aware of the quality improvement initiatives, resources, and regulatory requirements that are specific to each specialty involved in the multidisciplinary patient care team.

How does external regulation affect quality and safety? *Pages 199-208*

KEY POINTS

External regulatory agencies, such as the Centers for Medicare & Medicaid Services, set the rules for how services are reimbursed and, therefore, the level of services provided. Accrediting bodies, such as the surgical boards and some professional associations, set the standards for credentialing and verification.

WHY YOU NEED TO KNOW IT

It is imperative that surgeons work with internal and external stakeholders, including regulatory agencies, to enhance the quality and safety of care provided to patients and to maintain their autonomy and authority.

What is data analytics, and how can we use it to improve patient care? *Pages 213-214 and 239-248*

KEY POINTS

Data analytics uses information derived from clinical registries, such as outcome reports, to determine opportunities to improve patient care.

WHY YOU NEED TO KNOW IT

Surgeon leaders should be familiar with the range of clinical databases that collect and process data on surgical care and how to interpret and apply the data in quality improvement efforts. Data will continue to drive the future of health care, and surgeons are best able to interpret the data related to surgical care.

Why should surgical institutions participate in surgical quality improvement collaboratives? *Pages 253-260*

KEY POINTS

Substantive change is more likely to occur when institutions and individuals work together to solve a problem than when they work in isolation.

WHY YOU NEED TO KNOW IT

Participation in a collaborative represents the highest calling of surgeons to act as part of a fellowship that selflessly advances the interests of the surgical patient.

What are clinical practice guidelines (CPGs)? *Pages 265-270*

KEY POINTS

CPGs are sets of evidence-based recommendations that help health care professionals make decisions about the care they provide to individual patients and groups of patients with similar diseases.

WHY YOU NEED TO KNOW IT

Surgeon buy-in and input is necessary to ensure that guidelines are evidence-based and not overly prescriptive.

What are some other factors that affect the delivery of quality surgical care? *Pages 278-335*

KEY POINTS

Other factors that affect quality of care include:

- Education and training
- Adherence to professional values
- Modeling of key leadership principles, such as self-awareness, empathy, communication, and inclusion
- Correction of disruptive behavior
- Mentorship and coaching

WHY YOU NEED TO KNOW IT

The surgical care team looks to the surgeon as the leader of the patient care team to set the tone for delivering patient-centered care. The team must function optimally to achieve the best possible outcomes.

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: FW: [EXTERNAL] AATB Follow-up to January 19th VA Meeting
Date: Fri Feb 02 2018 16:11:57 CST
Attachments: LeaveBehindVATissueTrackingFINAL20180202.pdf
VALetterFINAL20180202pdf.pdf

Bruce - what do you think of this?

Sent with Good (www.good.com)

From: (b) (6) [REDACTED]
Sent: Friday, February 02, 2018 10:37:35 AM
To: Shulkin, David J., MD
Cc: Clancy, Carolyn; Hyduke, Barbara; Nechanicky, Penny L.; Christy, Phillip; Icardi, Michael S.;
(b) (6) [REDACTED] (SAC); (b) (6) [REDACTED]@lifelinkfound.org
Subject: [EXTERNAL] AATB Follow-up to January 19th VA Meeting

Secretary Shulkin:

Please find attached a letter from the American Association of Tissue Banks (AATB) and the AATB Tissue Policy Group (TPG) to thank the Department of Veterans Affairs (VA) for a very productive meeting on January 19, 2018. We found the exchange of key information regarding biological implants (including human tissue products) very informative.

As noted during the meeting, the AATB and the TPG would like to a partner with the VA to assist in the development of appropriate systems for tracking and tracing all devices, including human tissue devices.

Please do not hesitate to contact us should you require additional information.

Cordially,

(b) (6) [REDACTED]

[REDACTED]
American Association of Tissue Banks (AATB)
(b) (6) [REDACTED]
8200 Greensboro Drive, Suite 320

McLean, VA 22102
Email: (b) (6)@aatb.org
Office: (703) 229-(b) (6)
Fax: (703) 992-(b) (6)

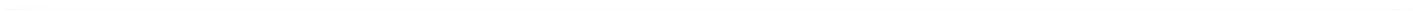
REGISTER TODAY!

2018 Quality & Donor Eligibility Workshop | April 30-May 2, 2018 | Hyatt Regency Baltimore Inner Harbor

2018 AATB Annual Meeting | October 9-12, 2018 | Hyatt Regency Dallas at Reunion

Find an AATB Accredited Bank

Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information. If you received this message in error and are not the intended recipient: any disclosure, copying, distribution or reliance on the contents of this e-mail and any attachment is strictly prohibited; please reply to the sender so that delivery to the intended recipient can be made; and promptly delete the message from your inbox and trash folder without further review of its contents.



Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: LeaveBehindVATissueTrackingFINAL20180202.pdf
Last Modified: Fri Feb 02 16:11:57 CST 2018



American Association of Tissue Banks®



AATB TPG, LLC

Tissue Tracking in VHA Facilities

Support the “Biological Implant Tracking and Veteran Safety Act of 2017”

The “Biological Implant Tracking and Veteran Safety Act of 2017” (H.R. 28/S. 23) directs the Secretary of Veterans Affairs to adopt a standard identification system for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the success of the implementation of the Unique Device Identifier (UDI), this legislation will ensure that biological implants used within the Department can be appropriately tracked from a human tissue donor or manufacturer all the way to the recipient. This critical capability for “track and trace” efforts will enhance patient safety, expedite product recalls when necessary, assist with inventory management, and improve efficiencies.

While many of the biological implants do have company specific bar coding information, by requiring a standardized format for those bar codes, as outlined in this legislation, it will be easier for the Department of Veterans Affairs’ medical facilities to utilize universal bar coding conventions and to realize the full benefit of a unique identification system. Finally, by applying a system that has been developed for devices to biological implants, such a solution should also be applicable to other health care settings and other health care systems (such as the Department of Defense health care system or the private sector).

Use of human tissue in VA facilities. Human tissue is used in a wide variety of medical procedures in the Veterans Health Administration (VHA) facilities, ranging from wound care management to hernia repair to orthopedic procedures. Human tissue is also used in a wide array of dental services, such as bone augmentation and gum tissue grafting procedures. In fact, according to a Government Accountability Office (GAO) report, biologics accounted for approximately \$75 million in VHA acquisitions in fiscal year 2013. That same GAO report noted that one VHA medical center had a high percentage of purchases missing serial numbers or lot numbers (16 percent in the first three quarters of fiscal year 2013).¹ The goal of the legislation is to address this outstanding concern, without providing an undue burden on the health care system.

Key provisions. The American Association of Tissue Banks (AATB) is pleased that this legislation ensures that our veterans receive high quality implants by requiring that the biological implants only be sourced from tissue processors accredited by the AATB or similar national accreditation organization. With this change, the Veterans Health Administration (VHA) will be joining the ranks of leading medical centers of excellence, which currently require all tissue to be sourced from AATB accredited tissue banks. We are also pleased that the legislation clarifies that human tissue procured by the VHA can be labeled with any of the three systems already identified by the Food and Drug Administration (FDA) to be appropriate for biological implants. Under the UDI final rule, FDA has done just that by providing for multiple entities called “issuing agencies.” At this time, FDA has provided for three different issuing agencies: (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA. By maintaining this appropriate flexibility, the VHA will ensure a more competitive marketplace.

Current status. On January 3, 2017, Rep. Roe (R-TN) introduced H.R. 28, and later that day, the House passed it by voice vote. On January 4, 2017, Sen. Cassidy introduced S.23. Sen. Tester (D-MT) joined as a cosponsor on January 9, 2017.

Supporting organizations. Besides the American Association of Tissue Banks (AATB), the American Legion,² the Disabled American Veterans (DAV)³ support the legislation.

¹<http://www.gao.gov/assets/670/660105.pdf>

²<http://www.legion.org/legislative/testimony/220552/pending-legislation> and <http://www.veterans.senate.gov/imo/media/doc/TAL%20I.%20de%20Planque%20Testimony%206.24.15.pdf>

³<http://www.veterans.senate.gov/imo/media/doc/DAV%20Atizado%20Testimony%206.24.15.pdf>

Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: VALetterFINAL20180202pdf.pdf
Last Modified: Fri Feb 02 16:11:57 CST 2018



American Association of Tissue Banks® AATB TPG, LLC

February 2, 2018

Honorable David J. Shulkin
Secretary
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

In Re: Meeting with AATB representatives on January 19, 2018

Submitted electronically via David.Shulkin@va.gov

Dear Secretary Shulkin:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group, LLC (AATB TPG) send this letter to thank you for a recent meeting on January 19 with your key Department of Veterans Affairs (VA) staff, including

- Barbara Hyde Deputy Chief of Staff, Veterans Health Administration;
- Penny L. Nechanicky, Director, Prosthetic and Sensory Aids Service Veterans Health Administration;
- Phillip Christy, Associate Executive Director, Strategic Acquisition Center;
- Michael S. Icardi, MD, Chairman, Department of Veterans Affairs/Molecular Genetics Pathology Workgroup; and
- (b) (6), (b) (6), Strategic Acquisition Center.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals more than 125 accredited tissue banks and 2,000 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the U.S. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB's Tissue Policy Group (TPG), LLC (AATB TPG or TPG) includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose

Letter to the VA re: Biological Implants

February 2, 2018

Page 2

of the TPG is to drive public policy in furtherance of the adoption of laws and regulations that foster the safety, quality and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

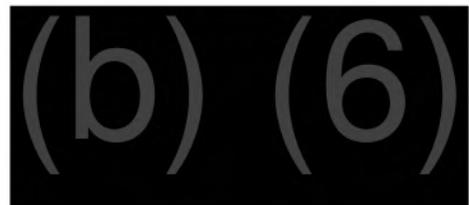
During our discussion, the AATB and the TPG were heartened by your staff's comments clarifying that it is the VA's policy position that all three issuing agencies – GS1, Health Industry Business Communications Council (HIBCC), and ICCBBA (i.e., ISBT-128) are appropriate labeling systems for human tissue products, including those that are also biological implants, and that the VA's position is thus aligned with Food and Drug Administration's authorization of these three labeling systems. Given this position, the AATB and the TPG urge you to review legislation pending before Congress -- HR 28/S 23, the "Biological Implant Tracking and Veteran Safety Act of 2017." The labeling systems that we discussed during our meeting are a key component to the tracking system (with the introduction of standardized bar codes) but are only one component of a larger process of tissue track and trace efforts (which will likely involve adoption of electronic health record standards, such as the 2015 certification criteria with the implantable device list).

As noted during the meeting, the AATB and the TPG would like to a partner with you to assist in development of appropriate systems for tracking and tracing all devices, including human tissue devices. Please do not hesitate to contact us should you require additional information.

Respectfully,

A large black rectangular redaction box covering the signature of the American Association of Tissue Banks. The text "(b) (6)" is printed in a large, light gray font over the redaction.

American Association of Tissue Banks

A large black rectangular redaction box covering the signature of the Tissue Policy Group. The text "(b) (6)" is printed in a large, light gray font over the redaction.

Tissue Policy Group

Cc: Carolyn Clancy, Barbara Hydeke, Penny Nechanicky, Phillip Christy, Michael Icardi, and (b) (6)

A small black rectangular redaction box covering a name in the distribution list.

Attachment: Background on the HR 28/S 23, the "Biological Implant Tracking and Veteran Safety Act of 2017"

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: RE: [EXTERNAL] AATB Follow-up to January 19th VA Meeting
Date: Fri Feb 02 2018 16:59:40 CST
Attachments:

Ok

Sent with Good (www.good.com)

From: Bruce Moskowitz
Sent: Friday, February 02, 2018 2:58:45 PM
To: DJS
Subject: Re: [EXTERNAL] AATB Follow-up to January 19th VA Meeting

Should be part of meeting for device registry

Sent from my iPhone

> On Feb 2, 2018, at 5:11 PM, DJS <vacodjs1@va.gov> wrote:

>
> Bruce - what do you think of this?
>
>
>
> Sent with Good (www.good.com)
>
>
> From: (b) (6) [REDACTED]
> Sent: Friday, February 02, 2018 10:37:35 AM
> To: Shulkin, David J., MD
> Cc: Clancy, Carolyn; Hyduke, Barbara; Nechanicky, Penny L.; Christy, Phillip; Icardi, Michael S.;
(b) (6) [REDACTED] (SAC); (b) (6) [REDACTED]@lifelinkfound.org
> Subject: [EXTERNAL] AATB Follow-up to January 19th VA Meeting

> Secretary Shulkin:

>
> Please find attached a letter from the American Association of Tissue Banks (AATB) and the AATB Tissue Policy Group (TPG) to thank the Department of Veterans Affairs (VA) for a very productive meeting on January 19, 2018. We found the exchange of key information regarding biological implants (including human tissue products) very informative.

> As noted during the meeting, the AATB and the TPG would like to a partner with the VA to assist in

the development of appropriate systems for tracking and tracing all devices, including human tissue devices.

>
> Please do not hesitate to contact us should you require additional information.

>
> Cordially,

>
> (b) (6)

> [Redacted]

> American Association of Tissue Banks (AATB)

> (b) (6)

> 8200 Greensboro Drive, Suite 320

> McLean, VA 22102

> Email: (b) (6)@aatb.org<mailto:(b) (6)@aatb.org>

> Office: (703) 229-(b) (6)

> Fax: (703) 992-(b) (6)

> _____

> REGISTER TODAY!

> 2018 Quality & Donor Eligibility Workshop <<http://www.cvent.com/events/2018-quality-and-donor-eligibility-workshop/event-summary-37c8ef297d584a8190f3d04318b7c6db.aspx>> | April 30-May 2, 2018 | Hyatt Regency Baltimore Inner Harbor

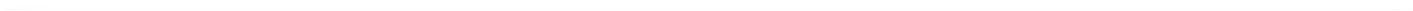
> 2018 AATB Annual Meeting<<https://www.aatb.org/?q=content/person-meetings>> | October 9-12, 2018 | Hyatt Regency Dallas at Reunion

> Find an AATB Accredited Bank<<http://www.aatb.org/?q=content/accredited-bank-search>>

> Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information. If you received this message in error and are not the intended recipient: any disclosure, copying, distribution or reliance on the contents of this e-mail and any attachment is strictly prohibited; please reply to the sender so that delivery to the intended recipient can be made; and promptly delete the message from your inbox and trash folder without further review of its contents.

> <VALetterFINAL20180202pdf.pdf>

> <LeaveBehindVATissueTrackingFINAL20180202.pdf>



From: Bruce Moskowitz
<(b) (6)@mac.com>
To: DJS </o=va/ou=exchange administrative
group (fydibohf23spdlt)/cn=recipients/cn=(b) (6)>
Cc:
Bcc:
Subject: Re: [EXTERNAL] AATB Follow-up to January 19th VA Meeting
Date: Fri Feb 02 2018 16:58:45 CST
Attachments:

Should be part of meeting for device registry

Sent from my iPhone

> On Feb 2, 2018, at 5:11 PM, DJS <vacodjs1@va.gov> wrote:

>
> Bruce - what do you think of this?

>
>
>
>
> Sent with Good (www.good.com)

>
> _____
> From: (b) (6)
> Sent: Friday, February 02, 2018 10:37:35 AM
> To: Shulkin, David J., MD
> Cc: Clancy, Carolyn; Hyduke, Barbara; Nechanicky, Penny L.; Christy, Phillip; Icardi, Michael S.;
(b) (6) (SAC); (b) (6)@lifelinkfound.org
> Subject: [EXTERNAL] AATB Follow-up to January 19th VA Meeting

>
> Secretary Shulkin:
>
> Please find attached a letter from the American Association of Tissue Banks (AATB) and the AATB
Tissue Policy Group (TPG) to thank the Department of Veterans Affairs (VA) for a very productive
meeting on January 19, 2018. We found the exchange of key information regarding biological implants
(including human tissue products) very informative.

>
> As noted during the meeting, the AATB and the TPG would like to a partner with the VA to assist in
the development of appropriate systems for tracking and tracing all devices, including human tissue
devices.

>
> Please do not hesitate to contact us should you require additional information.

>
> Cordially,

> (b) (6)

> _____
> American Association of Tissue Banks (AATB)
> (b) (6) r
> 8200 Greensboro Drive, Suite 320
> McLean, VA 22102
> Email: (b) (6)@aatb.org<mailto:(b) (6)@aatb.org>

> Office: (703) 229- (b) (6)

> Fax: (703) 992- (b) (6)

> _____

> REGISTER TODAY!

> 2018 Quality & Donor Eligibility Workshop <<http://www.cvent.com/events/2018-quality-and-donor-eligibility-workshop/event-summary-37c8ef297d584a8190f3d04318b7c6db.aspx>> | April 30-May 2, 2018 | Hyatt Regency Baltimore Inner Harbor

> 2018 AATB Annual Meeting<<https://www.aatb.org/?q=content/person-meetings>> | October 9-12, 2018 | Hyatt Regency Dallas at Reunion

> Find an AATB Accredited Bank<<http://www.aatb.org/?q=content/accredited-bank-search>>

> Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information. If you received this message in error and are not the intended recipient: any disclosure, copying, distribution or reliance on the contents of this e-mail and any attachment is strictly prohibited; please reply to the sender so that delivery to the intended recipient can be made; and promptly delete the message from your inbox and trash folder without further review of its contents.

> <VALetterFINAL20180202pdf.pdf>

> <LeaveBehindVATissueTrackingFINAL20180202.pdf>

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: RE: [EXTERNAL] Re: IPA Update
Date: Tue Jan 02 2018 14:02:15 CST
Attachments:

If you have time call me- I'm on a long car ride

(b) (6) [REDACTED]

Sent with Good (www.good.com)

From: Bruce Moskowitz
Sent: Tuesday, January 02, 2018 11:56:03 AM
To: DJS
Subject: [EXTERNAL] Re: IPA Update

Will explain the big D problem we spoke about Sundayoff line and how it relates to this.

Sent from my iPhone

> On Jan 2, 2018, at 2:48 PM, DJS <vacodjs1@va.gov> wrote:

>
>
>

> Sent with Good (www.good.com)

>
>

> _____
> From: DJS
> Sent: Tuesday, January 02, 2018 11:14:56 AM
> To: brucemoskowitz
> Subject: FW: IPA Update

>
> Bruce- this below is encouraging- it's using the IPA contract to get help from academic centers. I wanted you to be aware to make sure you know this is an available mechanism for us to use when we identify help. I'd be glad to discuss more if helpful

>
>

> David

>
>
>

> Sent with Good (www.good.com)

>
>
> _____
> From: Zenooz, Ashwini
> Sent: Tuesday, January 02, 2018 8:22:18 AM
> To: DJS
> Cc: Blackburn, Scott R.
> Subject: IPA Update
>
> Hello Dr. Shulkin:
>
> Happy New Year.
>
> I am sending you a note on IPAs ahead of the session coming up on hiring. After our last roundtable with MITRE, you had asked all the university participants to think about sending experts to VA through IPAs. I followed up on that with several university dean's offices and have received very positive responses.
>
>
> · After your visit to Yale, I connected with Harlan Krumholz who was very inspired by his conversation with you and he offered to take the lead on the IPA Transformation Center.
>
> · We now have a plan to source experts from universities and hospitals around the country in a strategic way, and his team is willing to coordinate the search & maintenance of the program through Yale Medical School (similar to what he does with CMS, NIH ad FDA).
>
> · I have identified 6 core areas requiring experts who can fill leadership and other positions in VHA/EHR space and associated hospital systems where the experts would come from (slide below).
>
> · In addition, we also have additional interest in having a group work with us through Dr. Shrestha at Univ. Of Pittsburgh.
>
> · The goal is to give you a larger pool of external experts who will be embedded into our system, have in-depth understanding of the work, produce literature and can bring in change by leading from the inside.
>
> Please let me know if you would like more information, any changes, approve/disapprove. Thanks,
ash
>
> [cid:image003.png@01D383BB.F2C583F0]
>
> Ashwini Zenooz, MD
> EHR Modernization
> Department of Veterans Affairs
> O: (202) 461-5903
> Assistant: (b) (6) @va.gov
> Web: <https://vaww.ehrm.va.gov/>
>
>

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: [REDACTED] (b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: FW: IPA Update
Date: Tue Jan 02 2018 13:48:13 CST
Attachments: image003.png

Sent with Good (www.good.com)

From: DJS
Sent: Tuesday, January 02, 2018 11:14:56 AM
To: brucemoskowitz
Subject: FW: IPA Update

Bruce- this below is encouraging- it's using the IPA contract to get help from academic centers. I wanted you to be aware to make sure you know this is an available mechanism for us to use when we identify help. I'd be glad to discuss more if helpful

David

Sent with Good (www.good.com)

From: Zenooz, Ashwini
Sent: Tuesday, January 02, 2018 8:22:18 AM
To: DJS
Cc: Blackburn, Scott R.
Subject: IPA Update

Hello Dr. Shulkin:

Happy New Year.

I am sending you a note on IPAs ahead of the session coming up on hiring. After our last roundtable with MITRE, you had asked all the university participants to think about sending experts to VA through IPAs. I followed up on that with several university dean's offices and have received very positive responses.

***** After your visit to Yale, I connected with Harlan Krumholz who was very inspired by his conversation with you and he offered to take the lead on the IPA Transformation Center.

***** We now have a plan to source experts from universities and hospitals around the country in a strategic way, and his team is willing to coordinate the search & maintenance of the program through Yale Medical School (similar to what he does with CMS, NIH ad FDA).

***** I have identified 6 core areas requiring experts who can fill leadership and other positions in VHA/EHR space and associated hospital systems where the experts would come from (slide below).

***** In addition, we also have additional interest in having a group work with us through Dr. Shrestha at Univ. Of Pittsburgh.

***** The goal is to give you a larger pool of external experts who will be embedded into our system, have in-depth understanding of the work, produce literature and can bring in change by leading from the inside.

Please let me know if you would like more information, any changes, approve/disapprove. Thanks, ash

Ashwini Zenooz, MD

EHR Modernization

Department of Veterans Affairs

O: (202) 461-5903

Assistant: (b) (6) @va.gov

Web: <https://vaww.ehrm.va.gov/>

Owner: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)
/cn=recipients/cn=[REDACTED]
Filename: image003.png
Last Modified: Tue Jan 02 13:48:13 CST 2018

Initial Focus Areas

Various VA functions could benefit from AMC best practice and content implementations that are trending in the market place

Initial Focus Area*	Relevance	Potential Partners
Quality and Metrics	<ul style="list-style-type: none"> Identifying relevant quality measure Aligning measures to VA Workflows Assessing success and continuous improvement 	 Veterans Affairs  JOHNS HOPKINS MEDICINE
Interoperability	<ul style="list-style-type: none"> Community Care, networks, community and regional health data exchange Identifying point of care need and regional capability 	 HARVARD MEDICAL SCHOOL  Stanford MEDICINE
MyHealtheVet	<ul style="list-style-type: none"> Online patient portal and engagement Patient empowerment tools and care team to patient communications 	 MAYO CLINIC  Cleveland Clinic
Innovation	<ul style="list-style-type: none"> Injecting innovative practices into hospital and clinics Adoption of pertinent programs, measurement, and lifecycle management 	 UW MEDICINE UW Medicine
VAMAGS	<ul style="list-style-type: none"> Workflow development and Standard Operating Procedures for standard care across the VA regardless of region 	 Veterans Affairs  GEORGETOWN UNIVERSITY
TeleHealth	<ul style="list-style-type: none"> Incorporation of telehealth best practices Focus on regions with limited services or regional coverage 	 KAISER PERMANENTE  UAB

From: Bruce Moskowitz
<(b) (6)@mac.com>
To: DJS </o=va/ou=exchange administrative
group (fydibohf23spdlt)/cn=recipients/cn= >
Cc:
Bcc:
Subject: [EXTERNAL] Re: IPA Update
Date: Tue Jan 02 2018 13:56:03 CST
Attachments:

Will explain the big D problem we spoke about Sundayoff line and how it relates to this.

Sent from my iPhone

> On Jan 2, 2018, at 2:48 PM, DJS <vacodjs1@va.gov> wrote:

>
>
>

> Sent with Good (www.good.com)

>
>

> _____
> From: DJS
> Sent: Tuesday, January 02, 2018 11:14:56 AM
> To: brucemoskowitz
> Subject: FW: IPA Update

>
> Bruce- this below is encouraging- it's using the IPA contract to get help from academic centers. I wanted you to be aware to make sure you know this is an available mechanism for us to use when we identify help. I'd be glad to discuss more if helpful

>
>

> David

>
>
>

> Sent with Good (www.good.com)

>
>

> _____
> From: Zenooz, Ashwini
> Sent: Tuesday, January 02, 2018 8:22:18 AM
> To: DJS
> Cc: Blackburn, Scott R.
> Subject: IPA Update

>
> Hello Dr. Shulkin:

>
>

> Happy New Year.

>
> I am sending you a note on IPAs ahead of the session coming up on hiring. After our last roundtable with MITRE, you had asked all the university participants to think about sending experts to VA through IPAs. I followed up on that with several university dean's offices and have received very positive responses.

>

>
> · After your visit to Yale, I connected with Harlan Krumholz who was very inspired by his conversation with you and he offered to take the lead on the IPA Transformation Center.
>
> · We now have a plan to source experts from universities and hospitals around the country in a strategic way, and his team is willing to coordinate the search & maintenance of the program through Yale Medical School (similar to what he does with CMS, NIH ad FDA).
>
> · I have identified 6 core areas requiring experts who can fill leadership and other positions in VHA/EHR space and associated hospital systems where the experts would come from (slide below).
>
> · In addition, we also have additional interest in having a group work with us through Dr. Shrestha at Univ. Of Pittsburgh.
>
> · The goal is to give you a larger pool of external experts who will be embedded into our system, have in-depth understanding of the work, produce literature and can bring in change by leading from the inside.
>
> Please let me know if you would like more information, any changes, approve/disapprove. Thanks, ash
>
> [cid:image003.png@01D383BB.F2C583F0]
>
> (b) (6), MD
> EHR Modernization
> Department of Veterans Affairs
> O: (202) 461-(b) (6)
> Assistant: (b) (6)@va.gov
> Web: <https://vaww.ehrm.va.gov/>
>
>

From: Bruce Moskowitz
<(b) (6)@mac.com>
To: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=(b) (6)>
Cc: IP <@frenchangel59.com>; Bowman, Thomas </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=(b) (6)>; <(b) (6)@gmail.com <(b) (6)@gmail.com>; Marc Sherman <(b) (6)@gmail.com>
Bcc:
Subject: Re: [EXTERNAL] Shulkin Interview on FoxNews - Friday, October 20, 2017
Date: Sun Oct 22 2017 08:29:18 CDT
Attachments:

Well done!

Sent from my iPad
Bruce Moskowitz M.D.

> On Oct 22, 2017, at 8:50 AM, DJS <vacodjs1@va.gov> wrote:
>
> Thank you Ike- the President saw it as well and called me- he had you exact sentiments and asked about how you and Laurie are and said to pass on his regards (that was on my list to do today)
>
> David
>
>
>
> Sent with Good (www.good.com)
>
> _____
> From: IP
> Sent: Sunday, October 22, 2017 3:11:05 AM
> To: DJS
> Cc: Bowman, Thomas; (b) (6)@gmail.com; Marc Sherman; (b) (6)@mac.com'
> Subject: [EXTERNAL] Shulkin Interview on FoxNews - Friday, October 20, 2017
>
> David,
>
> I caught your interview Friday on Fox news and want to congratulate you. You were superb. Your responses that focused on the VA and the principal issue of veterans' care was right on point. That interview really did a great service to what you (and we) are doing to improve the quality of care for our veterans for the long term.
>
> Ike
>
> <http://www.foxnews.com/transcript/2017/10/20/va-secretary-brave-soldiers-dont-deserve-to-be-politicized.html>
>

From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
<(b) (6) [REDACTED]@mac.com>
Cc:
Bcc:
Subject: RE: [EXTERNAL] Re: FW: VA issue - From Karen Donnelly
Date: Thu Sep 07 2017 10:55:16 CDT
Attachments:

I agree thanks

Sent with Good (www.good.com)

-----Original Message-----

From: Bruce Moskowitz [(b) (6) [REDACTED]@mac.com]
Sent: Thursday, September 07, 2017 11:43 AM Eastern Standard Time
To: Marc Sherman
Cc: DJS; (b) (6) IP
Subject: Re: [EXTERNAL] Re: FW: VA issue - From Karen Donnelly

To the patient it should be that the VA person can steer him in the right direction regardless.

Sent from my iPhone

On Sep 7, 2017, at 11:34 AM, Marc Sherman <(b) (6) [REDACTED]@gmail.com> wrote:

That was my first reaction when I read the story, but doubted myself when the problem was solved by someone in Building 10 at the VA hospital. Does that make sense?

Ike, if this is a DOD problem/issue, perhaps you should pass this on to someone who can get it to the DOD.

Marc Sherman
(202) 758-[REDACTED]

On Sep 7, 2017 11:27 AM, "DJS" <vacodjs1@va.gov> wrote:

I think this is the department of defense and not VA

Sent with Good (www.good.com)

-----Original Message-----

From: Marc Sherman [(b) (6) gmail.com]
Sent: Thursday, September 07, 2017 10:07 AM Eastern Standard Time
To: IP
Cc: (b) (6) Bruce Moskowitz; DJS
Subject: [EXTERNAL] Re: FW: VA issue - From Karen Donnelly

David

Assuming this email recounts the facts even somewhat accurately, i see huge implications...the system imposes hardships and anxiety that no one, especially someone hurting and crying for help, should have to endure. I would doubt that this is an isolated incident. Does it deserve a systemic examination of the existing policies and protocols and possible revamp (along with the ever-present required culture shock treatment) of the process?

Marc

Marc Sherman
(202) 758-[(b) (6)]

On Sep 7, 2017 9:47 AM, "IP" <[(b) (6)]@frenchangel59.com> wrote:

David,

I would like to share with you another real life example of the issues our great veterans are suffering with when trying to work with the VA. I know we are making very good progress, but this is an excellent reminder that we are also still very far away from achieving our goals.

Thank you,

Ike

From: [(b) (6)]
Sent: Tuesday, September 05, 2017 6:50 PM
To: [(b) (6)] [(b) (6)] @gmail.com); IP
Subject: FW: VA issue - From [(b) (6)]

FYI

From: [(b) (6)] [mailto:[(b) (6)]@fitegroup.co-m]

Sent: Tuesday, September 05, 2017 6:44 PM

To: (b) (6)

Subject: VA issue

(b) (6)

Ike wanted me to send him this info about my son and the trouble he had with trying to access his Military Medical Records:

(b) (6)

[Redacted text block containing multiple lines of blacked-out information]

(b) (6)

[Redacted text block containing multiple lines of blacked-out information]

(b) (6)

[Redacted]

[Redacted]

[Redacted]

(b) (6)

[Redacted]

[Redacted]

[Redacted]

(b) (6)

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (6)



(b) (6)



and

(b) (6)



561 358 (b) (6)



From: DJS </o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED]>
To: Bruce Moskowitz
(b) (6) @mac.com>; (b) (6) @mail.med.upenn.edu>
Cc: Shulkin, David J., MD
</o=va/ou=exchange administrative group (fydibohf23spdlt)/cn=recipients/cn=[REDACTED] (b) (6) mail.med.upenn.edu>; (b) (6) @hotmail.com>; (b) (6) gmail.com
(b) (6) gmail.com>; IP <[REDACTED]@frenchangel59.com>; (b) (6) (b) (6) @gmail.com>
Bcc:
Subject: RE: [EXTERNAL] Re: suicide efforts at Penn
Date: Thu Jun 01 2017 18:18:18 CDT
Attachments:

I agree- thank you

Sent with Good (www.good.com)

-----Original Message-----

From: Bruce Moskowitz [(b) (6)] @mac.com]
Sent: Thursday, June 01, 2017 03:06 PM Eastern Standard Time
To: (b) (6)
Cc: Shulkin, David J., MD; (b) (6); Poonam Alaigh; (b) (6) gmail.com; IP; (b) (6)
Subject: [EXTERNAL] Re: suicide efforts at Penn

Thank you this is excellent

Sent from my iPad
Bruce Moskowitz M.D.

On Jun 1, 2017, at 2:58 PM, (b) (6) @mail.med.upenn.edu> wrote:

Dear Drs. Shulkin and Moskowitz,

I just met with Dr. (b) (6) (Chairman of Psychiatry at the Philadelphia VAMC) and we will be pulling together a meeting of investigators to generate some ideas about suicide research in the VA, probably in collaboration with other VAMCs. We will be in touch soon.

Cheers!

(b) (6), M.D., Ph.D.
(b) (6) Professor and Chairman of Psychiatry
Perelman School of Medicine, University of Pennsylvania

American Psychiatric Association, Immediate Past President
International Academy of Suicide Research, President
NOTE NEW E MAIL ADDRESS (b) (6) @mail.med.upenn.edu
3535 Market Street, Suite 200
Philadelphia, PA 19104-3309
Telephone: 215.662.(b) (6)
Fax: 215.662.(b) (6)

On May 30, 2017, at 4:31 PM, (b) (6) @mail.med.upenn.edu> wrote:

<Suicide Related Activities for Dr. Moskowitz 2017 05 19.docx>

(b) (6), M.D., Ph.D.
(b) (6) Professor and Chairman of Psychiatry
Perelman School of Medicine, University of Pennsylvania
American Psychiatric Association, Immediate Past President
International Academy of Suicide Research, President
NOTE NEW E MAIL ADDRESS (b) (6) @mail.med.upenn.edu
3535 Market Street, Suite 200
Philadelphia, PA 19104-3309
Telephone: 215.662.(b) (6)
Fax: 215.662.(b) (6)

From: Bruce Moskowitz
<(b) (6)@mac.com>
To: (b) (6) </o=va/ou=exchange
administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6)>; DJS
</o=va/ou=exchange administrative group
(fydibohf23spdlt)/cn=recipients/cn=(b) (6)>
(b) (6) </o=va/ou=va martinsburg/cn=recipients/cn=(b) (6)>
Cc: (b) (6)@gmail.com>
Bcc:
Subject: [EXTERNAL] Fwd: Call re: Veterans Medical Treatment Pilot Project
Date: Fri Apr 28 2017 06:26:42 CDT
Attachments: EAS

(b) (6) will set up

Sent from my iPad
Bruce Moskowitz M.D.

Begin forwarded message:

From: "(b) (6)@Bruce Moskowitz,MD" (b) (6)@gmail.com>
Date: April 27, 2017 at 3:26:14 PM EDT
To: Bruce Moskowitz <(b) (6)@mac.com>
Subject: Fwd: Call re: Veterans Medical Treatment Pilot Project

FYI I scheduled the call for 6/14 @ 4:00pm

----- Forwarded message -----

From: (b) (6)@vikings.nfl.net>
Date: Thu, Apr 27, 2017 at 2:53 PM
Subject: Call re: Veterans Medical Treatment Pilot Project
To: (b) (6)@gmail.com" (b) (6)@gmail.com>

Hi (b) (6) Thanks for your help in scheduling a call with Dr. Moskowitz and the Minnesota Vikings. It would be with (b) (6), COO; (b) (6), EVP of Public Affairs; and (b) (6), VP of Legal and HR.

6/14 – 4:00 p.m. or 5:00 p.m. ET

6/15 – 12:00 p.m. ET

6/20 – 2:00 or 2:30 p.m. ET

Thanks again.

(b) (6)

Executive Assistant to Owners | Minnesota Vikings Football, LLC

9520 Viking Drive | Eden Prairie, Minnesota 55344

P: (952) 828-(b) (6) | F: (952) 828-(b) (6)

E: (b) (6)@vikings.nfl.net

:IMAGES:Facebook.png

The information contained in this transmission may contain privileged and confidential information. It is intended only for the use of the person(s) named above. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution or duplication of this communication is strictly prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. To reply to our email administrator directly, please send an email to administrator-min@vikings.nfl.-net

--

(b) (6), MPA
Patient Care Coordinator
Dr. Bruce Moskowitz, MD

Victor Ferris Me

Attachments:

- image001.jpg (3328 Bytes)
- image002.jpg (1293 Bytes)
- image003.jpg (1325 Bytes)
- image005.jpg (1146 Bytes)

Owner: Bruce Moskowitz <(b) (6)@mac.com>
Filename: EAS
Last Modified: Fri Apr 28 06:26:42 CDT 2017

Document ID: 0.7.10678.749841-000001

Attachment Name: EAS

Locator: esapst/*:\(b) (6) 01\MS\Collections\GCLAWS 97074 VoteVets Action Fund v. VA\Batch 1 Online\David Shulkin (b) (6) pst:00000000ddd1d847dc44de4ebb65729b0dd7de5d048a2b00: :0700da2cfddd42d9bb84276193fe84ff39b3406fe82345b8b73e0fee85d7422bc139

Reason: : This file is empty (i.e., its length is zero bytes)