123497

27513

UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

FEB 24 1984

Dr. Donald L. Custis
Chief Medical Director
Veterans Administration

Dear Dr. Custis:

Subject: Improvements Needed in Quality Assurance for Open Heart Surgery (GAO/HRD-84-22)

We have reviewed the policies, procedures, and practices of the Department of Medicine and Surgery (DM&S) for assessing and assuring the quality of open heart surgery programs at Veterans Administration (VA) medical centers. We did not attempt to evaluate the quality of care, but concentrated on what DM&S did to ensure that quality care was provided to veterans in open heart surgery programs which did not meet the DM&S standard for the minimum number of operations or which experienced a relatively high mortality rate.

DM&S relies on an expert committee of VA and non-VA physicians--the Cardiac Surgery Consultants Committee--to assess the quality of open heart surgery units where utilization is low or mortality rates are high. We found that DM&S has not required this committee to follow its guidelines regarding when the consultants would assess a program's quality and how the Committee would communicate the results of its assessments to the medical centers.

DM&S also relies on the medical centers to assure that quality care is provided in their open heart surgery programs by using problem-oriented, systematic internal reviews, among other techniques. Two of the three medical centers we visited did not perform systematic internal reviews to assess the quality of care provided in their open heart surgery programs even when those programs had consistently low utilization and high mortality rates.

(401935)

028111
123497

BACKGROUND

DM&S first established open heart surgery programs in February 1965 at 13 medical centers. As of October 1983, DM&S had such programs at 42 of its 172 medical centers. In addition, 10 other VA medical centers were affiliated with non-VA hospitals to which patients were routinely referred for open heart surgery. All VA open heart surgery programs are affiliated with university medical centers.

For several years, the Subcommittee on HUD-Independent Agencies, Senate Committee on Appropriations, has questioned DM&S about the utilization of open heart surgery programs. Responding to the Subcommittee's concerns that unless underutilized programs were closed, DM&S might have a higher incidence of mortality, VA testified that it uses "professional judgment" in addition to utilization statistics in determining whether to close programs. DM&S also testified--and we found--that a high mortality rate is a fundamental reason for closing an open heart surgery program.

The Administrator, through the Chief Medical Director, has ultimate responsibility for assuring that the care provided at VA open heart surgery programs is of an acceptable level of quality. The Director of the DM&S Surgical Service is responsible for maintaining a quality assurance system to review and evaluate the open heart surgery programs.

Since 1973 the Surgical Service Director has relied on the Cardiac Surgery Consultants Committee to assess the state of cardiac surgery in the VA. The Committee oversees the quality of the VA open heart surgery programs according to the following informal policy. The Committee meets twice a year to review each program's utilization and mortality rates. If the utilization is below the DM&S standard (100 procedures annually), the Committee recommends that the Surgical Service Director obtain the programs' comments on actions they are taking to increase utilization. If a program's mortality rate is twice the average of the 52 programs as a whole, the Committee is supposed to conduct a paper audit and summarize its conclusions. A paper audit is a review of information from the medical file of each patient who died within 30 days of surgery or as a result of the operation. It is used to identify preventable factors, such as errors in operative technique or judgment, which may have caused the deaths. The Director is then supposed to formally transmit these results to local program officials. In certain cases, the Committee makes site visits to review the quality of open heart surgery programs. Between fiscal years 1977 and 1982, for example, the Committee

conducted seven site visits to review programs which had either low volume or high mortality rates.

According to the Surgical Service Director, all VA medical centers with open heart surgery programs are required by the Joint Commission on Accreditation of Hospitals to have quality assurance activities which include a presurgical conference between cardiologists and surgeons to assure that the surgery is justified; regularly scheduled morbidity and mortality conferences to review any complications, including death, that resulted from the surgery; and systematic internal reviews.

OBJECTIVE, SCOPE, AND METHODOLOGY

Our objective was to determine whether DM&S and VA medical centers have adequately assessed and assured the quality of care in underutilized open heart surgery programs. We assessed DM&S efforts to assure that quality care is provided in open heart surgery programs; however, we did not attempt to make our own evaluation of the quality of open heart surgery in these programs.

To determine how DM&S discharged its quality assurance responsibilities, we reviewed DM&S manuals, regulations, and internal directives; interviewed the Director of the DM&S Surgical Service, the Chairman of the Cardiac Surgery Consultants Committee, and other DM&S officials; and reviewed relevant correspondence and files.

To determine whether the Consultants Committee conducted required paper audits, we analyzed utilization and mortality data reported by the programs and reviewed files maintained by the Chairman of the Committee at the VA medical center in Asheville, North Carolina. To determine whether the Committee communicated the audit results to DM&S and whether DM&S, in turn, conveyed the evaluation results to program officials at the medical centers, we reviewed DM&S and Committee files and contacted officials of six of the programs.

To determine how the medical centers were assessing and assuring the quality of care provided in open heart surgery programs, we visited VA medical centers in East Orange, New Jersey; Indianapolis, Indiana; and Hines, Illinois. At each center we interviewed open heart surgery program officials and reviewed documentation and correspondence on Consultants Committee paper audits, cardiology/cardiovascular surgery conferences, morbidity and mortality conferences, and systematic internal reviews.

Our work was performed in accordance with generally accepted government auditing standards.

PROBLEMS WITH CARDIAC SURGERY CONSULTANTS COMMITTEE AND DM&S QUALITY ASSURANCE ACTIVITIES

We found that the Cardiac Surgery Consultants Committee was not performing paper audits as often as required, auditing all the cases required, or preparing summaries of its reviews. In addition, DM&S was not adequately communicating the results of the Committee's audits to the medical centers and following up to ensure that medical centers were taking corrective action to alleviate preventable problems identified in paper audits. Under the Committee policy, the consultants should have conducted 59 paper audits at 37 medical centers at which 330 deaths occurred between April 1978 and March 1982. Our examination of the Committee's files showed the following:

--The Committee reviewed only 44 percent of the cases which should have been reviewed.

--The Committee performed 29 audits, covering 146 deaths.

--In 14 of these 29 audits, the Committee did not review all the deaths which had been reported.

Open heart surgery program officials at three of six medical centers we contacted had not received the results of the audits conducted between June and December 1982.

According to Surgical Service officials, DM&S does not verify that (1) the Committee conducts paper audits for all programs whose mortality rates exceeded twice the VA average, (2) the number of cases audited by the Committee agrees with the number of cases reported by the program, and (3) all audit results have been received by the appropriate program officials after they are sent to them by DM&S. Surgical Service officials told us that, until our review, they were not aware of any discrepancies or difficulties which warranted verification. The Director of the Surgical Service could not explain why there was no record of paper audits being conducted, as required, in 30 of the 59 instances between April 1978 and March 1982.

According to the Committee's December 1978 minutes, summaries of each audit should be sent to the individual medical center. The Chairman told us that at about the same time the Committee developed a standardized assessment form to be used in evaluating each case and the consensus among Committee members appeared to be that the form would convey problems to program directors more effectively than an overall summary letter. The decision not to require summaries was never formally noted in the Committee's minutes. Consultants nevertheless prepared

summaries on 2 of the 29 audits; these summaries were sent in December 1979 and December 1982. The Chairman told us, however, that physicians serving as consultants volunteer their services to the Committee and, in view of other medical and teaching responsibilities, may not have time to complete overall summaries and conclusions.

Individual assessment forms and overall summaries serve different purposes. An individual assessment form is prepared for each mortality case and documents whether the reviewers considered the death to be preventable. A summary was to be prepared for all deaths included in the paper audit to communicate the reviewers' overall conclusions. Between May and December 1982, for example, the Committee evaluated five cardiac surgery deaths which occurred in the Minneapolis VA medical center during the previous reporting period. The consultant used the form to identify preventable factors in four of the five cases. In December 1982, the consultant also prepared a summary with recommendations on three major deficiencies he observed in reviewing the five deaths.

A basic component of the DM&S quality assurance program includes evaluating the effectiveness of corrective measures taken. We found, however, only one instance in which the Surgical Service Director requested feedback from program officials on their actions to overcome the problems identified by the Committee's audit. The Surgical Service Director told us that he relies on the director and the chief of staff of the medical center to ensure that these problems are corrected.

In the one case where DM&S requested feedback, medical center officials disagreed with the Committee's conclusions. DM&S did not try to resolve the disagreement.

MEDICAL CENTERS SHOULD USE SYSTEMATIC INTERNAL REVIEWS TO ASSESS THE QUALITY OF THEIR OPEN HEART SURGERY PROGRAMS

DM&S Surgical Service officials told us that they expect medical centers whose programs have experienced low utilization or high mortality rates to conduct systematic internal reviews as part of their quality assurance programs. DM&S expects these reviews to be problem oriented, i.e., directed toward overcoming obstacles to providing high quality care.

Two programs we visited (East Orange and Indianapolis) experienced consistently low utilization and high mortality rates between April 1978 and March 1980. Neither of these medical centers conducted a problem-oriented, systematic internal review of its program during that period. The Chief of Staff at the East Orange VA medical center told us that

the program did not have enough deaths or complications attributable to a single cause that would warrant such a review. Program officials conducted two systematic internal reviews in March and December 1982.

The Chief of Surgery at the Indianapolis VA medical center told us that the program has not conducted problem-oriented, systematic internal reviews in open heart surgery because of a lack of qualified staff. Systematic internal reviews at the Indianapolis VA medical center have been confined to administrative matters.

CONCLUSIONS

The medical community considers quality assurance programs to be a very important part of any health care delivery system. Because VA's health care system is so diverse--in this case, open heart surgery is offered in 42 of its 172 medical centers--DM&S quality assurance program is two dimensional. Individual medical centers are responsible for assuring that they provide quality care, and DM&S is responsible for assuring that quality care is provided throughout the VA system.

The Surgical Service's process for identifying "problem" open heart surgery programs--ones with low utilization or high mortality rates--could be an effective way to focus attention where it is probably needed most. However, shortcomings in the way that DM&S--through the Consultants Committee--has carried out its quality assurance activities indicate that it has not been able to ensure that all of its open heart surgery programs were providing quality care. We believe that, because the consultants were not performing paper audits as often as required or auditing all the cases required, the Committee's conclusions about the quality of "problem" programs may be questionable. DM&S may not have adequate information when considering whether to close or retain cardiac surgery programs with low utilization or high mortality rates. We also believe that VA's open heart surgery programs are not benefiting fully from VA's quality assurance system because

- --the Committee has not been routinely preparing overall summaries of its audits,
- --DM&S has not adequately followed up to determine whether medical centers accept and implement the Committee's recommendations, and
- --medical centers we visited with "problem" programs are not conducting problem-oriented, systematic internal reviews.

RECOMMENDATIONS TO THE CHIEF MEDICAL DIRECTOR

We recommend that the Chief Medical Director require the Director of the Surgical Service to

--issue specific directives stating when the Cardiac Surgery Consultants Committee is to conduct paper audits, what the audits are to include, and how the results are to be communicated to DM&S and the individual open heart surgery programs;

--ensure that the Committee conducts audits and makes visits when appropriate, that the audits include all reported mortality cases, and that the conclusions reached by the Committee are communicated to the program officials; and

--follow up on the actions taken as a result of recommendations in the Committee's paper audits and site visit reports.

We also recommend that the Chief Medical Director require medical centers whose open heart surgery programs experienced low utilization or high mortality rates to conduct problem-oriented, systematic internal reviews of their programs.

- - - -

The Assistant Chief Medical Director for Professional Services and the Surgical Service Director have reviewed this report and generally agreed with the conclusions and recommendations.

We are sending copies of this report to the Surgical Service Director and the center directors and open heart surgery program directors for the programs we contacted. We are also sending a copy to the Chairman of the Cardiac Surgery Consultants Committee.

We appreciate the courtesy and cooperation shown us by the Cardiac Surgery Consultants Committee and the staffs of the Surgical Service and the medical centers we contacted. We would appreciate your comments on the report's contents and recommendations.

Sincerely yours,

Norman Rabkin
Group Director