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Report to the Chairman, Subcommittee on HUD-Independent Agencies, Committee on Appropriations, U.S. Senate

May 1988

VA HEALTH CARE

Monitoring of Cardiac Surgery and Kidney Transplantation

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Human Resources Division

B-207930

May 26, 1988

The Honorable William Proxmire
Chairman, Subcommittee on
HUD-Independent Agencies
Committee on Appropriations
United States Senate

Dear Mr. Chairman:

This report responds to your August 7, 1987, request that we review the Veterans Administration's (VA's) monitoring of its cardiac surgery and kidney transplant programs. The report focuses on VA's performance standards for the programs and how VA uses its standards to assess medical centers' performance. The report recommends steps that VA can take to improve its monitoring process.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 14 days from the date of this letter. At that time, we will send copies to the Chairmen, House and Senate Committees on Veterans' Affairs; the Chairman, Subcommittee on HUD-Independent Agencies, House Committee on Appropriations; the Director, Office of Management and Budget; the Administrator of Veterans Affairs; and other interested parties. Copies will be available to others on request.

Sincerely yours,

Lawrence H. Thompson

Lawrence H. Thompson
Assistant Comptroller General

Executive Summary

Purpose

The Veterans Administration (VA) operates one of the largest health care delivery systems in the United States, spending more than $9 billion annually through 172 medical centers. The Chairman of the Subcommittee on HUD-Independent Agencies, Senate Committee on Appropriations, asked GAO to review VA's cardiac surgery and kidney transplantation programs because of his concern that they were being underutilized. Utilization of a program such as cardiac surgery is important because mortality rates generally decrease as the number of surgical procedures increases. For the two programs, GAO examined whether (1) VA has developed adequate performance standards, (2) the centers are meeting VA's standards, and (3) VA is adequately monitoring the centers' performance.

Background

VA established a cardiac surgery program at 13 medical centers in 1965. During fiscal year 1987, 43 centers performed cardiac surgery on 6,848 veterans. The program covers 66 surgical procedures that require use of a heart-lung machine to perform the function of circulation during surgery. One procedure, coronary artery bypass graft, accounts for the majority of procedures performed.

Since 1973, VA has relied primarily on a Cardiac Surgery Consultants Committee, consisting of physicians from various VA medical centers, for routine monitoring of the centers' performance. A center's utilization and its mortality rates are considered to be important performance indicators. Utilization is generally measured by the number of surgical procedures performed, and mortality is measured by the number of operative deaths (attributable to the surgery), as a percentage of the total procedures performed. (See p. 14.)

VA performed its first kidney transplant in 1961; in fiscal year 1975, 29 medical centers performed 383 transplants. Since then, the number of centers, as well as the number of transplants, has declined; 9 centers performed 117 transplants in fiscal year 1987.

The centers work closely with dialysis programs, which provide life support for veterans with chronic renal failure. A kidney transplant is a less complex procedure than cardiac surgery and results in few operative deaths. Therefore, the length of time that the patient and transplanted kidney survive is a more meaningful performance measure than the number of operative deaths. VA uses a Transplant Consultants Committee, on a referral basis, to assist in its routine monitoring of the centers' performance. (See p. 28.)

GAO analyzed data that medical centers reported to VA for fiscal years 1985 to 1987 and interviewed officials of VA, the Department of Health and Human Services (HHS), and various private organizations, including the American College of Surgeons, the Society of Thoracic Surgeons, and the American College of Cardiology. GAO focused on the routine monitoring activities of VA's consultant committees and did not attempt to evaluate the quality of care provided by medical centers or assess other VA quality assurance activities. (See p. 12.)

Results in Brief

VA has established minimum standards for determining whether a medical center performing cardiac surgery is maintaining an acceptable level of utilization and patient mortality. While VA uses centers' utilization rates as a performance indicator, it places a higher priority on patient mortality rates in making judgments about centers' performance. During fiscal year 1987, 28 of 43 centers met both standards. Of these, 15 also met both standards during fiscal years 1985 and 1986. VA does not use the standards as the sole basis for judging a center's performance but rather as a means of identifying centers that may be experiencing performance problems. However, VA's monitoring is not adequate to (1) help centers not meeting the standards to improve their performance or (2) assess their potential for meeting the standards.

VA also has established a minimum utilization standard for assessing the performance of centers performing kidney transplants. In fiscal year 1987, four of the nine centers met VA's standard. However, VA has not adopted standards for assessing the centers' survival rates for patients and transplanted kidneys. While the centers' survival rates may represent acceptable performance, VA needs to establish survival rate standards and use them to evaluate each center's performance so that centers not performing at an acceptable level are identified promptly.

Principal Findings

Cardiac Surgery Standards Established

During fiscal years 1985-87, VA's standards for an individual cardiac surgery center were (1) 100 procedures a year, (2) a mortality rate of 5 percent or less for coronary artery bypass grafts, and (3) a mortality rate for all procedures of not more than twice VA's national average. VA increased the minimum number of procedures from 100 to 150, effective in fiscal year 1988; the other standards did not change.

In 1978, HHS established guidelines which stated that at least 200 cardiac surgery procedures should be performed annually. Since then, private organizations, such as the American College of Surgeons, and the Society of Thoracic Surgeons, have supported 150 procedures as the minimum needed to maintain effective use of equipment and personnel. Although none of the organizations GAO contacted endorsed specific mortality rates to be used as indicators of acceptable performance, a special advisory committee on cardiac surgery composed of VA and outside experts endorsed a mortality standard of 5 percent for coronary artery bypass graft procedures. (See p. 14.)

The number of centers meeting VA's utilization and mortality standards increased from 26 to 28 between fiscal years 1985 and 1987. Of the 15 centers not meeting the standards in fiscal year 1987, 10 met the utilization standard, but not the mortality standards; 1 met the mortality standards, but not the utilization standard; 1 met only one mortality standard and did not meet the utilization standard; and 3 met none of the mortality or utilization standards. Based on an analysis of VA's data, GAO believes that VA's use of centers' mortality rates as the principal performance indicator is reasonable. (See p. 17.)

More Effective Monitoring Needed

To monitor the performance of centers' cardiac surgery activities, VA has relied on semiannual reviews of patient medical records by its Cardiac Surgery Consultants Committee to assess the surgical techniques being used and pre- and postoperative care. The usefulness of this approach is limited because insufficient information is developed to (1) assess a center's potential for meeting the standards and (2) make specific recommendations for improving performance. Nor did the reviews address other problems, such as recruitment and retention of qualified surgeons and support staff, patient selection, infection control, and outdated equipment and facilities.

Site visits, however, provide the opportunity for physician reviewers to thoroughly assess such aspects of a center's performance. According to VA's 1986 guidelines, a visit should be made if there is a concern about any phase of a center's performance. Five site visits were made by committee members during fiscal years 1986 and 1987.

But under VA's guidelines, a site visit is not required even if a center does not meet the standards over an extended period, such as 12 consecutive months. Without visiting such centers, VA staff cannot ensure that all factors affecting the centers' performance are adequately evaluated and

appropriate actions initiated to improve performance. Had VA's guidelines required visits to centers not meeting the mortality standards for a 12-month period during fiscal years 1986 and 1987, visits to another 13 centers would have been required. (See p. 21.)

Kidney Transplant Standards Should Be Strengthened

In August 1987, VA reduced its standard for performance of kidney transplants from 15 to 12 a year because many centers were not performing 15. The change would not affect the quality of care, according to VA. In 1986, an HHS Task Force on Organ Transplantation proposed a minimum of 25 transplants per hospital annually to maintain adequate experience and skill levels. The task force also proposed standards for patient and transplanted kidney survival rates. Although VA recognized the need for such standards, it has not established them. (See p. 27.)

Recommendations

GAO recommends that VA arrange for site visits to be made to each cardiac surgery center that does not meet the mortality standards for a prescribed time, such as 12 consecutive months. During each site visit, reviewers should assess the center's potential to meet the utilization and mortality standards. The reviewers should (1) recommend actions needed to improve performance and (2) set time frames for the centers to demonstrate the ability to achieve the standards. If a center shows little or no potential for achieving the standards, either after an initial site visit or after taking corrective actions, VA should consider terminating the cardiac surgery program at the center and consolidating its workload with other centers.

GAO also recommends that VA (1) adopt, for its kidney transplant program, the HHS task force's proposed standards for patient and transplanted kidney survival or establish alternative standards and (2) regularly monitor the centers' performance against the standards. If a center does not show potential for meeting the standards, VA should consider terminating the center's kidney transplant activities.

VA Comments

In an April 21, 1988, letter, the Administrator of Veterans Affairs concurred with GAO's recommendations (see app. III).

Contents

Abbreviations

GAO	General Accounting Office
HHS	Department of Health and Human Services
VA	Veterans Administration

Introduction

The Veterans Administration (VA) operates one of the largest health care delivery systems in the United States, spending more than $9 billion in fiscal year 1987 through 172 VA medical centers. The Chairman of the Subcommittee on HUD-Independent Agencies, Senate Committee on Appropriations, asked us to review two VA medical programs—cardiac surgery and kidney transplantation—because of his concern that they were being underutilized. The utilization of programs, such as the cardiac surgery program, is important because mortality rates generally decrease as the number of surgical procedures increases.

VA Health Care Delivery System

The Administrator of Veterans Affairs has delegated responsibility for monitoring the surgical programs to the Department of Medicine and Surgery, headed by the Chief Medical Director. Within that department, the Director of Surgical Service has the responsibility for preparing and recommending policies, plans, and professional standards for the programs as well as maintaining systems for monitoring the programs' performance. VA medical centers report directly to a regional director, who acts as a liaison between the centers in the region and the Chief Medical Director.

VA's Cardiac Surgery Program

VA established a cardiac surgery program in February 1965 at 13 medical centers. The program covers 66 different surgical procedures on the heart and thoracic great blood vessels requiring use of a heart-lung bypass machine to perform the functions of circulation during surgery. During fiscal year 1987, 43 medical centers performed cardiac surgery and another 8 had contracts or sharing agreements under which veterans requiring cardiac surgery were referred to local hospitals. The locations of the 51 medical centers and contract facilities providing cardiac surgery to veterans are shown in figure 1.1.

Coronary artery bypass grafts generally account for most of the procedures performed (see table 1.1). In this procedure, a vein from the leg (saphenous vein) and/or an internal mammary artery is used to circumvent blocked coronary arteries that are restricting the flow of blood to the heart.

Figure 1.1: Location of VA Cardiac Surgery Centers (Fiscal Year 1987)

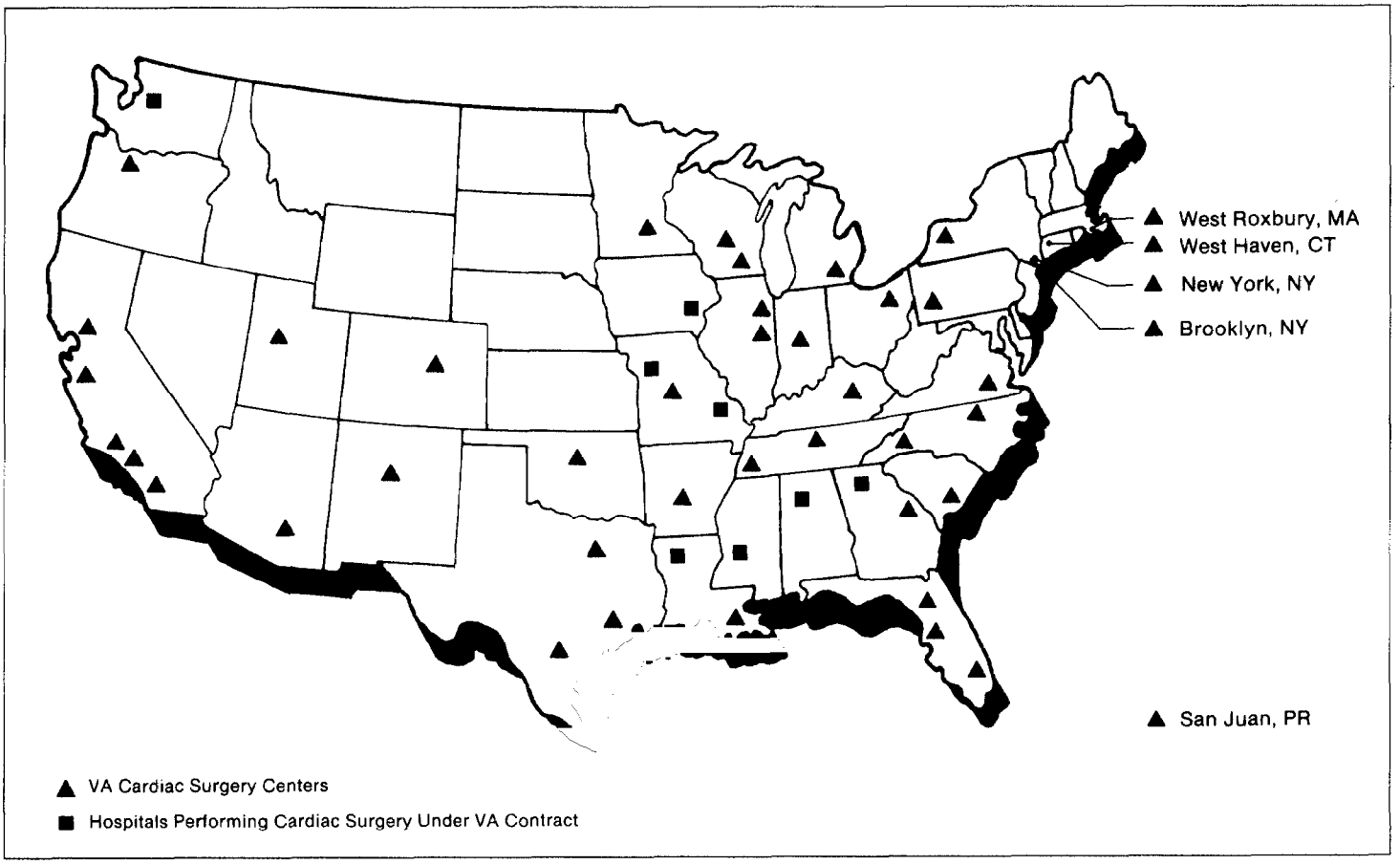
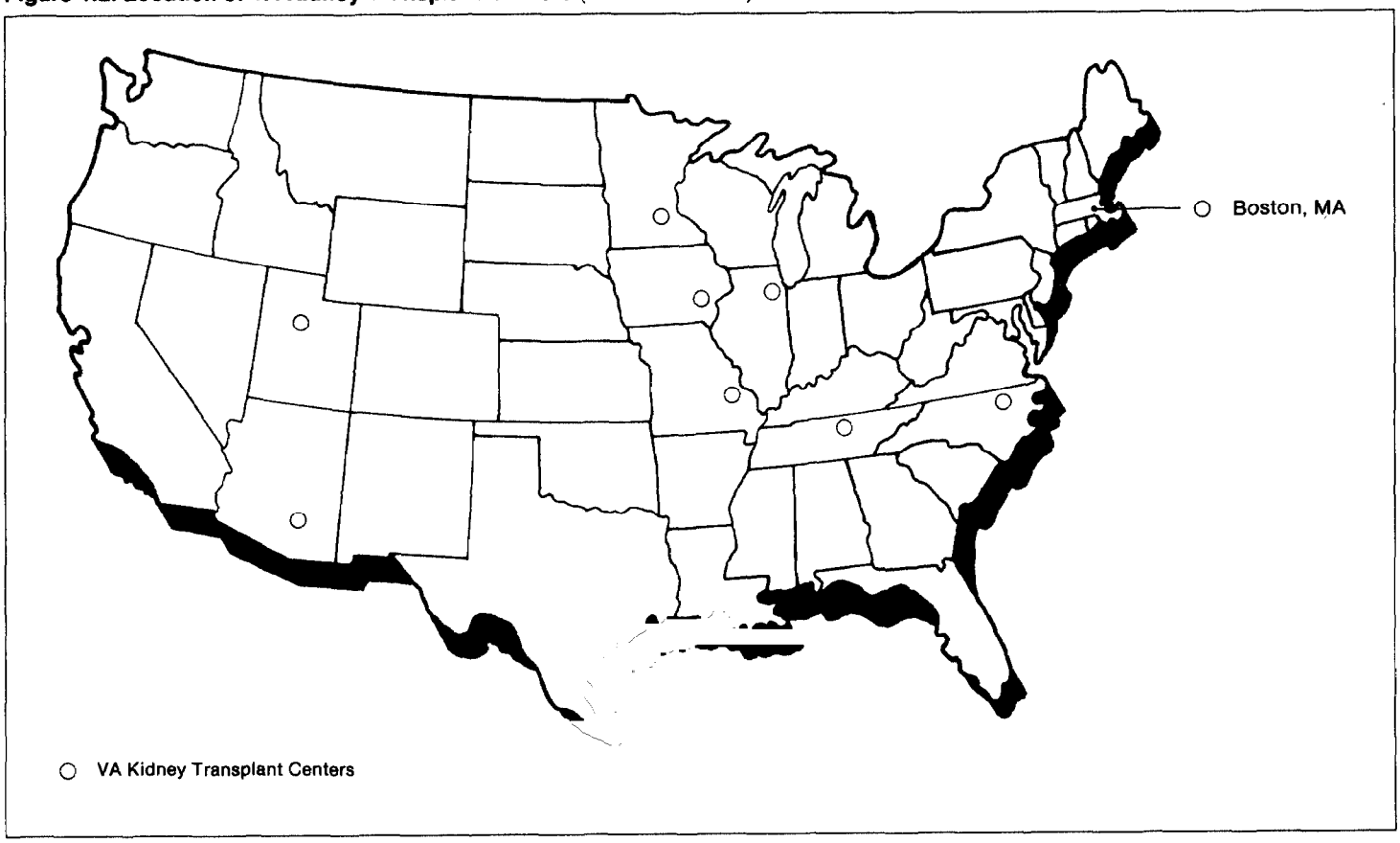


Table 1.1: Number of VA Cardiac Surgery Procedures Performed (Fiscal Year 1987)

	Number of procedures		
Procedure	**VA medical centers**	**Contract hospitals**	**Total**
Coronary artery bypass graft	5,404	499	5,903
Other	1,444	115	1,559
Total	**6,848**	**614**	**7,462**

Since 1973, VA's Director of Surgical Service has relied primarily on a Cardiac Surgery Consultants Committee for routine monitoring of VA's cardiac surgery program. The Committee's membership includes the Director, the Chief of Cardiovascular Diseases, and selected physicians from VA medical centers and non-VA hospitals. In response to a 1984 GAO

Figure 1.2: Location of VA Kidney Transplant Centers (Fiscal Year 1987)



report,[1] VA issued guidelines designed to improve the committee's monitoring activities. Other such safeguards include:

- Quality assurance activities are required by the Joint Commission on Accreditation of Healthcare Organizations of medical centers performing cardiac surgery. Among these are a presurgical conference between cardiologists and surgeons to assure that surgery is justified; regularly scheduled morbidity and mortality conferences to review any complications, including death, that resulted from surgery; and systematic internal reviews.
- A VA-operated Systematic External Review Program provides a periodic peer review of the effectiveness of each medical center's medical care and related services, including surgical care.

[1] Improvements Needed in Quality Assurance for Open Heart Surgery (GAO/HRD-84-22, Feb. 24, 1984).

- A Medical District Peer Review Organization identifies and assesses patient care and medical practices at VA medical centers that do not meet acceptable standards.
- The Department of Medicine and Surgery's Risk Management Program, for which VA's Medical Inspector is responsible, requires that each center report events involving patients' deaths within 24 hours.

VA's Kidney Transplantation Program

VA initiated its kidney transplantation program in 1961. In fiscal year 1975, 29 centers performed 383 kidney transplants. Since then, the number of centers, as well as the number of transplants, has declined. The decline was caused, according to the Director of Surgical Service, by a change in Medicare coverage that allows veterans eligible for Medicare to choose non-VA hospitals for kidney transplants. The nine medical centers that performed this surgery during fiscal year 1987 (see fig. 1.2) provided kidney transplants for 117 veterans.

Kidney transplant centers work closely with dialysis programs, which provide life support for patients with chronic renal failure until appropriate donor organs become available for transplantation. The surgical procedure involves removing the existing kidney and grafting a donor kidney. Unlike cardiac surgery, kidney graft failure does not frequently result in patient death, as the patient again can be placed on renal dialysis and may survive until another donor organ becomes available.

Initially, VA relied on a Kidney Transplantation Consultants Committee to monitor each center's performance. Over time, the Committee's responsibilities were expanded to cover all transplants performed in VA medical centers, except bone marrow transplants. Also, the kidney transplantation program uses the same type of monitoring techniques previously discussed for cardiac surgery.

Objectives, Scope, and Methodology

At the request of the Chairman of the Subcommittee on HUD-Independent Agencies, Senate Committee on Appropriations, we collected information to respond to the following questions:

- Has VA developed adequate standards for identifying when a center performing cardiac surgery or kidney transplantation is operating at an acceptable level of performance?
- Are the centers meeting VA's standards?
- Is VA adequately monitoring the centers' performance?

To assess the adequacy of VA's standards, we reviewed the policies and procedures for establishing, operating, and monitoring the two programs. We also interviewed VA's Director of Surgical Service and other officials responsible for managing and monitoring the programs. In addition to reviewing literature on cardiac surgery and kidney transplantation issues, we contacted a wide range of public and private organizations, including the Department of Health and Human Services (HHS), the American College of Surgeons, the Society of Thoracic Surgeons, and the American College of Cardiology. Appendix I lists the organizations contacted.

To identify which cardiac surgery centers were meeting VA's performance standards, we analyzed data on the number of surgical procedures and patient deaths that each center reported to VA for fiscal years 1985-87 and compared them to VA's standards. For the kidney transplantation program, we contacted the centers operating during fiscal years 1986 and 1987 to obtain data on the number of procedures performed and patient deaths and graft failures. Because of time constraints, we did not assess the reliability of the statistical data provided by the medical centers.

To assess VA's monitoring of the centers' performance, we examined the monitoring activities of the Cardiac Surgery Consultants Committee, as well as a special management review undertaken during fiscal year 1985. We interviewed committee members, including the chairman; reviewed the committee's records; and interviewed officials at 11 centers[2] the committee reviewed for fiscal year 1986—the latest data available at the time of our field work. Because we focused on how VA uses its standards to monitor centers' performance, we did not attempt to evaluate the quality of care provided by individual centers or assess the adequacy of other quality assurance activities, such as those discussed on page 10.

For the kidney transplantation program, we reviewed the activities of the Kidney Transplantation Consultants Committee and interviewed the Director of Surgical Service and other officials responsible for managing and monitoring the kidney transplantation program.

We conducted our review between September and December 1987 in accordance with generally accepted government auditing standards,

[2]We did not contact one center the committee had reviewed because it had suspended its cardiac surgery program at the time of our fieldwork.

except for assessing the reliability of the medical centers' data, as previously discussed.

Cardiac Surgery Program

VA has established both utilization and mortality standards for assessing a center's cardiac surgery performance. In fiscal year 1987, 28 centers met VA's standards; 15 of the 28 also met the standards in fiscal years 1985 and 1986. VA uses the standards, not as the sole basis for judging centers' performance, but to identify centers that may be experiencing performance problems. However, VA's monitoring is inadequate to (1) help centers not meeting the standards to improve their performance or (2) assess their potential for meeting the standards.

VA's Standards for Cardiac Surgery Program

VA bases its performance standards on both (1) a center's utilization, as measured by the number of surgical procedures performed, and (2) the rate of mortality, as measured by the number of operative deaths[1] as a percentage of total surgical procedures performed.

Although several studies of cardiac surgery have indicated that medical facilities with higher volumes of procedures can generally be expected to have lower mortality rates, VA believes that the relationship between its centers' utilization and mortality rates is not as strong as has been portrayed in the studies. Thus, while VA uses utilization as one of its indicators of center performance, VA believes that mortality rates represent a more important factor in assessing performance.

Utilization Standard

During fiscal years 1985-87, VA's utilization standard was performance by each cardiac surgery center of at least 100 cardiac surgery procedures a year. For fiscal year 1988, VA's Chief Medical Director increased the minimum to 150, based on the recommendation of a Special Advisory Committee on Cardiac Surgery.[2]

Guidelines published in 1978 by the Department of Health, Education, and Welfare (now HHS) called for a minimum of 200 cardiac surgery procedures annually in any institution performing cardiac surgery. When these guidelines were published, the American College of Cardiology found 200 to be an acceptable annual number.

Hospitals and surgical teams that specialize in coronary artery bypass surgery and perform more than 200 procedures per year have better

[1] An operative death is defined as any death within 30 days of surgery, plus any death caused by a complication that was first manifested within 30 days of surgery.

[2] A 12-member panel of distinguished cardiac surgeons and academics from VA and private institutions.

outcomes in terms of mortality rates, according to a 1987 report.[3] It presented the results of a study conducted by Blue Shield of California and the Institute for Health Policy Studies of the University of California School of Medicine in San Francisco.

Information we obtained from the American College of Surgeons and the Society of Thoracic Surgeons showed that these organizations endorsed a minimum of 150 procedures annually per surgical team and a minimum of 150 cases per hospital to maintain effective use of equipment and personnel. Nine other organizations we contacted did not publish or endorse a specific number of procedures to be used as a utilization standard.

A VA surgical team or an individual surgeon may perform cardiac surgery in other non-VA hospitals. Although each VA center reports only the number of procedures performed in the center, VA established a policy in November 1987 that an exception to the standard can be made on a case-by-case basis after considering various reasons for temporary noncompliance and the surgeon's total workload, including the number of procedures performed in non-VA hospitals.

Figure 2.1 shows that the number of VA medical centers[4] performing at least 100 or 150 cardiac surgery procedures increased slightly from 1985 to 1987. Cardiac surgery performed in non-VA hospitals under a contract or sharing agreement with a VA medical center is discussed separately on page 23.

Thirty-eight of 43 centers performing cardiac surgery met the 100-procedure standard in 1987. Of the 38 centers, 30 also had performed at least that many procedures in 1985 and 1986. A significantly lower number of centers would have met VA's fiscal year 1988 standard (150 procedures) had it been in effect during the period, as figure 2.1 shows. Only 12 centers performed at least 150 procedures in each of the 3 years. However, the number of centers performing at least 150 procedures increased from 15 in fiscal year 1985 to 25 in fiscal year 1987.

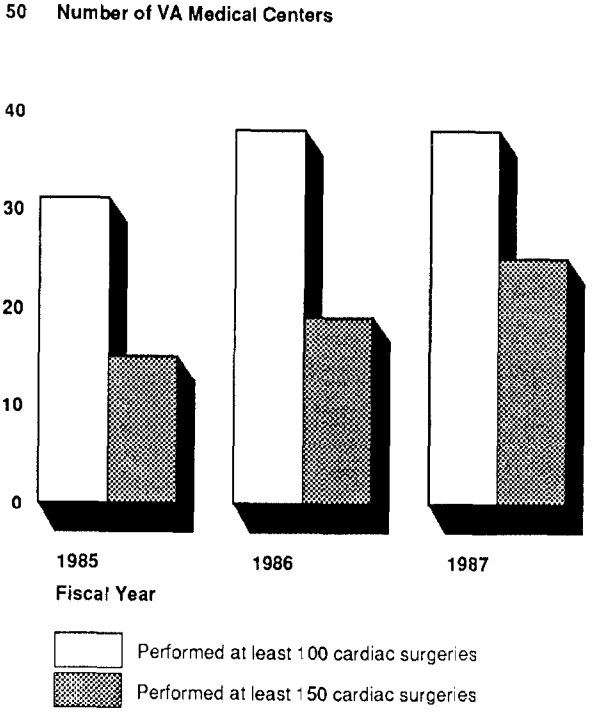
Mortality Standards

During fiscal years 1985 through 1987, VA used two cardiac surgery mortality standards. Each center's operative mortality rates for

[3]HHS, Office of the Inspector General, Coronary Artery Bypass Graft Surgery, OAI-09-86-00076, Aug. 1987.

[4]In fiscal years 1985 and 1986, 45 centers performed cardiac surgery, but in 1987 only 43 centers did.

Figure 2.1: VA Medical Centers That Met Cardiac Surgery Utilization Standards (1985-87)



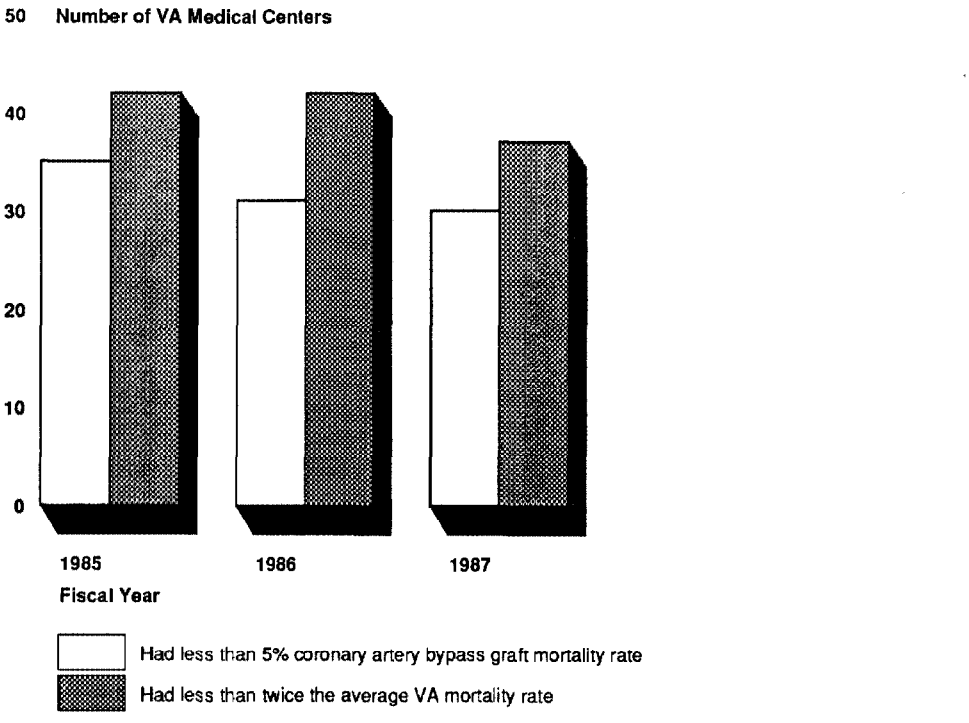
- coronary artery bypass graft procedures should not exceed 5 percent of the total number of such procedures performed and
- all cardiac surgery procedures should not exceed twice VA's national average for such surgery.

Unlike the utilization standard, none of the organizations we contacted issued or endorsed mortality standards. However, the Special Advisory Committee on Cardiac Surgery endorsed VA's use of the 5-percent mortality rate for coronary artery bypass grafts as a standard for identifying centers that might be experiencing problems and need review.

The number of VA centers meeting the mortality rate standards for coronary artery bypass grafts and total surgical procedures during the last 3 fiscal years decreased, as figure 2.2 shows.

Thirty of the 43 centers met the 5-percent mortality standard for coronary artery bypass grafts in fiscal year 1987. Of the 30 centers, 20 also had mortality rates of 5 percent or less in fiscal years 1985 and 1986.

Figure 2.2: VA Medical Centers That Met Cardiac Surgery Mortality Standards
(Fiscal Years 1985-87)



Unlike the bypass graft mortality standard, most VA centers maintained an overall cardiac surgery mortality rate that was less than twice VA's national average, which was 9.6, 10.0, and 9.8 percent for fiscal years 1985, 1986, and 1987, respectively.

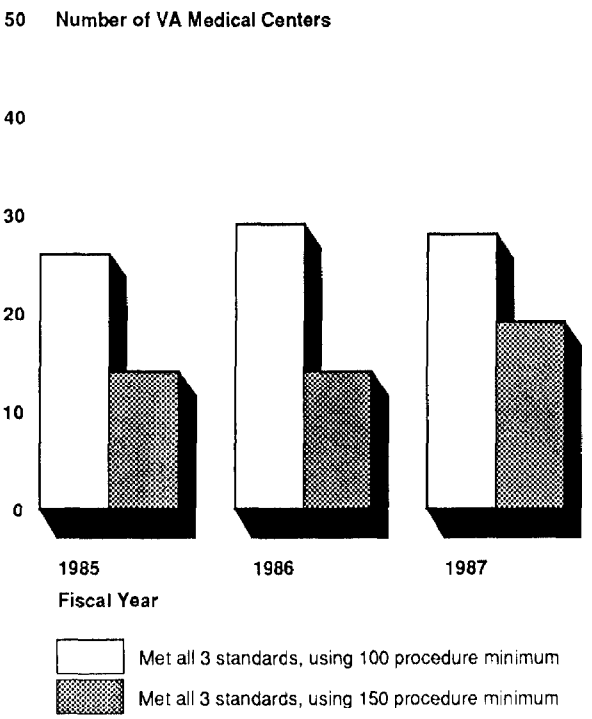
Utilization and Mortality Standards

The number of VA centers meeting all three standards (one for utilization and two for mortality) relating to cardiac surgery increased from 26 to 28 between 1985 and 1987 (see fig. 2.3).

Twenty-eight of VA's 43 centers met all three standards in fiscal year 1987, when the utilization standard was 100 procedures a year. Fifteen of these 28 centers also met the three standards in 1985 and 1986.

Our analysis of VA utilization and mortality data for its 43 centers supports VA's contention that a strong relationship may not exist between utilization and mortality rates experienced by its centers. For example, of the 15 centers that did not meet all three standards in 1987, 10 met

Figure 2.3: VA Medical Centers That Met Cardiac Surgery Utilization and Mortality Standards (Fiscal Years 1985-87)



the utilization standard but did not meet both the mortality standards; 1 met both the mortality standards but did not meet the utilization standard; 1 met only one of the mortality standards and did not meet the utilization standard; and 3 met none of the mortality or utilization standards.

Had VA's new utilization standard (150 procedures) been in effect during fiscal year 1987, 18 of the 43 centers would not have met it. However, 10 of these 18 centers met VA's mortality standards. The fact that these 10 met VA's mortality standards tends to support VA's judgment that a center's performance should not be based solely on utilization. Although these centers were not able to meet the utilization standard, their performance was acceptable, according to VA's mortality standards.

Conversely, 6 of the 25 centers that performed 150 procedures did not meet both mortality standards. The six centers demonstrate that high utilization does not—by itself—ensure good performance as measured by VA's mortality standards.

While the utilization and mortality standards can be used to identify centers that appear to have performance problems, a decision on whether a center is performing satisfactorily should only be made after a review of other factors affecting its performance. For example, the number of procedures a center reports may not be a good indication of its performance because surgeons and surgical teams may perform additional procedures at local hospitals not included in the center's report.

Mortality rates—by themselves—may also be misleading, depending on such factors as the age or severity of illness of the veteran being treated. For example, a low mortality rate may suggest an acceptable performance level, but it may also mean that high-risk patients are being referred to other medical facilities. Conversely, a high mortality rate may suggest an unacceptable performance, or it may mean that many of the veterans were high-risk surgical patients.

VA's Monitoring of Cardiac Surgery Program

VA routinely monitors its cardiac surgery program through its Cardiac Surgery Consultants Committee. The committee uses VA's standards to assess each center's performance and recommends to the Director of Surgical Service whether management action, such as a site visit, is needed. The Director is responsible for assuring that appropriate actions are taken to improve the performance of centers not meeting the standards. In addition to its routine monitoring activities, in 1985 VA convened a Special Advisory Committee to review its cardiac surgery program because of public concern about the centers' mortality rates.

Routine Monitoring

Every 6 months, each medical center submits to the Director of Surgical Service information on the number and type of cardiac surgeries performed and the number of related operative deaths. The Director then forwards the data to the committee, which uses it to identify centers not meeting the utilization and mortality standards. Based on the committee's analysis, the Director may decide to (1) send letters to the centers regarding their low utilization, (2) review operative deaths, or (3) authorize site visits by committee members.

Medical Record Reviews

Medical centers not meeting the mortality standards provide medical records for operative deaths to the committee for a review, known as a paper audit. From the medical records, the committee formulates medical opinions regarding such factors as the operative techniques used and the potential for either pre- or postoperative error. The committee uses

a checklist to indicate whether the factors that contributed to a patient's death were deemed preventable, but does not include, as part of its assessment, recommendations for improving a center's performance. The Director of Surgical Service provides the review results to the center's Chief of Surgical Service.

In fiscal year 1986 (the latest data available at the time of our fieldwork), the committee performed paper audits on operative deaths at eight centers not meeting the standards. The committee records contain no information on whether (1) the centers took action as a result of the audits or (2) the committee followed up on its findings.

To obtain such information, we interviewed the Chiefs of Staff, Surgical Service, or Cardiology at seven of the eight centers.[5] Four centers had taken some action as a result of the committee's audits; for example, one center (1) instituted new procedures for monitoring temperatures of a patient's heart and (2) now requires surgeons to be more involved in postoperative care, according to the officials interviewed. Officials at the other three centers told us that actions had already been taken before they received the committee's results or that no action was needed. Only one center provided feedback to the committee about actions taken as a result of its reviews. Thus, the Director of Surgical Service did not know what changes, if any, most of the centers had made.

Some of the officials at the centers told us that because the results of the committee's reviews are not provided in a timely manner, corrective actions may be taken before review results are received. The committee's assessments of the operative deaths occurring in fiscal year 1986 were provided to the centers, on average, about 13 months after the surgical procedures had been performed.

Some of the officials at the centers also questioned the "soundness" of conclusions based on reviews of selected medical records. Since the committee had focused on individual patient records, problems such as nursing shortages, difficulties encountered by some centers in retaining qualified surgeons, and outdated facilities and equipment were not identified. In some instances such factors have adversely affected the centers' cardiac surgery performance, according to these officials. In their

[5]We did not interview officials at one medical center that the committee paper audited because the center had suspended its cardiac surgery program at the time of our fieldwork.

opinion, site visits are more effective because they include discussions with a center's staff and provide a more comprehensive review.

Site Visits

Currently, the committee recommends site visits solely at its discretion because VA has not established specific guidelines for when site visits should be conducted. VA's 1986 instructions for paper audits state: "If the Committee is concerned about any phase of a program it may recommend a site visit. VA Central Office (VACO), in turn, when practical, based on availability of funds, will arrange such a site visit."

Ideally a center not meeting the mortality standards for two 6-month review periods should be site visited, according to the committee chairman. However, according to the Director of Surgical Service, because physicians serving on the committee have other medical and teaching responsibilities, their time available to make site visits may be limited. Also, the chairman cited funding limitations as a consideration in deciding how frequently to make such visits. A typical site visit by two or three committee members lasts one or two days and costs from $1,000 to $3,000, including transportation and per diem.

Committee members made a total of five site visits during fiscal years 1986 and 1987. Had VA's guidelines required a visit to each center not meeting the mortality standards for a prescribed time frame (such as 12 months), visits to another 13 centers would have been required during this period. Through such site visits, all factors affecting the centers' performance could have been assessed and actions initiated to improve performance.

Our review of the committee's reports on the five site visits confirmed that visits were generally more comprehensive and thorough than paper audits. In addition to reviewing patient records, the visiting physician(s) considered such other factors as patient selection, infection control, condition of facilities and equipment, and staffing difficulties.

The utility of site visits was illustrated when two committee members visited a medical center that had done 45 to 80 surgical procedures annually over a 5-year period. The center's staff were not getting adequate experience, the committee found, and the center lacked certain types of staff with appropriate training and experience. In their report, the committee members recommended that the center (1) continue to perform cardiac surgery on a conditional basis pending another review

in 12 months and (2) consider medical therapy, rather than surgery, for certain high-risk patients.

Although reports on the other site visits contained some recommendations, only two set specific time frames for centers to make needed changes and demonstrate that they could meet VA standards. Also, the reports did not recommend suspension or consolidation of programs that evidenced a continued inability to meet the standards.

Special Management Review

In addition to the routine monitoring, in 1985 the Chief Medical Director appointed a Special Advisory Committee of experts to review the cardiac surgery program agencywide. This review was initiated in response to a growing public concern about the overall quality of cardiac surgery in VA medical centers, especially those experiencing potentially excessive mortality rates.

The committee made several recommendations to the Chief Medical Director in September 1985. In addition to endorsing an increased utilization standard (150 procedures), it recommended that

- a regional network of VA cardiac surgery centers be identified and assigned sufficient resources to ensure cardiac care for all eligible veterans,
- most of the centers that did not meet the utilization standard (100 procedures) in fiscal years 1983 and 1984 be closed and their caseloads assigned to a regional center,
- appropriate cardiac consultants (1) promptly review centers not meeting the mortality rates for coronary artery bypass grafts over a 24-month period and (2) recommend that the Chief Medical Director consider terminating the program at centers that do not demonstrate the potential for meeting the standard in 1 year, and
- a center's request to begin a cardiac surgery program be examined carefully and approved only if there is identifiable need for patient care and realistic prospects for the center to meet utilization and mortality standards within a 3-year period.

In 1986, several groups within VA addressed the Special Advisory Committee's recommendations and the potential consolidation of programs. Site visits were made to five centers. In January 1987, the Administrator announced that four of the five cardiac surgery centers would close because they were experiencing low utilization and high mortality rates.

Also, over an 18-month period the Cardiac Surgery Consultants Committee was to closely monitor 16 centers that had experienced problems with low utilization and high mortality rates, the Administrator announced. But the "close monitoring" of these 16 centers during calendar year 1987 entailed nothing more than the committee's routine monitoring reviews of medical records and site visits if the committee expressed concern to the Director of Surgical Service, a VA official subsequently told us. As of February 26, 1988, VA had not visited these centers to determine whether they were able to meet agency standards.

VA's Monitoring of Cardiac Surgery at Contract Hospitals

Eight VA medical centers have contractual arrangements with local hospitals to perform cardiac surgery where a need exists and the VA center lacks such capability, according to the Director of Surgical Service. Typically, the surgery is done at the contract hospital, but pre- and post-operative care takes place at the VA center. Four of the eight VA centers are in the process of establishing their own capability to perform cardiac surgery. These centers accounted for 77 percent of the 614 procedures performed at contract hospitals in fiscal year 1987.

VA routinely monitors these eight hospitals as it does its centers. There is a significant difference, however, between the information reported for the contract hospitals and for the VA medical centers. Rather than figures on overall cardiac surgery performance by the contract hospitals, only statistics on veterans' cardiac surgery are available. Although VA's contracts do not include a provision that hospitals provide overall data on utilization and mortality rates, VA is not legally precluded from requiring such information in the contracts, according to an official in VA's Office of General Counsel.

The committee reviewed the medical records of operative deaths for veterans at four contract hospitals because the mortality rates for cardiac surgery exceeded VA's standards in fiscal year 1986. The committee followed the same procedures as it did in reviewing VA medical centers, our review of these paper audits showed. The results of the reviews were provided to the four VA medical centers that contracted with the non-VA hospitals, but feedback was not provided to the committee in response to the reviews, according to the VA officials.

Conclusions

VA has established both utilization and mortality standards that can be used to identify centers that may be experiencing performance problems. While VA uses centers' utilization rates as a performance indicator,

VA places a higher priority on centers' mortality rates in making judgments about centers' performance. We believe that this represents a reasonable approach based on our analysis of VA's data on the utilization and mortality rates of its 43 centers.

While VA's standards should be used as indicators to identify centers that may not be performing at acceptable levels, decisions as to whether a particular center is performing satisfactorily should be made only after a comprehensive review of the center's performance. VA has relied on the committee's review of information, such as patient records, to make these decisions. The usefulness of this approach is limited because it does not include sufficient information to (1) assess the center's potential for meeting standards and (2) make specific recommendations for improving the center's performance.

Site visits provide the opportunity to assess the center's potential for meeting standards and to review other factors, such as patient selection, infection control, the condition of facilities and equipment, and staffing difficulties. Without first-hand detailed information and insights obtained from the site visits, we do not believe that VA can make informed judgments about (1) the corrective actions needed at the centers, (2) the time frames needed by the centers to make the changes and show they can meet the standards, and (3) whether cardiac surgery at the centers should be consolidated or terminated.

Because VA lacks adequate guidelines for when site visits should be performed, many centers that failed to meet mortality standards for several consecutive 6-month review periods continued to operate without a site visit. In this regard, we believe that a failure to meet these standards for a 12-month period represents a reasonable guideline as to when a site visit should be made. While such a guideline could cause an immediate increase in the number of site visits, we believe the number would decrease over time as (1) the centers improved their performance and demonstrated an ability to meet the standards and (2) the centers that did not have the potential to meet the standards were identified and their cardiac surgery programs terminated.

The performance of contract hospitals should be reviewed in the same manner as VA centers. However, VA does not collect sufficient information to adequately assess such hospitals' overall performance. Without information on the number of cardiac surgery procedures the contract hospitals performed on nonveterans (and the corresponding operative

deaths), VA cannot determine whether the contract hospitals' performance is at a level consistent with VA's standards.

Recommendations

We recommend that the Administrator of Veterans Affairs direct the Chief Medical Director to require that a site visit be conducted at each cardiac surgery center that does not meet the mortality standards for a prescribed time period, such as 12 consecutive months. During each site visit, physician reviewers should assess the center's potential to meet utilization and mortality standards. If the center shows potential for achieving the standards, the reviewers should (1) recommend specific actions a center needs to take to improve performance and (2) set time frames for achieving the standards. If the reviewers find that a center has little or no potential for achieving the standards or a center previously visited could not achieve the standards within the prescribed time frames, the Chief Medical Director should consider terminating the center's cardiac surgery program.

To better assess whether contract hospitals are providing cardiac surgery to veterans at an overall level consistent with VA's standards, we recommend that the Administrator require that the Chief Medical Director develop a procedure for collecting and monitoring these hospitals' utilization and mortality information for nonveterans as well as veterans.

VA Comments

In an April 21, 1988, letter (see app. III), the Administrator concurred with our recommendation to establish guidelines regarding site visits. He said that the Director of Surgical Service will present new monitoring guidelines to the Cardiac Surgery Consultants Committee at the June 1988 meeting. The guidelines clarify when and under what circumstances site visits should be made and a center's cardiac surgery program should be recommended for termination.

For example, as presently drafted, the guidelines would require the Committee to recommend that a site visit be made to each center that fails to meet the mortality standard for coronary artery bypass grafts for two successive 6-month review periods, unless factors other than those related directly to patient care are identified, such as loss of the cardiac surgeon or key nursing personnel. According to the Administrator, each of the 16 centers targeted by the Special Advisory Committee for close monitoring is expected to be site visited between September

and December 1988, although additional time may be needed to complete some visits.

The Administrator also concurred with our recommendation to develop procedures for monitoring the results of cardiac surgery provided to nonveterans as well as veterans by contract hospitals. VA's Surgical Service, Clinical Affairs, and the Office of Quality Assurance will be instructed to work with VA's general counsel to develop procedures for collecting and monitoring data on the care of nonveterans as well as veterans at hospitals performing cardiac surgery under contracts or sharing agreements. The Administrator pointed out, however, that contract hospitals may not be willing to disclose to VA mortality data on non-VA patients.

Kidney Transplantation

VA has established a minimum utilization standard for its kidney transplantation program. In fiscal year 1987, only four of the nine VA centers that performed kidney transplants met VA's utilization standard. A kidney transplant is a less complex surgical procedure than cardiac surgery and is accompanied by an extremely low operative death rate. Therefore, the length of time that the transplanted kidney functions (generally referred to as kidney graft survival) or the patient survives provides a more meaningful performance measure than operative mortality rates. Although an HHS task force proposed that patient and kidney graft survival rates be used as indicators of a center's performance, VA has not adopted them nor established alternative standards. Nonetheless, VA's centers' patient and kidney graft survival rates compared favorably with the proposed standards even though most of the centers performed fewer than 25 transplants annually.

VA's Utilization Standard

Before August 1987, VA's utilization standard for its kidney transplantation program was 15 procedures a year—since reduced to 12. The standard should be 12, according to a VA ad hoc committee on organ transplants, because a substantial number of VA centers would be unable to achieve a higher number, and this lower number of procedures should not affect the quality of care. As discussed on page 11, the number of veterans electing to have kidney transplants in VA medical centers has declined over the last decade.

In 1986, the HHS Task Force on Organ Transplantation proposed as a minimum standard 25 procedures per hospital per year to gain and maintain the necessary experience and skill levels. Neither our review of literature on kidney transplants nor our discussions with professional organizations produced any other utilization standards.

In fiscal year 1987, nine centers performed 117 kidney transplants. Of these, four performed more than 12, including one center that did more than 25. The other five centers performed between 2 and 10 transplants.

Survival Rate Standards

The HHS task force proposed that the following standards be used as indicators of a center's performance:

- For kidneys taken from living related donors, 90 percent of the patients and 70 percent of the kidney grafts should survive at least 1 year after the transplant.

- For kidneys taken from deceased donors, 85 percent of the patients and 60 percent of the kidney grafts should survive at least 1 year after the transplant.

Although VA has not adopted these standards, it recognized the need for them in an August 1987 circular. Patient and kidney graft survival standards were to be developed as part of quality assurance standards to be used by VA's Surgical Service, in cooperation with the Office of Quality Assurance, according to the circular. Although VA plans to continue performing kidney transplants, the Director of Surgical Service said there are no current plans to establish patient and kidney graft survival standards because VA centers are performing fewer transplants. According to the Director, 1-year patient survival rates are not meaningful because the likelihood of patients dying within 12 months of a kidney transplant is slight. This is because patients who experience a kidney graft failure can be placed on renal dialysis and may survive until another donor organ becomes available. He felt a more valid measurement of the program's success would be kidney graft survival standards of 3 and 5 years.

All VA centers that used kidneys from living related donors met the HHS task force's recommended standards of 90 percent patient survival and 70 percent kidney graft survival 1 year after the transplantation, our analysis showed. (We obtained data on patient and kidney graft survival times from the 10 VA kidney transplantation centers operating in fiscal year 1986, the latest available data at the time of our fieldwork).

For kidneys taken from deceased donors, 8 of the 10 centers met the standard of 85 percent patient survival after 1 year; the other two had 75 percent of their patients survive for 1 year. All VA centers met the 60 percent kidney graft survival standard following 1 year for kidneys taken from deceased donors.

VA's Monitoring of Kidney Transplant Program

Until 1980, a Kidney Transplantation Consultants Committee met annually to review information provided by medical centers on the numbers of transplants performed by type of donor (deceased or living related) and patients surviving after 6 months, according to VA officials. The committee identified centers with problems and made recommendations to the Director of Surgical Service.

Since 1980, the committee has met only twice.[1] It no longer monitors the program closely, the Director of Surgical Service told us, because (1) travel funds are lacking, (2) the number of kidney transplants is declining, and (3) kidney transplant surgery has become a routine, low-risk procedure. Further, the medical center directors are responsible for monitoring kidney transplants at their centers and ensuring the quality of care, he said, reducing the need for close surveillance by his office.

Although the committee does not meet annually, the centers continue to submit biannual kidney transplant activity reports to the Director of Surgical Service. He scans the reports to identify any obvious problem areas and files them for future reference. Any obvious problems identified are referred to the Transplantation Consultants Committee for review.

Conclusions

VA's minimum utilization standard for its kidney transplantation program is less than half the level proposed by the HHS task force. We do not agree with VA's rationale for reducing its standard because its centers are performing a lower number of kidney transplants. However, as previously discussed, the VA centers' patient and kidney graft survival rates compared favorably with the proposed standards even though most of the centers performed fewer than 25 kidney transplants annually.

Given the centers' low utilization of this procedure, we believe it is important that patient and graft survival rates be monitored regularly to ensure that centers not operating at acceptable performance levels are identified promptly. In this regard, we believe that the HHS task force patient and kidney graft survival rates are reasonable standards to use in identifying such centers.

Recommendations

We recommend that the Administrator of Veterans Affairs require the Chief Medical Director to (1) adopt the HHS task force patient and kidney graft survival rates or establish alternative standards and (2) regularly monitor the centers' performance against the standards. If a center does not show potential for meeting the standards, the Chief Medical Director should consider terminating the center's kidney transplant activities.

[1]The committee's name was changed in 1985 to the Transplantation Consultants Committee.

Organizations Contacted to Identify Performance Standards for Cardiac Surgery and Kidney Transplantation

Air Force Office of Quality Control
American Association of Thoracic Surgery
American College of Cardiology
American College of Surgeons
American Heart Association
American Medical Peer Review Association
American Society of Transplant Surgeons
Council of Teaching Hospitals, Association of Medical Colleges
International Society for Cardiac Surgery
Joint Commission on Accreditation of Healthcare Organizations
Office of Organ Transplantation, Health Resources and Services Administration, Public Health Service, HHS
Society for Vascular Surgery
The Society of Thoracic Surgeons
United Network for Organ Sharing

VA Comments

The Administrator concurred that the patient and graft survival rates proposed by the HHS task force are reasonable and appropriate. He said VA has accepted these standards and has used them, along with data from current transplant literature, to assess patient and kidney graft survival rates at its transplant centers.

VA Medical Centers Performing Cardiac Surgery and Kidney Transplants in Fiscal Year 1987

Centers With Cardiac Surgery Programs (43)

Albuquerque, NM	Memphis, TN
Ann Arbor, MI	Miami, FL
Asheville, NC	Minneapolis, MN
Augusta, GA	Nashville, TN
Brooklyn, NY	New Orleans, LA
Buffalo, NY	New York, NY
Charleston, SC	Oklahoma City, OK
Chicago (West Side), IL	Palo Alto, CA
Cleveland, OH	Pittsburgh, PA
Columbia, MO	Portland, OR
Dallas, TX	Richmond, VA
Denver, CO	Salt Lake City, UT
Durham, NC	San Antonio, TX
Gainesville, FL	San Diego, CA
Hines, IL	San Francisco, CA
Houston, TX	San Juan, PR
Indianapolis, IN	Tampa, FL
Lexington, KY	Tucson, AZ
Little Rock, AK	West Haven, CT
Long Beach, CA	West Roxbury, MA
Los Angeles, CA	Wood, WI
Madison, WI	

Contract Cardiac Surgery Programs (8)

Atlanta, GA
Birmingham, AL
Iowa City, IA
Kansas City, MO
Jackson, MS
St. Louis, MO
Seattle, WA
Shreveport, LA

Centers With Kidney Transplantation Programs (9)

Boston, MA
Durham, NC
Hines, IL
Iowa City, IA
Minneapolis, MN
Nashville, TN
St. Louis, MO
Salt Lake City, UT
Tucson, AZ

Comments From the Veterans Administration

Office of the
Administrator
of Veterans Affairs

Washington DC 20420

Veterans
Administration

APR 21 1988

Mr. Lawrence H. Thompson
Assistant Comptroller General
Human Resources Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Thompson:

This responds to your request that the Veterans Administration (VA) review and comment on the General Accounting Office (GAO) March 11, 1988, draft report VA HEALTH CARE: Monitoring of Cardiac Surgery and Kidney Transplantation. GAO reviewed these two programs to determine whether (1) VA has developed adequate performance standards, (2) medical centers that have cardiac surgery or kidney transplant programs are meeting VA's standards, and (3) VA is adequately monitoring the centers' performance.

The draft report states that VA uses established minimum standards for determining whether a medical center's cardiac surgery program is maintaining an acceptable level of utilization and patient mortality, but, when judging centers' performance, places a higher priority on mortality rates. The standards are not the sole basis for judging performance, but a means of identifying centers that may be experiencing performance problems. GAO concluded that VA's monitoring of cardiac surgery centers is not adequate.

The draft report also states that while VA has established a minimum utilization standard for assessing the performance of medical centers performing kidney transplants, the Agency has not adopted standards for assessing survival rates for patients and transplanted kidneys.

GAO recommends that the Chief Medical Director require that the Director of Surgical Service arrange for a site visit to be conducted at each cardiac surgery center that does not meet the mortality standards for a prescribed time period, such as 12 consecutive months. During each site visit physician reviewers should assess the center's potential to meet utilization and mortality standards. If the center shows potential for achieving the standards, the reviewers should: (1) recommend specific actions a center needs to take in order to improve operations, and (2) set time frames for achieving the standards. If the reviewers find that the center has little or no potential for achieving the standards, or if a center previously site visited could not achieve the standards within the prescribed timeframe, the Chief Medical Director should consider terminating the center's open-heart surgery program.

2.

Mr. Lawrence H. Thompson

We concur. The Acting Director of Surgical Service in Central Office has drafted Criteria for Monitoring the Cardiac Surgery Program (enclosed) that he will present to the Cardiac Surgery Consultants Committee at the June 1988 meeting. This blue ribbon committee, appointed by the Chief Medical Director to evaluate the Cardiac Surgery Program, recommended that the 16 programs not meeting VA standards be closely monitored semiannually. It has been decided that each of those programs be site-visited by the Cardiac Surgery Consultants Committee between September and December 1988. This may present a problem to the Committee, so additional time beyond December 1988 may have to be allowed to complete the site visits.

The Committee will continue to rely on their review of patients' charts for information on case selection as determined by the preoperative assessment of the patient, the procedures used during the operation, and the specific condition of the patient and the care provided in the postoperative period. These factors are basic in any quality assurance review.

To better assess whether contract hospitals are providing cardiac surgery to veterans at an overall level consistent with VA's standards, GAO recommends that the Chief Medical Director develop a procedure for collecting and monitoring these hospitals' utilization and mortality information for both nonveterans and veterans.

We concur. Surgical Service, Clinical Affairs, and the Office of Quality Assurance will be instructed to work with VA's General Counsel to develop a procedure for collecting and monitoring data on the care of veteran patients whose cardiac surgery is performed under contract or sharing agreement as well as on the care of nonveterans patients. However, regarding the disclosure of mortality data to the VA on non-VA patients, contract hospitals may not be willing to disclose this information.

GAO recommends that the Chief Medical Director (1) adopt the Department of Health and Human Services' patient and kidney graft survival rates or establish alternative standards and (2) regularly monitor the centers' performance against the standards. If a center does not show potential for meeting the standards, the Chief Medical Director should consider terminating the center's kidney transplant activities.

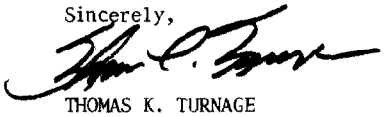
We concur that the patient and kidney graft survival rates recommended by the Department of Health and Human Services (HHS) are reasonable and appropriate, as they were determined using criteria derived from the transplant literature. We have accepted these standards and have compared our patient and graft survival with these survival rates as well

3.

Mr. Lawrence H. Thompson

as with survival data obtained from current transplant literature. As stated in the draft report, the VA data for patient and graft survival rates compared favorably with those recommended in 1986 by the HHS. These data and accompanying data from all surgical procedures performed in the VA are reviewed as part of the quality assurance mechanism at the local level as well as in VA Central Office.

Sincerely,



THOMAS K. TURNAGE
Administrator

Enclosure

Enclosure

VETERANS ADMINISTRATION COMMENTS ON THE MARCH 11, 1988 GAO REPORT VA HEALTH CARE: MONITORING OF CARDIAC SURGERY AND KIDNEY TRANSPLANTATION

D R A F T

CRITERIA FOR MONITORING THE CARDIAC SURGERY PROGRAM

This document expresses the concern of the Acting Director, Surgical Service, VA Central Office, that finite guidelines have not been developed for guidance of the Cardiac Surgery Consultants Committee in monitoring the Cardiac Surgical Program, with specific reference to indications for site visits. During previous deliberations of your Committee, it was agreed that a site visit should be made before a program is placed on probation, or before a program is recommended for closure. In addition, at the semiannual audits of those programs not meeting VA standards, the Committee has in the past recommended site visits at the 6-months' review of a program when deemed appropriate. I would agree with this flexibility based upon the decision of the Committee whether a site visit should be made at this early 6-month period. In addition to this flexible guideline, however, I present for your evaluation the following suggested guidelines regarding site visits:

1. If, at the end of two successive 6-month evaluations, the operative mortality for Coronary Artery Bypass Graft (CABG) exceeds the VA standards, the Committee will review all operative data for the 12-month period, as well as the relationship of the program with the Cardiac Surgery Program of the affiliated medical school. The Committee then will recommend a site visit, unless factors other than those related directly to patient care are identified. These factors, for example, would be those associated with the loss of the cardiac surgeon, loss of operating room nursing personnel, loss of Surgical Intensive Care Unit nursing personnel, or construction preventing optimal utilization of the operating room suite. If such are identified, the Committee may then defer the recommendation for a site visit.

2. If, at the end of a 24-month period, the operative mortality for CABG alone exceeds the VA standard, a site visit will be recommended. As a result of that site visit, the program should be placed on probation. If, at the end of the probationary period of 12 months the program has not met VA standards (overall operative mortality, CABG operative mortality, and an operative workload at least approaching the VA standard), a site visit will be made. Unless extraordinary circumstances (such as indicated above) are identified, the Committee should then recommend the program be closed.

D R A F T

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