

February 8, 2007

## QUALITY REVIEWS OF SURGICAL PROGRAMS AND OUTCOMES

**1. PURPOSE:** This Veteran Health Administration (VHA) Directive sets policy for the standardized assessment and review of VHA surgical programs based on surgical outcomes data.

### 2. BACKGROUND

a. The goal of the VHA Surgical Programs is to provide the highest quality of care as evidenced by excellent surgical outcomes in a compassionate, timely, and cost-effective manner. The review of surgical outcomes began in 1972 when the Chief Medical Director (now the Under Secretary for Health) developed the Cardiac Surgery Consultants Work Group charging it with providing an on-going review mechanism for cardiac surgery programs in the Department of Veterans Affairs (VA) health care system, and establishing the Continuous Improvement in Cardiac Surgery Program. Risk adjustment commenced in 1987. This was followed by the Neurologic Surgery Consultants Work Group, which was charged with ensuring excellence in neurosurgical outcomes. In 1991, VA implemented the National Surgical Quality Improvement Program (NSQIP), which was charged with the development and implementation of a risk-adjusted model to assess the outcomes of major non-cardiac surgical cases across VHA.

b. In December 1991, Congress mandated a comprehensive program to monitor and evaluate the quality of health care furnished by VA. This law requires the Under Secretary for Health

(1) To determine whether there are significant deviations in mortality and morbidity rates for surgical procedures in VA from the prevailing national morbidity and mortality standards for similar procedures.

(2) To determine the prevailing national mortality and morbidity standards for each type of surgical procedure performed by VA; collect data and other information on mortality and morbidity rates for each type of surgery; and compile that data and other information collected for each medical facility in VA in the case of cardiac surgery, heart transplants and renal transplant programs and in the aggregate, for each other type of surgical procedure.

c. Operative mortality is defined as any death within 30 days of surgery, plus any death after 30 days caused by a complication that was first manifested within 30 days of surgery. Additionally the Cardiac Program includes any death within the index (original) hospitalization for the surgical procedure.

d. The intent of this Directive is to set a common approach and standards for the review of all surgical programs based on risk-adjusted outcomes along with actual (unadjusted) outcomes

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for selected procedures for major surgical cases performed in VHA. **NOTE:** *VHA Directive 2005-056, Mortality Assessment, provides for local review of surgical mortality and major morbidity within 30 days of occurrence from the original procedure; using aggregated data does not abrogate that responsibility; it is congruent and supportive of local review consistent with national surgical guidance.*

**3. POLICY:** It is VHA policy to assess outcomes for all major surgical cases and actual mortality and morbidity using risk-adjusted and actual (unadjusted) morbidity and mortality outcomes.

### 4. ACTION

a. **National Director of Surgery.** The National Director of Surgery, or designee, is responsible for ensuring that:

(1) The following Consultants Boards are established: Cardiac surgical, Neurological surgical and National Surgical Quality Improvement and appoint their members.

(a) A Board will be comprised of full-time and part-time permanent Federal Government employees. As a result, these Boards will not be “advisory committees” for purposes of the Federal Advisory Committee Act.

(b) The Boards may seek facts, information, and the individual views of experts, who are not full-time or part-time permanent VA employees. The views of these experts must be obtained separately and independently of each other. These outside experts cannot, however, participate in other activities of a Board, such as its deliberations or decision-making.

(2) Those surgical programs that do not meet published standards and/or whose outcomes fall significantly above national averages for mortality or morbidity receive further assessments, which may include a site visit.

(3) Cardiac (Open Heart Surgery) outcomes and programs are assessed and reviewed by the Cardiac Surgery Consultant’s Board which is charged with ensuring the minimum number of annual cardiac operations are performed and that Quality Assurance criteria are met.

(a) There should be a minimum of 100 cardiac (open heart) surgery procedures performed at a VA medical center per year. VA medical centers currently performing fewer than 100 procedures per year are reviewed on a case-by-case basis by the Board considering the:

1. Reasons for current volume.
2. Total workload of the surgeon.
3. Number of cases performed at the affiliated hospital.
4. Outcomes of the cases.

(b) Any program performing fewer than 100 cases per year may be site visited.

(4) Neurologic Surgery outcomes and programs are assessed and reviewed by the Neurological Surgery Consultants Board which is charged with ensuring the minimum annual number of procedures are performed and that the following Quality Assurance criteria are met:

(a) A minimum of 100 major neurological surgery procedures are performed at the VA medical center per year. Designated Neurologic Surgery Programs must have adequate volume to ensure that neurological surgery staff and support services attain and sustain required clinical skills.

(b) VA medical centers currently performing fewer than 100 procedures per year are reviewed on a case-by-case basis by the appropriate Board considering the:

1. Reasons for current volume.
2. Total workload of the surgeon.
3. Number of cases performed at the affiliated hospital.
4. Outcomes of the cases.

(c) Any program performing fewer than 100 cases per year may be site visited.

(5) All other General and Specialty Surgical outcomes and programs are assessed and reviewed every 6 months using the NSQIP process to ensure that minimum number annual major surgeries are performed to ensure adequate numbers for risk adjustment.

(a) Calculation of actual mortality for selected procedures, including cardiac surgery and neurosurgery, along with selected complex general surgery procedures, must be done.

(b) The NSQIP Board uses objective data for highly complex procedures to determine relationships between volume and outcome as compared to statistically valid national averages. In the event of excess unadjusted mortality rates greater than two times the national averages, the NSQIP Board requests the same review processes and procedures used by the Continuous Improvement in Cardiac Surgery Program (CICSP) Board. If the trend continues after two 6-month periods, the Board may recommend a site visit. **NOTE:** *Facilities with low volumes of specific general surgical procedures with acceptable outcomes will not have their aggregate numbers used to implement program changes unless unfavorable trends occur.*

(6) The following Quality Assurance process is utilized to review all surgical programs and specialties.

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(a) Indication for Evaluation by the Work Group

1. Any cardiac, neurological, or overall surgical program that has an overall unadjusted operative mortality greater than two times the VA national average for a 6-month period, or greater than or equal to 10 percent of the overall mortality, will be evaluated by the appropriate Board.

2. All operative deaths resulting from transplantation will be audited.

3. A written request for assessment from VHA Leadership, a VISN Director, or a Medical Center Director.

(b) Indications for Written Evaluation for Specific Procedures

1. Any program that has greater than a 5 percent average operative cardiac surgical mortality for a 2-year period will be required to perform a written assessment of all surgical deaths occurring during the second year of that 2-year period, unless they were audited during that 2-year period or the death(s) were reviewed during a previous “root cause” analysis and submitted to the VISN Director. The respective Cardiac Board or National Quality Board reviews these assessments which they receive from the appropriate service chiefs through the facility Director, or designee.

2. Any program that, in the opinion of the Board, is not within reasonable compliance with submission of VA Form 10-0049c, VA Cardiac Operative Risk Assessment, or VHA Form 10-038, Semi-Annual Report of Neurologic Surgery on Veterans, is required to perform a written assessment of all deaths during that 6-month period.

3. Based on Time Series Monitors of Outcome (TSMO) criteria during the most recent 3-year period, a paper audit of all mortalities occurring during the past 6-month period based on a high mean Observed and/or Expected (O/E) ratio using an 90 percent confidence interval over time, is required, unless the program has been audited within the last year.

4. Any program that has a statistically significantly high O/E ratio (using 90 percent confidence intervals) during the 6-month period must perform a written assessment of all mortalities which occurred during the most recent 6-month period. The respective Cardiac Board or National Quality Board reviews these assessments which they receive from the appropriate service chiefs through the facility Director, or designee.

5. Findings that indicate the facility has been an outlier for a specific operation for 3 years utilizing risk-adjusted data or actual (unadjusted) mortality data.

(c) Indications for a Site Visit (see Att. A)

1. Two consecutive 6-month periods that required written assessment.

2. Findings from written assessment that suggest possible deficiencies which are a source of concern to the Board or to the VISN Director.

3. Two consecutive years where volume does not meet criteria delineated in subparagraphs:

a. 4a.(6)(b) Indications for Written Evaluation for Specific Problems

b. 4a.(6)(c) Indications for a Site Visit

c. 4a.(6)(d) Indications for Placing Programs on Probation

4. A special request from a VA Medical Center Director, a VISN Director, or VHA Central Office to review a Cardiac Surgery Program.

(d) Indications for Placing Programs on Probation. When a site visit team recommends, and the Board concurs that:

1. Serious problems exist at VA medical centers which need to be corrected as a matter of some urgency, but are not immediately life threatening or impact negatively on the mortality and/or morbidity rate based on O/E ratios.

2. These problems must be corrected in an established period of time (6 to 12 months). If this does not occur, the surgical program or the specialty surgical program at that VA medical center may be recommended for suspension or closure. The subsequent procedure must be followed:

a. In collaboration with the site visit team, and at the direction of the VISN Director and facility Director, the program must be placed on probation for a period of 6 to 12 months (under unusual circumstances this period could be extended) and instructed to meet certain requirements and correct specific deficiencies.

b. Before the end of the probation period, the VISN or facility Director must report the facility's progress to the Board.

c. A site visit is made when deficiencies are reported to have been corrected or, at the latest, at the end of the probationary period, to determine whether the:

(1) Probation should be lifted.

(2) Probation should continue.

(3) Program should be closed.

d. Lifting of the program probation must be done in collaboration with the recommendations of the site visit team, Office of the National Director of Surgery, VISN Director, and facility Director.

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(e) Indications for Placing Programs on Suspension. In this case, the site visit team recommends, and the Board must concur that:

1. Serious problems are present at a VA medical center which has life threatening potential, or that mortality and/or morbidity rates, or O/E ratios indicate cause for concern. As a result, the Board determines that immediate action needs to be taken, and recommends the suspension of surgery services and/or one of its surgical service programs to the National Program Director for Surgery who will inform Patient Care Services, the VISN Director, and the facility Director and, through appropriate channels, the Office of the Under Secretary for Health through the Office of the Deputy Under Secretary for Health for Operations and Management (10N) and the Principal Deputy Under Secretary for Health (10A).

2. If these problems are deemed uncorrectable in a short period of time, the applicable program(s) at that medical center must be reported to the VISN Director and the facility Director who must adhere to the following procedure:

a. In collaboration with the site visit team, and at the direction of the VISN Director and facility Director, all specific surgery in that specialty must cease at that medical center for 30 days to allow for a submission of a plan to correct the specific problem(s).

b. Before the end of the established time frame, the VISN or facility Director must report progress to the Board.

c. Once deficiencies are reported to have been corrected, a site visit is conducted to re-evaluate the program to determine whether:

(1) The suspension should be lifted; or

(2) Program closure is recommended.

d. Lifting of the program suspension must be done in collaboration with the recommendations of the site visit team, national surgical program office, VISN Director, and facility Director.

### (f) Indications for Program Closure

1. At the end of the probationary or suspension period, if specific critical deficiencies identified during the initial site visit have not been corrected, and/or mortality, volume, and other standards continue to be below accepted criteria, the program will be recommended for closure.

2. The Consultants Boards may elect to defer a decision to recommend closure of a program if extraordinary circumstances (such as immediate changes in personnel, procedures, and processes of care) warrant that recommendation.

b. **Facility Director.** The facility Director is responsible for ensuring that the:

(1) Operative workload with actual (unadjusted) morbidity and mortality statistics for each 6-month period of each Cardiac (Open Heart) Surgery Program and Neurologic Surgery Program are submitted to the Office of the National Director of Surgery, for review by the appropriate Board.

(2) Operative Workload Statistics with risk-adjusted morbidity and mortality rates for all other programs for each 6-month period are submitted to the Office of the National Director of Surgery, for review by the appropriate Board. **NOTE:** *Actual (unadjusted) mortality for selected procedures will be reviewed annually to detect trends.*

## 5. REFERENCES

a. Grover FL, Hammermeister KE, Burchfiel C et al. "Initial report of the Veterans Administration Preoperative Risk Assessment Study in Cardiac Surgery," Annals of Thoracic Surgery.1990; 10: 12-28.

b. Khuri, S., Daley, J., Henderson, WG. et al; "The Department of Veterans Affairs NSQIP: The First National, Validated, Outcome Based, Risk Adjusted, and Peer Controlled Program for Measurement and Enhancement of the Quality of Surgical Care," Annals of Surgery. 1998: 228: 591-507.

c. Grover, FL., Shroyer, AD., Hammermeister, K. et as. "A Decade's Experience with Quality Improvement in Cardiac Surgery Using the Veterans Affairs and the Society of Thoracic Surgeon's National Data Bases," Annals of Surgery. 2001; 4: 464-472.

d. Title 38 United States Code, Section 7311, enacted in section 204(a) of Public Law (Pub. L.) 99-166, "Veterans' Administration Health-Care Amendments of 1985."

e. VHA Directive 2005-056, Mortality Assessment.

**6. FOLLOW-UP RESPONSIBILITY:** National Director, Surgical Services (111B), is responsible for the contents of this Directive. Questions may be directed to 202-273-8505.

**7. RESCISSION:** None. This VHA Directive expires December 31, 2010.

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ATTACHMENT A

A SITE VISIT

1. A site visit conducted must be prospectively designated in writing as a protected review under Title 38 United States Code (U.S.C.) Section 5705. This is to be included in the memorandum issued by the Veterans Health Administration (VHA) Central Office, Director, Surgical Service, designating the site visit team. *NOTE: The documents generated or gathered by this activity that are protected under 38 U.S.C. 5705 may be accessed and released only as authorized by 38 U.S.C. 5705 and the implementing regulations.*
2. Each site visit team must consist of a minimum of three individuals, to include:
  - a. A member of the Surgical Board who is a surgeon or a physician with expertise in the specialty under evaluation;
  - b. A Department of Veterans Affairs (VA) Central Office representative; and
  - c. Other members to include clinical nurse reviewers or administrative personnel to satisfactorily complete the program assessment.
3. Travel costs for the Consultants Work Group member and others are paid by the Veterans Integrated Service Network (VISN) or facility. Travel expenses for the VA Central Office representative are paid by the National Surgical Program, Patient Care Services (11).
4. All chart reviews, evaluations, reports, e-mails, and other documents created or gathered by the Board, site visit team, facility, or VISN in performing the activities described in this Directive, or in providing a response to an inquiry issued as part of the activities covered by this Directive are considered as medical quality assurance records. As such, they are protected by, and to the extent provided in, 38 U.S.C. 5705, VA implementing regulations, Title 38 Code of Federal Regulations (CFR) 17.500-511, and current VHA policy.
5. The recommendation notification for a site visit is sent by the Chair of the responsible Board with copies to Patient Care Services, the VISN Director, the Principal Deputy Under Secretary for Health (10A), and the Deputy Under Secretary for Health for Operations and Management (10N). Travel must be coordinated with VA Central Office by the responsible facility.