CRITERIA AND STANDARDS FOR CARDIAC (OPEN HEART) SURGERY PROGRAMS

1. REASON FOR ISSUE: This VHA Handbook updates the previous procedures for the Department of Veterans Affairs (VA) Veterans Health Administration (VHA) Cardiac (Open Heart) Surgery Programs.

2. SUMMARY OF CHANGES: This Handbook defines newly-resolved issues regarding the quality assurance programs and correctly references the changed authority for professionally monitoring and evaluating such programs.

3. RELATED ISSUES: VHA Directive 1102, Surgical Service (to be published).

4. RESPONSIBLE OFFICE: The Chief Consultant, Acute Care Strategic Healthcare Group (111), is responsible for the contents of this VHA Handbook. Questions may be referred to 202-273-8530.

5. RESCISSIONS: VHA Manual M-9, Chapter 9, Appendix 9E, is rescinded.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working day of August 2004.

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CONTENTS

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PARAGRAPH **PAGE**

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1. PURPOSE

This Veterans Health Administration (VHA) Handbook defines the Cardiac (Open Heart) Surgery Program criteria and standards which have been developed to meet the planning needs of Department of Veterans Affairs (VA) medical centers, Veterans Integrated Service Networks (VISNs), and for use by VHA Headquarters in the uniform review of Cardiac (Open Heart) Surgery Program proposals. ***NOTE***: *The term must is used throughout this document to indicate what is mandatory. The term should is used to reflect preferred practice, yet allows effective alternatives to be used. Staffing guidelines are intended to represent the best current judgment of health care professionals regarding safe and clinically effective levels; they are not mandatory.*

2. BACKGROUND

a. The Cardiac Surgery Committee of the Surgical Service was established in 1972 by the Chief Medical Director (now the Under Secretary for Health) to develop cardiac surgical programs and provide an on-going review mechanism for these programs in the VA health care system. The Committee, which is composed of VA cardiac surgeons and cardiologists, and sometimes non-VA experts in these fields, is responsible for monitoring all Cardiac Surgery Programs for compliance with established criteria and standards. The programs are established in highly affiliated facilities with residency training programs in cardio-thoracic surgery. All programs must adhere to, and operate within, the guidelines of the criteria and standards that have been established to assure quality programs.

b. Sophisticated risk techniques also have been developed that compare programs with each other. These risk factors are especially useful as a tool for predicting outcomes following cardiac surgery.

3. SCOPE

a. Cardiac (open heart) surgery includes operations on the heart and thoracic great vessels requiring the use of a heart-lung machine. For the purpose of this handbook, cardiac surgery refers to open heart surgical procedures provided in paragraph 14.

b. There will be ongoing professional monitoring and evaluation of the quality and appropriateness of care and treatment of patients by the Cardiac Surgery Committee, including review of operative mortality and morbidity at each VA medical center performing cardiac (open heart) surgery. Such reviews will be performed in accordance with requirements of Title 38 United States Code (U.S.C.) 7311, VA regulations, and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) policy.

c. The Cardiac Surgery Committee will report its findings directly to the Director, Surgical Service. The Director, Surgical Service, will report program concerns to the VISN Director(s)

affected by these concerns. When adverse actions such as probation, suspension, closure, etc., are recommended, both the VISN Director and the Under Secretary for Health will be advised of these findings. It will be the final decision of the Under Secretary for Health to determine the appropriate action.

d. The criteria and standards for cardiac (open heart) surgery will be reviewed by VHA Headquarters periodically, or at least every 2 years, and revised as necessary based upon further analyses and experience with their use. It is recognized that in certain circumstances local conditions may exist which justify an adjustment of these standards. Such adjustments will be reviewed by VHA Headquarters on a case-by-case basis when accompanied by supportive information justifying the need for the proposed adjustment.

4. GOAL

The goal of the Cardiac (open heart) Surgery Program is to provide the highest quality of care in the most cost-effective manner possible.

5. DEFINITIONS

a. **Criterion.** A criterion is defined as "a measurable characteristic of a health service."

b. **Standard.** A standard is defined as "a quantitative and/or qualitative value or level of achievement with respect to a specific criterion which represents acceptable performance."

c. **Cardiac. "**Cardiac" means "pertaining to the heart."

d. **Cardiac Surgery.** Cardiac surgery includes operations on the heart and thoracic great vessels requiring use of a heart-lung machine (see par. 14).

e. **Cardiac Arrhythmia (or Dysrhythmia).** Cardiac Arrhythmia (or Dysrhythmia) is an abnormal rhythm of the heart.

f. **Cardiovascular.** "Cardiovascular" means pertaining to the heart and blood vessels. ("Cardio" means the heart; "vascular" means blood vessels.) The circulatory system of the heart and blood vessels is the cardiovascular system.

g. **Cardiac Catheterization.** Cardiac catheterization is the process of examining the heart by introducing a thin tube (catheter) into a vein or artery and passing it into the heart.

h. **Coronary Care Unit.** A Coronary Care Unit is a specialized facility in a hospital that is equipped with monitoring devices and staffed with trained personnel designed specifically to treat coronary patients.

i. **Morbidity.** Morbidity is the extent of illness, injury or disability in a defined population. It is usually expressed in general or as specific rates of incidence or prevalence. Sometimes it is used to refer to an episode of disease

j. **Affiliation.** Affiliation means an established affiliation with an approved residency training program in cardio-thoracic surgery. This is a requirement for new programs. ***NOTE:*** *It is desirous that current programs preserve their residency programs. If a cardio-thoracic surgery residency program is closed by the Residency Review Committee, an equivalent coverage with comparable outcomes must be demonstrated and maintained. A site visit by members of the Committee is mandatory to assure the continuity of quality patient care.*

6. MINIMUM ANNUAL CARDIAC (OPEN HEART) SURGERIES PERFORMED

There should be a minimum of 150 cardiac (open heart) surgery procedures performed at a VA medical center per year. VA medical centers currently performing fewer than 150 procedures per year will be reviewed on a case-by-case basis by the Committee considering:

a. Reasons for non-compliance.

b. The total workload of the surgeon.

c. The number of cases performed at the affiliated hospital.

d. The outcomes of the cases.

NOTE: *Any program performing fewer than 100 cases per year may be site-visited.*

7. REQUIREMENTS FOR ESTABLISHING "NEW" CARDIAC (OPEN HEART) SURGERY PROGRAMS:

VA VISNs desiring to initiate Cardiac (Open Heart) Surgery Programs must demonstrate the following:

a. **Caseload.** New programs should project at least 150 cases per year to be attained within 3 years.

b. **Impact.** New programs will not adversely affect existing VA medical center in-house programs that are currently performing 150 or more open heart surgery procedures per year.

c. **Affiliation.** New programs must have an affiliation with an approved residency training program in cardio-thoracic surgery.

d. **Staff.** New programs must provide appropriately-trained personnel for cardiac surgery to include, but not limited to:

(1) Cardiac surgeons,

(2) House staff,

(3) Anesthesiologists,

(4) Perfusionists,

(5) Operating room nurses,

(6) Intensive care nurses, and

(7) Rehabilitation staff.

d. **Facility Requirements.** Each facility must provide:

(1) Laboratories with capability for:

(a) Diagnostic and interventional cardiac catheterizations and other support services,

(b) Therapeutic procedures, and

(c) Cardiopulmonary assessments.

(2) Adequate operating room space, equipment, and scheduled time to perform open heart surgery.

(3) A comprehensive cardiac rehabilitation program.

(4) A Cardiac Surgery Outpatient Clinic.

8. SURGICAL INTENSIVE CARE UNIT (SICU)

a. **Guideline.** At least 4 SICU beds must be available for a Cardiac (Open Heart) Surgery Program which performs a minimum of 150 procedures annually.

b. **Rationale.** It is necessary for VA medical centers to ensure adequate facilities for care of post-operative cardiac surgical patients.

c. **Continuing Education.** Operating Room (OR) and SICU personnel should receive appropriate in-service and continuing medical education for competency in their respective areas.

d. **Ratio.** The SICU ratio of nurses to patients must be at least one-to-one for the care of cardiac (open heart) surgery patients for the first 24 hours post-operatively.

9. STEP-DOWN BEDS FOR TELEMETRY

a. **Guideline.** Step-down beds should be available for telemetry and the number should be at least equal to the number of SICU beds dedicated to cardiac (open heart) surgery.

b. **Rationale.** Step-down beds for telemetry provide earlier transfer of patients from SICU and provide more cost-effective continuous monitoring for cardiac arrhythmias.

10. REFERRAL OF PATIENTS REQUIRING CARDIAC (OPEN HEART) SURGERY

Patients requiring cardiac (open heart) surgery should be referred to VA medical centers with in-house cardiac (open heart) surgery programs whenever possible. Needs of the patients, as well as effectiveness, must be considered when transferring patients from VA medical centers with no in-house program to VA medical centers with programs, especially when distances are long.

11. COST-EFFECTIVE ALTERNATIVES FOR PERFORMING CARDIAC (OPEN HEART) SURGERY

a. Total VA costs of Cardiac (Open Heart) Surgery Programs are to be reduced either through increased use of existing in-house programs at VA facilities or through contract programs where quality can be assured.

b. When proposing new VA in-house programs, the network must perform cost-benefit analyses to ensure that the local VA in-house cost of open heart surgery is, in fact, lower than contract costs.

12. STAFFING

a. **Guideline.** A surgical team must have at least two trained cardiac surgeons, at least one of whom participates in each cardiac (open heart) operation.

(1) It is desirable to have a cardiac (open heart) surgery nurse coordinator for management and coordination of the patients' nursing care.

(2) This team should be supported by consultants in various disciplines as needed, such as:

(a) Cardiologists,

(b) Dentists,

(c) Nurses,

(d) Hematologists, and

(e) Pulmonary medical specialists.

(3) The following is a suggested cardiac (open heart) surgical team to perform a volume of 150 cases annually:

CARDIAC SURGICAL TEAM	Full-time Employee Equivalent (FTEE)
(a) Surgeons	2.00
(b) Surgeon (house staff physician or surgical resident)	1.00
(c) Cardiac anesthesiologist	1.00
(d) Scrub nurse and/or technician	1.50
(e) Circulating nurse	2.00
(f) Perfusionist	2.00
Total	9.50

NOTE: *Substitutions may be provided by contract with University surgeons, anesthesiologists, and/or technicians.*

b. **Standards.** Staffing standards for performing cardiac (open heart) surgery are as follows:

(1) All staff cardiac surgeons must be certified by the American Board of Thoracic Surgery or eligible for Board examination within the following 12 months. Specialization in cardiac surgery by operating room nurses and technicians is desirable.

(2) Heart-lung machine technicians (perfusionists) must be qualified, and preferably certified. Each case must be supervised by a Board Certified Anesthesiologist.

(3) The Professional Standards Board must review general competency of the cardiac surgeons and anesthesiologists every 2 years.

13. QUALITY ASSURANCE

a. **Operative Workload Statistics With Morbidity And Mortality Rates**. Each Cardiac (Open Heart) Surgery Program will submit to VHA Headquarters an operative workload with morbidity and mortality statistics for each 6-month period for review by the Cardiac Surgery Committee.

NOTE: *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.*

b. **Indications for Written Evaluation**

(1) Any program that has a Coronary Artery Bypass Graft **(**CABG) or overall operative mortality greater than two times the VA national average for a period of 6 months, or

greater than or equal to 10 percent, will be evaluated by the Cardiac Surgery Committee.

(2) Any program that has greater than a 5 percent average operative mortality for a 2-year period for primary (first time - not redo) CABG will be required to perform a written assessment of all CABG deaths occurring during the second year of that 2-year period, unless the program was audited during that 2-year period or the death(s) were reviewed during a previous "root cause" analysis submitted to the VISN Director. ***NOTE:*** *The Cardiac Surgery Committee is to receive a copy of this review.*

(3) All operative deaths resulting from heart transplantation will be audited.

(4) Any program that, in the opinion of the Committee, is not within reasonable compliance with submission of VA Form 10-0049c will be required to perform a written assessment of all deaths during that 6-month period.

(5) Based on 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 a 90 percent confidence interval over time will be required.

NOTE: *Facilities will be exempt from an additional audit if they were audited within the last year for other audit criteria.*

(6) Any program that has a statistically significantly high O/E ratio (using 90 percent confidence intervals) during the 6-month period will perform a written assessment of all mortalities which occurred during the most recent 6-month period unless it was reviewed during a "root cause" analysis submitted to the VISN Director. ***NOTE:*** *The Cardiac Surgery Committee is to receive a copy of this review.*

c. **Indications for Site Visit**

(1) Two consecutive 6-month periods which required written assessment.

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

(3) A volume of fewer than 100 cases per year for 2 consecutive years.

(4) Special requests from a VA Medical Center Director, VISN Director, or VHA Headquarters to review a cardiac surgery program.

d. **Indications for Placing Programs on Probation**

(1) The site visit team recommends, and the Committee concurs, that:

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

(b) If these problems are not corrected in an established period of time (usually 6 to 12 months), cardiac surgery at that VA medical center could be recommended for suspension or closure**.**

(2) The subsequent procedure will be as follows:

(a) The program shall 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 Director will report progress to the Cardiac Surgery Committee.

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

1. Probation should be lifted.

2. Probation should continue.

3. The program should be closed.

e. **Indications for Placing Programs on Suspension**

(1) The site visit team recommends, and the Committee concurs, that:

(a) Serious problems are present at a VA medical center which have the potential of becoming life threatening or have reflected negatively on the mortality and/or morbidity based on the O/E ratios. As a result, the Cardiac Surgery Committee determines that immediate action should be taken and recommends the suspension of cardiac surgery to the Under Secretary for Health. At the same, time the Cardiac Surgery Committee is to notify the VISN Director of the recommendation.

(b) If these problems are deemed uncorrectable in a short period of time, cardiac surgery at that VA medical center will be recommended for closure.

(2) The subsequent procedure will be as follows:

(a) Once suspension has been approved, all cardiac surgery will cease at that medical center for a short period of time to allow correction of the specific problem(s).

(b) Before the end of the established time frame, the VISN Director will report progress to the Committee.

(c) Once deficiencies are reported to have been corrected, a site visit will be conducted to re-evaluate the program to determine whether:

1. Suspension should be lifted.

2. Program closure recommended.

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 Committee may elect to defer a decision to recommend closure of a program if extraordinary circumstances warrant it.

14. CARDIAC (OPEN HEART) SURGERY PROCEDURES

a. This list identifies surgical procedures suggested by VA surgical specialty groups as appropriate for open heart surgery. This list of open heart surgery procedures is not all inclusive. ***NOTE:*** *The absence of a surgical procedure from this list does not necessarily indicate its lack of suitability.*

b. The list is meant for planning purposes and has been divided into two parts:

(1) **Part I.** Part I consists of a range of open heart surgery procedures that must be performed using a heart and/or lung machine.

NOTE: *These procedures must be performed using the extra corporeal circulation pump. (International Classification of Diseases, 9th Revision, Clinical Module [ICD-9-CD], Code 39.610 or 39.611)*

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(1) Lung transplant	33.5
(2) Heart and/or lung transplant	33.6
(3) Open heart valvuloplasty of aortic valve without replacement	35.11
(4) Mitral valve repair	35.12
(5) Open heart valvuloplasty of mitral valve without replacement	35.12
(6) Open heart valvuloplasty of pulmonary valve without replacement	35.13
(7) Open heart valvuloplasty of tricuspid valve without replacement	35.14

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(8) Ross procedure	35.21, 35.25
(9) Replacement of aortic valve with tissue graft	35.21
(10) Creation of conduit between right ventricle and pulmonary artery	35.92
(11) Other replacement of aortic valve	35.22
(12) Replacement of ascending aorta Repair	35.92, 39.52 35.22
(13) Replacement of mitral valve with tissue graft	35.23
(14) Mitral valve replacement	35.23-24
(15) Other replacement of mitral valve	35.24
(16) Replacement of pulmonary valve with tissue graft	35.25
(17) Other replacement of pulmonary valve	35.26
(18) Replacement of tricuspid valve with tissue graft	35.27
(19) Other replacement of tricuspid valve	35.28
(20) Operations on papillary muscle	35.31
(21) Operations on chordae tendineae	35.32
(22) Annuloplasty	35.33
(23) Infundibulectomy	35.34
(24) Operations on trabeculae carneae cordis	35.35
(25) Operations on other structures adjacent to valve of the heart (repair aneurysm of sinus of valsalva)	35.39
(26) Repair of atrial septal defect with prosthesis open technique	35.51
(27) Repair of ventricular septal defect with prosthesis	35.53
(28) Closure of ventricular septal defect following infarction (with prosthesis)	35.531

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(29) Repair of endocardial cushion defect with prosthesis	35.54
(30) Repair of atrial septal defect with tissue graft	35.61
(31) Repair of ventricular septal defect with tissue graft	35.62
(32) Closure of ventricular septal defect following infarction (with tissue graft)	35.621
(33) Repair of endocardial cushion defect with tissue graft	35.63
(34) Other and unspecified repair of atrial septal defect	35.71
(35) Other and unspecified repair of ventricular septal defect	35.72
(36) Other and unspecified repair of endocardial cushion defect	35.73
(37) Total repair of tetralogy of fallot	35.81
(38) Total repair of total anomalous pulmonary venous connection	35.82
(39) Total repair of truncus arteriosus	35.83
(40) Interatrial transposition of venous return	35.91
(41) Creation of conduit between left ventricle and aorta	35.93
(42) Creation of conduit between atrium and pulmonary artery	35.94
(43) Revision of corrective procedure on heart	35.95
(44) Other operations on septa of heart	35.98
(45) Aortic valve replacement	35.22
(46) Removal of coronary artery obstruction	36.0
(47) CABG	36.10-36
Heart and/or lung bypass machine (if used)	39.61
(48) Aortocoronary bypass of one coronary artery	36.11
(49) Aortocoronary bypass of two coronary arteries	36.12
(50) Aortocoronary bypass of three coronary arteries	36.13

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(51) Aortocoronary bypass of four or more coronary arteries	36.14
(52) Single internal mammary-coronary artery bypass	36.15
(53) Bilateral internal mammary-coronary artery bypass	36.16
(54) Other bypass anastomosis for heart revascularization	36.19
(55) Repair of aneurysm of coronary vessel	36.91
(56) Other operations on vessels of heart (repair of arteriovenous fistula)	36.99
(57) Cardiotomy	37.11
(58) Left ventricular aneurysmectomy	37.321
(59) Excision of other lesion of heart	37.33
(60) Infarctectomy	37.331
(61) Heart transplantation	37.5
(62) Implant of other heart assist system (exclude intraaortic balloon pump)	37.62
(63) Transmyocardiac laser procedure	36.03

(2) **Part II**. Part II of the list consists of procedures that may or may not be performed as open heart surgery. They may be performed either with or without the extra corporeal circulation pump. For planning purposes, only those procedures that are performed with the use of extracorporeal circulation pump (ICD-9-CM Code, 39.610 or 39.611) are considered as open heart surgery cases.

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(1) Enlargement of existing atrial septal defect	35.41
(2) Creation of septal defect in heart	35.42
(3) Other operations on valves of heart	35.99
(4) Heart revascularization by arterial implant	36.2
(5) Pericardiectomy	37.31

OPEN HEART SURGERY PROCEDURES	ICD-9-CM CODE
(6) Excision of aneurysm of heart	37.32
(7) Repair of heart and pericardium	37.4
(8) Replacement and repair of heart assist system	37.63
(9) Removal of heart assist system with no replacement	37.64
(10) Embolectomy, pulmonary artery	38.05
(11) Aneurysmectomy, thoracic aorta	38.44
(12) Traumatic injuries of heart and great vessels	862.8

15. NEEDS ASSESSMENT METHODOLOGY

a. A needs assessment methodology will aid in determining whether there are sufficient numbers of projected cases to justify programs.

(1) It is suggested that patient origin studies be done to identify referral patterns and potential service areas.

(2) Since Cardiac Surgery is a specialized program, inter-network needs must be considered.

b. The following is a needs assessment methodology that should be used to project the number of cardiac surgery cases for the Cardiac Surgery Program:

(1) Cases **ijk** = Σ National UR k X Vet Pop ijk

(a) Where Cases **ij** is the projected number of cases at VA medical center **i** in year **j**

(b) National UR **k** is the most recent 3-year national use rate (UR) of cardiac surgery by veterans of age

(c) **k**, as shown as follows:

Veteran Pop **ijk** is number of veterans in service area of VA medical center **i** in year **j** and age group **k** (in 10,000's),

(2) The service area of VA medical center **i** consists of all counties with a population centroid (center of mass of population) closer to VA medical center **i** than to any other VA medical center with a Cardiac Surgery Program.

3-Year National Use Rates for Cardiac Surgery

Age	Use Rate per l0,000 Veterans
35-44	0.51
45-54	1.53
55-64	4.29
65-74	4.27
75+	2.04

(3) **Example.** Assume that the sum of the veteran populations by age group of the counties closer to a given cardiac surgery program than to any other cardiac surgery program for the year 2005 follow:

Age	Veteran Population
35-44	8.0 (in 10,000s)
45-54	9.0
55-64	9.5
65-74	7.5
75+	6.0

(4) Then the projected number of cardiac surgery cases for the year 2005 can be computed as follows:

Age	Use Rate	Veteran Population	Cases
35-44	.51	8.0	4.1
45-54	1.53	9.0	13.8
55-64	4.29	9.5	40.8
65-74	4.27	7.5	32.0
75+	2.04	6.0	12.2
Total			102.9